

SILVER JUBILEE EDITION



Pharma Web
Newsletter of
Tamilnadu Pharmaceutical
Sciences Welfare Trust

April - May - June 2016



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**Tamilnadu Pharmaceutical
Sciences Welfare Trust**

Pharma Web

Newsletter of Tamilnadu Pharmaceutical Sciences Welfare Trust

ISSUE : 30

Apr. - May. - Jun. 2016

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EDITORIAL

Dear Readers,

The 30th issue of Pharma Web Newsletter for the months of Apr-Jun 2016, is being released by a month's delay in Jul-16 as a special issue for the Silver Jubilee of our Tamilnadu Pharmaceutical Sciences Welfare Trust.

The silver jubilee celebrations of the Trust are going to be held on 16th July 2016 at Hotel Le Royal Meridien. It will be a day's celebration from 10.00AM to 5.00PM. Dr. V. K. Subburaj I.A.S, Former Secretary, Department of Pharmaceuticals, Ministry of Chemicals & Fertilizers, Govt of India , and Dr. J. Radha Krishnan, I.A.S. Secretary for Health and Family Welfare, Govt of Tamil Nadu will be the chief guests. We also have Dr. B. Suresh, President, Pharmacy Council of India, Shri. S. Abdul Khader, Director of Drugs Control, Tamilnadu and Dr. S. Manivannan, Dy. Drugs Controller (India), CDSCO, South Zone as guests of honour.

Dr. Shailesh Ayyangar, M.D.- Sanofi India ltd will be Speaking on “Road Map for Marketing to small & Medium Pharma companies in the current scenario” and Mrs. Swapna Sundar, CEO IP DOME strategy on “Intellectual Strategies to Indian Pharma Companies”. The afternoon will have a lively session “PATTIMANDRAM” on “Online Pharmacy – Required / Not Required” with stalverts from Pharma Profession arguing for and against. Dr. V. Ravichandiran, Director, NIPER, Kolkata, Shri. T.S. Jaishankar, M.D. Quest Life Sciences, Shri. R. K. Radhakrishnan, Senior Dy. Editor, Frontline, speaking for FOR and Shri. R. Srinivasan, M.D. Essen Associates, Shri. T. Elango, Registrar, Pharmacy Council, Tamil Nadu and Shri. M. R. Krishnan, Dy. Director, CONCERT Trust arguing AGAINST. with Prof. K. Chinnaswamy, President, Pharmacy Council Tamilnadu as NADUVAR and Shri. J. Jayaseelan, Secretary. IPA, TN as Moderator.

In addition to the regular Articles, Notifications, information, events and News, we have in this issue a brief history of the Trust, its Chairmen and Trustees, its activities etc. Hope you will all enjoy reading.

In the absence of our editor Mr. R. Narayanaswamy, who is away in US, I am very happy to be amongst you once again through this editorial. We will be happy to receive your views, comments and suggestions for the improvement of the news letter.

With Best Regards

Prafulla Chandra

Associate Editor

MESSAGE



I am very happy to learn that Tamilnadu Pharmaceutical Sciences Welfare Trust is celebrating its silver jubilee year during July 2016. I am also happy to learn that during these 25 years the Trust has made substantial contribution to the Pharmacy profession in Tamilnadu through its interaction with the Academia, Industry and Drug Regulatory bodies by conducting seminars / Lectures / Training Programmes, awarding scholarships etc. and providing useful information through their newsletter Pharma Web. I am sure that the Trust will continue its services to the Pharma fraternity in future also.

I congratulate the Chairman and all the members of the Trust for their remarkable efforts and take this opportunity to wish Tamilnadu Pharmaceutical Sciences Welfare Trust a very bright future.

V. K. Subburaj, I.A.S.
Former Secretary, Department of Pharmaceuticals,
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MESSAGE

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Dated: 13.7.2016

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Hon'ble Chief Minister of Tamil Nadu has been exhorting the officials to achieve the targets attained by the developed countries in the Health Sector. Among other areas, the Pharma industry has an important role in contributing to it.

I congratulate the Chairman and all the members of the Trust for their remarkable efforts and take this opportunity to wish Tamil Nadu Pharmaceutical Sciences Welfare Trust a very bright future.

(Dr.J.Radhakrishnan)

MESSAGE



I am extremely happy to know that the prestigious pharmaceutical event – Silver Jubilee Celebration of Tamil Nadu Pharmaceutical Sciences Welfare Trust is being organized by Indian Pharmaceutical Association, Tamil Nadu Branch at Le Royal Meridien, Chennai on 16th July 2016.

I am sure this would be a wonderful platform for pharmaceutical fraternity in Tamil Nadu to share and upgrade technological advancements in pharmaceutical sciences.

On this special occasion, my heartfelt appreciations & wishes for the grand success of Silver Jubilee Celebration of Tamil Nadu Pharmaceutical Sciences Welfare Trust



S. ABDULKHADER, B.Pharm.,
Director of Drugs Control
359, Anna Salai, CHENNAI-6.

MESSAGE



I am happy to know that Silver Jubilee Celebration of Tamil Nadu Pharmaceutical Sciences Welfare Trust at Le Royal Meridien, Chennai on 16th July 2016, along with Indian Pharmaceutical Association, Tamil Nadu Branch

I am sure it will be an opportunity for the academicians, research scholars and people related with pharmacy to share their views and update their knowledge on various scopes relating to pharmacy.

I extend my warm greetings and felicitations to the participants and the organizers.

Dr. S. Manivannan
Dy. Drugs Controller (India)
CDSCO, South Zone

MESSAGE



I am happy that our Tamilnadu Pharmaceutical Sciences Welfare Trust has completed 25 years of service to the Pharmaceutical Community in Tamilnadu. This is possible due to the noble contribution from well wishers and sincere and dedicated work put-forth by our Trustees.

Lasting 25 years, the Trust is now poised for greater contribution for the welfare of all members of Pharmaceutical Community here, whether they are Industrialists, Academicians, Regulators or Students.

I wish our Trust all the very best in their future endeavours.

S V Veerramani
Chairman – Tamilnadu Pharmaceutical Sciences Welfare Trust
National President – IDMA

MESSAGE



I am really happy to know that our Taminadu Pharmaceutical Sciences Welfare Trust is celebrating its Silver jubilee during 2016. This trust is rendering services to the whole area of our pharma fraternity. Scholarship to students, Training centre, Certificate courses, Library, Seminars, Lecture programme, job opportunity guidance, factory visit, exposure to technical advancement are the areas where it hold the feathers in its crown. This was carried out untiredly for the last two decades and set the bench mark to the other related trusts. The trust reach this height with great hurdles but with success. I am proud to be one among the trustee's since 1999.

To mark this occasion **“Pharma Web”** is coming out with the special issue and I wish and pray Almighty for its grand success.

M M Yousuf
President – IPA(TN)
Secretary – TANIPA Trust
Joint Secretary – TNPSWT Trust

MESSAGE

Chairman - Silver Jubilee Celebration



Tamilnadu Pharmaceutical Science Welfare Trust has been contributing to pharmacy profession in Tamilnadu by supporting the activities of Indian Pharmaceutical Association and by organizing Seminars, Lectures, Training programs pertaining to pharma profession.

I am very happy to be part of the Silver Jubilee celebration of Tamilnadu Pharmaceutical Science Welfare Trust on 16th July 2016.

This New Letter “PHARMA WEB” is very useful to all the pharma professionals to know about various useful informations connected with the pharma profession and pharmaceutical industry.

I take this opportunity to wish Tamilnadu Pharmaceutical Science Welfare Trust a very bright future and wish the trust to continue its good efforts towards its Golden Jubilee Celebrations.

J. Jayaseelan
Chairman - IDMA (TNPBSB)
Secretary - IPA (TN)
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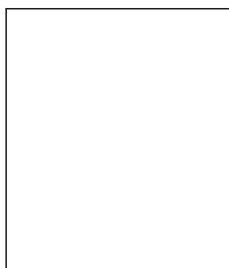
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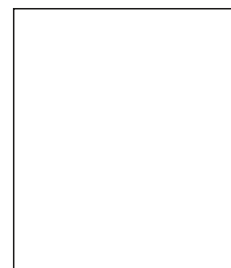
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South Zone, 2nd floor, Shastri Bhavan, Annexe 26
Haddows Road, Chennai 600 006
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Mr. M.S. Theivendran
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M/s Swiss Garnier Life Sciences
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Madras Pharma Group Companies

- ❖ Maral Labs - Chennai
- ❖ Accent Pharma - Pondy
- ❖ Accent Pharma - Jammu
- ❖ Tristar Formulations - Pondy
- ❖ Anphar Organics - Jammu
- ❖ Soft gel Health care - Chennai
- ❖ Steril-Gene Life Sciences - Pondy



TAMILNADU PHARMACEUTICAL SCIENCES WELFARE TRUST

A Decade of Fruitful Existence

At the 39th IPC LOC meeting held on 9th April 1988, it was decided that savings of 39th IPC will be utilized by a Trust. Hence all the members agreed to form a Trust and named it as “Tamilnadu Pharmaceutical Sciences Welfare Trust”

The members recommend that the already existing Trust formed after 26th IPC (Tamilnadu Pharmaceutical Trust) be merged with the newly formed Trust .

Tamilnadu Pharmaceutical Trust formed after 26th IPC had a balance amount of Rs. 75,000/-

The committee discussed various proposals and it was unanimously agreed to buy a property of 1500 to 2000 sqft in decent locality in Chennai.

The Trust Deed was registered on 10th March 1989, in sub registrar office of the district registrar, Madras central, document no 107 of 1989, executed by Mr. K. Prafulla Chandra and Mr. N. Sreenivasen. The various committee Chairmen and patrons of the LOC of the 39th IPC held in Chennai are the first Trustees .

Authors of Trust

- | | | |
|------------------------------|-----------------------|------------------------|
| 1. Mr. K. S. Chandrasekaran, | 2. Mr. R. Santhanam, | 3. Mr. K. C. Sharma, |
| 4. Mr. N. P. Mathur | 5. Mr. N. Sreenivasen | 6. Mr.R. Thiruvengadam |

First Trustees

- | | | |
|------------------------|-----------------------------|-------------------------------|
| 1. Mr. G. Rangachari | 2. Mr. V. Ramamurthy | 3. Mahendra Dadha |
| 4. Mr. V. Janardhanan | 5. Mr. R. K. Jhaver | 6. Dr. A. M. Salahudin |
| 7. Mr. G. Swaminathan | 8. Mr. Salvador Fernandez | 9. Dr. Rajam Jaishankar |
| 10. Mr. G. Swaminathan | 11. Mr. K. Prafulla Chandra | 12. Dr. K. A. Narendra Nath |
| 13. Dr. M. D. Nair | 14. Mr. V. Shyam | 15. Mr. M. Sardarmal Chorida, |
| 16. Dr. V. Permal | 17. Prof. K. Chinnaswamy. | |

03.02.1990 – Mr. G. Rangachari, informed that the amount available with the trust was Rs. 11.80 lakhs and with TPT Trust was Rs. 90,000/-. The total amount would be around 12.7 lakhs. Members decided to acquire a portion of 6th floor in Spencer Plaza measuring 1970 sqft (1540 carpet area) costing Rs. 13,81,800/- stamp duty extra. Decided To raise additional funds required for purchasing and furnishing of premises, decided to approach the banks for loan.

25.04.1990 – Members debated on various proposals made for collecting Rs. 1.2 lakhs immediately and 3 to 3.5 lakhs subsequently for furnishing the premises.

08.03.1991 – The Trust obtained a donation of Rs. 50,000/- from M/s. Sakthi sugars.

06.12.1991 – The members decided to rise funds by organizing a seminar with IPA

31.03.1992 – Due to shortfall of money and high maintenance charges (Rs. 2,000/- per month). Decided to sell the property and buy another property.

20.05.1992 – Since it was not possible to furnish the premises due to shortage of funds The members decided to let out the premises on long lease, the accrued rent could be utilized for achieving the objectives of the Trust.

On 30th May 1992 we lost our Secretary Mr. N. P. Mathur, due to illness, the acting secretary Mr. K. Prafulla Chandra took over as secretary.

27.06.1992 – 1st AGM of the trust held at Drive-in-woodlands.

1992 – 1996

The Spencer plaza property was registered on 25th May 1993.

On 8th September 1993 The premises at spencer plaza was leased out to M/s. LKP Forex, Bombay.

1997 - 2000

At the AGM held on 30th March 1997, It was decided to alter the objectives of the Trust by changing the total number of Trustees from the present 30 to 36

At 7th AGM 26th June 1998 decided to award 10 Scholarships of Rs. 5,000/- each to M. Pharm students of colleges in Tamilnadu.

It was decided to open Drug Information Center at PMA office with a capital expenditure of Rs. 2 lakhs. Mr. K. Prafulla Chandra, Mr. N. Sreenivasen, and Mr. R. Thiruvengadam, visited JSS college of Pharmacy Ooty, to understand the functioning of their DIC. The Trust christened the drug information center as Pharma Information Centre(PIC). PIC was officially inaugurated on 5th September 1999 by Vice-Chancellor, Dr. Kalanithi, Anna University. PIC started functioning from the PMA TN office. Mrs. Pratima Mathur was appointed as Deputy Director of PIC

2000-2001

On 12th March 2000 at the General Body Meeting it was decided to purchase a flat in Baid Metha Complex, and the Trust acquired a ground floor flat of 1261 sqft. at a cost of Rs. 13.97 lakhs. The premises was registered on 22nd February 2001.

The newly purchased premises of TNPSWT Trust was inaugurated by Mr. Ashwini Kumar, DCGI, India. PIC was shifted to the new premises and inaugurated by the then Director, Drugs Control Tamilnadu Mr. G. Dhakshinamurthy on 22nd September 2001. The Trust finalized the Logo and also established A Website.

2002-2003

5th April 2003 MOU was signed with JSS college of Pharmacy, Ooty for providing Drug Information for queries raised by PIC.

LOC Office of 55th IPC Chennai 2003. Functioned from the premises of the Trust

2004 – 2005

Trust deed was amended and registered on 4th March 2004 – for increasing the number of trustees,

In Dec 2005 due to heavy rain and flooding computer, furniture & library books were extensively damaged.

2006 – 2010

On 8th and 9th August 2008, a 2 day certificate course on GMP was held for Technical personnel engaged in Pharmaceutical Manufacturing companies, particularly SSIs. 20 participants from 13 companies participated.

Trust started publication of its newsletter Pharma Web 1st issue of Pharma Web released by Mr. K. Sundaraswamy, the then director of Drugs control (i/c), Tamilnadu .

2010 - LOC secretariat for 2nd IPA Convention, opened at the trust office.

2011 - 2012

On 1st July 2011 Mr. S. V. Veerraamani, was elected as chairman of the Trust. Mr. G. Rangachari, after rendering services to the trust as chairman for 22 years relinquished the post.

The trust Initiated Essay competition for the final year B. Pharm students of colleges of Tamilnadu

2013 – 2015

Trust organized Soft skill Training program for Pharmacy students.

The Trust got renovated, at an expense of Rs. 12 lakhs.

The newly furnished premises was used as LOC office of the 64th IPC

Some of the Trustees felt that the activities of the Trust need to be increased. Since to increase the activities, more funds are required, an appeal was made to likeminded Trusts and Philanthropies. TANIPA & TPT came forward to donate substantial amount.

An Extra-Ordinary General Body meeting was called on 25th of March 2013 to discuss as special business - to discuss the letters received from TANIPA & TPT for their merger with TNPSWT and also for increasing the Trust activities. After discussion and deliberations, it was resolved to increase the membership of the Board of Trustees to 70 from the present level of 50 and to increase the strength of the Governing Council to from 9 to 18. It was further resolved that new positions of Office Bearers be created, One Vice Chairman, One Joint Secretary and One Joint Treasurer, with the same terms and conditions with regard to Election, Nomination, Powers and Tenure of office as it prevails now for the existing set of Office Bearers.

Pharma Knowledge and Training Institute (PKTI) – (Finishing School) was inaugurated on 12th May 2014. 3 training programs were conducted, of which 2 programs on Quality Control and 1 program on Production Management.

The latest addition to the Trust activities is the University Merit awards initiated in 2015. The students securing top 3 ranks of B. Pharmacy from Dr. MGR Medical University, Chennai, are awarded cash prizes and certificates.

The following Conferences & Conventions were held at Chennai

Event year & Date	Place of Event	President	Chairman	Secretary
1974 26 th IPC	IIT Chennai	Mr. P. S. Ramachandran	Mr. P. V. Ramani	Mr. P. Krishnamurthy
1988 39 th IPC	Loyola College Chennai	Dr. B. D. Miglani	Mr. G. Rangachari	Mr. N. P. Mathur
1996 48 th IPC	IIT Chennai	Dr. P. M. Naik	Mr. T. P. Gurumurthy	Mr. K. Prafulla Chandra
2003 55 th IPC 19 – 21 st Dec	Sri Ramachandra University, Chennai	Mr. Ashwini Kumar	Mr. S. S. Vanangamudi	Dr. B. Suresh
2010 IPA Convention	Sri Ramachandra University, Chennai	-----	Mr. S. V. Veerramani	Mr. J. Jayaseelan
2012 64 th IPC 7 – 9 th Dec	SRM University, Chennai	Dr. K. Chinnaswamy	Mr. S. V. Veerramani	Mr. J. Jayaseelan Mr. B. G. Shivananda

SEMINARS / SCIENTIFIC SESSIONS SPONSORED

1992 - 2015

S. No	Event	Month & Year	Amount (Rs.)
1.	Donation to IPA TN branch– Seminar	March 1992	20,000/-
2.	Sponsorship of Scientific Session- 45 th IPC, Delhi	October 1993	25,000/-
3.	Sponsorship of Seminar JSS College of Pharmacy, Ooty	October 1993	10,000/-
4.	Joint Meeting of Trust & IPA DCI lecture	March 1994	15,000/-
5.	Workshop on “Carrier in Pharmaceutical Marketing” JSS College of Pharmacy, Ooty	April 1994	20,000/-
6.	Mathur Memorial Lecture with IPA TN Branch	May 1994	12,500/-
7.	Sponsorship of Scientific Session - 46 th IPC, Chandigarh	October 1994	25,000/-
8.	Sponsorship of International Symposium on Pharmacology of Receptors & Ion Transportation at JSS College of Pharmacy, Ooty	February 1995	2,00,000/-
9	Sponsorship of Scientific Session - 47 th IPC at Vizag	August 1995	25,000/-
10	Donation for Library Books to PMA, Tamilnadu	August 1995	50,000/-

SEMINARS / SCIENTIFIC SESSIONS SPONSORED
1992 - 2015

S. No	Event	Month & Year	Amount (Rs.)
11.	Annamalai University	February 1996	10,000/-
12.	Workshop, Sri Ramakrishna Institute of Paramedical Sciences, Coimbatore	February 1996	10,000/-
13.	Seminar – IPGA, TN Branch	May 1996	10,000/-
14.	Donation for Library books PMA, Tamilnadu	May 1996	20,000/-
15.	Mathur Memorial Lecture IPA, TN branch	July 1996	9,500/-
16.	National Pharmacy Week with IPGA & IPA, TN Branch	November 1996	20,000/-
17.	Sponsorship of Scientific Session 48 th IPC at Chennai	November 1996	2,00,000/-
18.	APTI, Second Annual Convention, Bangalore	March 1997	50,000/-
19.	Scientific Session - goal towards Total Quality Management by IPGA held at Madurai	September 1997	50,000/-
20.	Donation to IPA, TN branch - Seminar	October 1997	1,00,000/-
21.	Sponsorship Scientific Session 49 th IPC at Trivandrum	October 1997	60,000/-
22.	National Pharmacy Week celebrations – IPA TN	November 1997	15,000/-
23.	Workshop on Medical Detailing of Drugs Marketing & Placement, Periyar College of Pharmaceutical Sciences for Girls, Trichy	February 1998	15,000/-
24.	Mr. K. C. Sharma Memorial Seminar on “Recent Trends in Drug Analysis” IPA TN Branch	March 1998	50,000/-
25.	Mathur Memorial Lecture - TN Branch	August 1998	30,000/-
26.	National Seminar on “Pharmaceutical Sciences in the next millennium, Emerging Trends & Challenges Ahead” J S S College of Pharmacy, Ooty	November 1998	25,000/-
27.	National Pharmacy Week Celebration – IPA TN	November 1998	20,000/-
28.	Annamalai University	November 1998	10,000/-
29.	Sponsorship Scientific Session - 50 th IPC at Mumbai	December 1998	25,000/-
30.	Sponsorship of Scientific Seminar on Pharmaceutical Technology in the Next Millennium by IPA TN Branch	March 1999	75,000/-

SEMINARS / SCIENTIFIC SESSIONS SPONSORED

1992 - 2015

S. No	Event	Month & Year	Amount (Rs.)
31.	Sponsorship of Seminar on "Pharmaceutical Sciences Challenges & Opportunities in the next Millennium by KMCH College of Pharmacy, Coimbatore	June 1999	30,000/-
32.	Refresher Course-cum-workshop for Pharmacist conducted by C L Baid Metha College of Pharmacy, Chennai	September 1999	15,000/-
33.	National Seminar on Hospital & Clinical Pharmacy - JSS College of Pharmacy, Mysore	October 1999	15,000/-
34.	National Convention of APTI at Coimbatore	November 1999	50,000/-
35.	National Pharmacy Week celebrations - IPA TN Branch	November 1999	15,000/-
36.	Donation for Library books PMA, Tamilnadu	November 1999	50,000/-
37.	To Periyar College of Pharmaceutical Sciences for Girls, Trichy for Seminar & Workshop	November 1999	10,000/-
38.	International Symposium on Stability Testing & Regulatory Requirements for Drugs & Pharmaceuticals held at Mysore	December 1999	20,000/-
39.	Global Congress on Cosmetic Technology at Pondicherry	February 2000	20,000/-
40.	For Madras Medical College Souvenir - "PHARMAT"		10,000/-
41.	Pharmacy Council of India for the Golden Jubilee celebrations		50,000/-
42.	Seminar " <i>An Approach to Schedule M</i> " - IPA TN Branch	September 2000	50,000/-
43.	National Seminar on " <i>Pharmaceutical Technology in the New Millennium</i> ", Annamalai University	October 2000	12,500/-
44.	Registration Fee to Prof. Pulok Mukherjee, JSS College of Pharmacy, Ooty to attend International Conference on <i>Phytomedicine</i> at Munich, Germany	October 2000	5,800/-
45.	National Pharmacy Week Celebrations - IPA TN Branch	November 2000	15,000/-
46.	Sponsorship Scientific Session - 52 nd IPC, Hyderabad	December 2000	50,000/-
47.	Purchase of Books for the library		50,000/-
48.	To IDMA Seminar on " <i>Effective Supervision - GMP Angle in the Manufacturing of Tablets & Oral Liquids</i> "	April 2001	10,000/-
49.	To IPA, TN Branch Shri. N. P. Mathur Memorial Lecture on "Trends in Pharmaceutical Sciences"	June 2001	10,000/-
50.	National Pharmacy Week Celebrations - IPA TN Branch	November 2001	15,000/-
51.	Sponsorship Scientific Session - 53 rd IPC, New Delhi	December 2001	25,000/-
52.	To IPA, TN Branch The Role of Information Technology in Pharmaceutical Industry by Dr M D Nair	May 2002	17,210/-
53.	To IPA TN Branch on Developing Trends in ISM	August 2002	35,000/-
54.	To MADITSSIA, Madurai Seminar on " <i>Pharma Manufacturers at the outset of Good Manufacturing Practice</i> "	October 2002	3,000/-
55.	National Pharmacy Week Celebrations - IPA TN Branch	November 2002	20,000/-

SEMINARS / SCIENTIFIC SESSIONS SPONSORED
1992 - 2015

S. No	Event	Month & Year	Amount (Rs.)
56	Sponsorship Scientific Session - 54 th IPC, Pune	December 2002	25,000/-
57	Shri. N. P. Mathur Memorial Lecture on “ <i>Bioequivalence Evaluation in Human Subjects – The Present Scenarion</i> ” by Dr. M. Ravichandran and on “ <i>Perspectives in Bio-analytical Method Development and Validation</i> ” by Dr. M. Vasudevan of JSS College of Pharmacy, Ooty	June 2003	20,801/-
58	Sponsorship Scientific Session - 55 th IPC	August 2003	1,00,000/-
59	National Pharmacy Week Celebrations – IPA TN Branch	December 2003	10,000/-
60	To Seminar on “Pharma Scope” by Indian Pharmacy Graduates Welfare Trust, Madurai	February 2004	10,000/-
61	To IPA, TN Branch, Shri N P Mathur Memorial Lecture on “Recent Trends in Pharma Marketing” By Mr. R. S. Raghavan, Sr Vice President, M/s Tablets India, Chennai	May 2004	13,111/-
62	National Level Symposium at PSG College of Pharmacy, Coimbatore, on” Herbal Therapy in viral Infections, A perspective”	July 2004	5,000/-
63	National Pharmacy Week Celebrations – IPA TN Branch	November 2004	15,000/-
64	Sponsorship Scientific Session - 56 th IPC 2004, Kolkata	December 2004	25,000/-
65	National seminar at J S S College of Pharmacy , Ooty	March 2005	3,000/-
66	IPA, TN Branch Shri N P Mathur Memorial Lecture on “Increasing Trends for the Scope of Ayurveda Doctors View on Formulation” by Dr. Acharya, Head of Department, Anna Hospital (Ayurveda), Chennai	June 2005	10,948/-
67	National Pharmacy Week Celebrations – IPA TN Branch	November 2005	15,000/-
68	Scientific session - 38 th Annual Conference of Indian Pharmacological Society at Chennai	December 2005	30,000/-
69	To IPA Education Division, Scientific Session II National Convention of Pharmacy Educators at Coimbatore	March 2006	10,000/-
70	To IPA TN Branch, Shri N P Mathur Memorial Lecture on “The need for focusing Research on Management of Diseases by Mr. S. Dhansekar	July 2006	20,000/-
71	National Pharmacy Week Celebrations – IPA TN Branch	November 2006	50,000/-
72	Sponsorship Scientific Session 58 th IPC, Mumbai	December 2006	25,000/-
73	58 th IPC Registration charges to Dr. K. A. Narendra Nath & Mrs. Pratima Mathur	December 2006	5,000/-
74	To IPA TN Branch Shri N P Mathur Memorial Lecture on “Pharmaceutical Industry and Globalisation by Dr. Veerappan Subramaniam, President & CEO, Novel Laboratories, Samersset New Jersey, USA	June 2007	22,924/-
75	National Pharmacy Week Celebrations – IPA TN Branch	November 2007	20,000/-

SEMINARS / SCIENTIFIC SESSIONS SPONSORED
1992 - 2015

S. No	Event	Month & Year	Amount (Rs.)
76	IPA, TN Branch Shri N P Mathur Memorial Lecture on "Comparative Review of Revised Schedule M (GMP) with other International GMP norms" by Dr D Roy, Dy Drug Controller CDSCO (South Zone)	October 2008	25,000/-
77	National Pharmacy Week Celebrations – IPA TN Branch	November 2008	23,716/-
78	To Madras Medical College 2 nd Annual National Convention 2008 of Indian Association of Pharmaceutical Scientists and Technologists (IAPST)	November 2008	25,000/-
79	IPA meeting and release of first issue of Pharma Web	January 2009	30,441/-
80	National Pharmacy Week Celebrations – IPA TN Branch	November 2009	30,000/-
81	To IPA, TN Branch IPA Convention 2010	March 2010	75,000/-
82	National Pharmacy Week Celebrations – IPA TN Branch	November 2011	25,000/-
83	To Sponsorship of 63 rd IPC Registration fee For Mr. R. Narayanaswamy	December 2011	3,000/-
84	To IPA, Nilgiris Branch, Indian Pharmaceutical Association Student Congress 5	April 2013	1,00,000/-
85	Seminar on Intellectual Property rights – IPA TN	July 2013	1,00,000/-
86	1 st Pharmacist Day Celebration – IPA TN Branch	September 2013	2,25,000/-
87	To IPA, TN Branch Current Trends in the Indian Pharmaceutical Industry	February 2014	71,986/-
88	To Indian Pharmacist Association, TN branch State Conference at Erode	March 2014	1,50,000/-
89	Refresher course for registered working Pharmacists at Erode & Srivilliputhur	March 2014	20,000/-
90	IPA Tamilnadu Conducted Pharmacist Day in Raja Annamalai Mandram 2014	September 2014	3,03,328/-
91	IPA TN Branch 53 rd National Pharmacy Week	November 2014	3,00,000/-
92	To Indian Pharmacist Assn & IPA, TN branch One day workshop on Intellectual Property Rights & Patents at Vinakaya Missions, Salem	February 2015	98,012/-
93	To IPA, TN Branch Seminar on Opportunities & Challenges of Pharma Exports to Row Markets	March 2015	1,13,880/-
94	61 st IPSF World Congress, Hyderabad IPA- Students forum & Intl Pharm. Students Federation	July 2015	1,00,000/-
95	IPA, TN Branch Pharmacist Day 2015	September 2015	2,20,000/-
96	To IPA, TN Branch 54 th National Pharmacy Week	November 2015	3,17,719/-
97	Scientific Session for 67 th IPC 2015 at Mysuru	December 2015	4,00,000/-

LIST OF TRAVEL GRANT

S No.	Particulars	Month & Year	Amount (Rs.)
1.	Prof. Dhanraj, J S S College of Pharmacy, Ooty - Presentation of paper in Milan	August 1998	10,000/-
2.	Mr. V. Murugan and Dr. G. V. S. Ramasarma, Asst Prof JSS College of Pharmacy, Ooty	June 1999	20,000/-
3.	Prof. K. Samanta, JSS College of Pharmacy, Ooty	2000	10,000/-
4.	Mr. S. Ponumsankar, JSS College of Pharmacy, Ooty, 62 nd Congress of FIP (Nice, France)	August 2002	5,000/-
5.	Dr. B. Suresh, JSS College of Pharmacy, Ooty to attend 19 th FAPA Congress, Korea	October 2002	10,000/-
6.	Dr. K. Ashok Kumar, Asst Prof SRIPMS, CBE to Attend Intl Conference at Singapore	May 2004	7,500/-
7.	Dr. T. Sivakumar, JKK Nataraja College of Pharmacy, Komarapalayam to present a Paper at symposium at the 11 th Natural Product Network for Eastern & Central Africa at Madagascar, Africa	August 2005	7,500/-
8.	Dr. S. Mohan, KMCH College of Pharmacy, Coimbatore, to present a paper at MPS Pharmacy Scientific Conference 2005, Malaysia	November 2005	7,500/-
9.	Mr. Ravichandran, Lecturer, PSG College of Pharmacy, Coimbatore for paper presentation in CPA MPS conference in Kuala Lumpur, Malaysia	August 2007	10,000/-
10.	Dr. C. Vijaya Raghavan for paper presentation in 2 nd World Conference on Magic Bullet at Numburg, Germany	October 2008	10,000/-
11.	Ms. M. Uma Maheswari, SRIPMS, Coimbatore for Paper presentation in the 22 nd FAPA Intl Conference, Singapore	November 2008	10,000/-
12.	Travel Grant to Dr. T. K. Ravi, Principal, SRIPMS Coimbatore, for paper presentation in the 4 th AASP, 9 th MPSPSC – 2009, Malaysia	June 2009	10,000/-
13.	Travel Grant to Ms. Radhika Ramaswamy for Paper presentation in 5 th FIP Pharmaceutical Sciences World Congress, Australia	April 2014	20,000/-
14.	Travel Grant to Dr. P. Ramasubramaniyan for Paper presentation in 5 th FIP Pharmaceutical Sciences World Congress, Australia	April 2014	10,000/-
15.	Travel Grant to Prof. A. S. William Arputha Sundar for poster presentation at the International Conference on Beneficial Microbes 2014 (ICOBM) in Penang, Malaysia	May 2014	10,000/-
16.	Travel Grant for Mr. M. R. Jeyaprakash for 74 th World Congress 2014 of FIP at Bangkok	August 2014	10,000/-
17.	Travel Grant for Dr. V. Sankar for attending the 25th Federation of Asian Pharmaceutical Associations Congress 2014 in Kota Kinabalu, Malaysia	October 2014	15,000/-

TAMILNADU PHARMACEUTICAL SCIENCES WELFARE TRUST

A brief history of Activities done during 25 years

The activities of the Trust started with the Organisation of various lecture programs and seminars along with The Indian Pharmaceutical Association Tamilnadu Branch. And grant of Travel Grants and sponsorships to Faculty and students of Pharma institutions.

M. Pharm Scholarships

In order to motivate the student community, in the year 1998, TNPSWT decided to award scholarships to M. Pharm students of Colleges of Pharmacy in Tamilnadu. Every year, applications are invited from M. Pharm students of various colleges in Tamilnadu, These are codified and sent for evaluation to an institute outside Tamilnadu. From the year 2013 - 2014, awards are also being given to Pharm D students.

Based on merit of the synopsis of the ongoing M. Pharm projects submitted by the students, 3 awards are given in each of the six branches of M. Pharm viz. Pharmaceutics, Pharmaceutical Chemistry, Pharmaceutical Analysis, Pharmacology, Pharmacognosy, Pharmacy Practice and in two branches of Pharm D – Clinical Pharmacy and Pharmacy Practice.

The year-wise record of the scholarships awarded is as follows:

Sr. No.	Year	Total Appl Recd	Awarded	No of awards			Amt. (Rs)			Total
				1 st	2 nd	3 rd	1 st	2 nd	3 rd	
1	1998		13	NA	NA	NA	5,000/-	NA	NA	65,000/-
2	1999	49	13	NA	NA	NA	7,500/-	NA	NA	97,500/-
3	2000	57	16	NA	NA	NA	7,500/-	NA	NA	1,20,000/-
4	2001	94	20	NA	NA	NA	5,000/-	NA	NA	1,00,000/-
5	2002	93	16	7	9	NA	7,500/-	5,000/-	NA	97,500/-
6	2003	67	16	8	8	NA	7,500/-	5,000/-	NA	1,00,000/-
7	2004	68	16	7	9	NA	7,500/-	5,000/-	NA	97,500/-
8	2005	130	21	8	13	NA	7,500/-	5,000/-	NA	1,25,000/-

TAMILNADU PHARMACEUTICAL SCIENCES WELFARE TRUST

Sr. No.	Year	Total Appl Recd	Awarded	No of awards			Amt. (Rs)			Total
				1 st	2 nd	3 rd	1 st	2 nd	3 rd	
10.	2007	137	29	7	13	9	7,000/-	5,000/-	3,500/-	1,45,500/-
11.	2008	189	43	10	13	20	6,000/-	4,000/-	2,000/-	1,52,000/-
12	2009	252	21	7	7	7	8,000/-	7,000/-	6,000/-	1,47,000/-
13	2010	268	21	7	7	7	8,000/-	7,000/-	6,000/-	1,47,000/-
14	2011	268	21	6	6	9	8,000/-	7,000/-	6,000/-	1,44,000/-
15	2012	148	19	6	6	7	10,000/-	7,000/-	5,000/-	1,37,000/-
16	2013	134	24	8	8	8	10,000/-	8,000/-	6,000/-	1,92,000/-
17	2014	90	24	8	8	8	10,000/-	8,000/-	6,000/-	1,96,000/-
18	2015	178	24	8	8	8	12,000/-	10,000/-	8,000/-	2,54,000/-



Pharma Information Centre

With the advent of computers and internet there was an exponential growth in the available information. Recognizing the growing need of up-to-date, crucial, in-depth and unbiased information, in the year 1999 the Trust established **Pharma Information Centre (PIC)**. The PIC was formally inaugurated on 5th September 1999 by Prof. A. Kalanithi, Vice Chancellor, Anna University. The Centre very quickly established itself as a major centre catering to scientific information for Pharma Industrial professionals, researchers, students, medical and related healthcare professionals

In the year 1999 the PIC which was functioning in the premises of Pharmaceutical Manufacturers Association office (PMA office) shifted to its own office, equipped with all the latest facilities for providing the information, such as Pharmacopoeias, medical and Pharmaceutical reference books, journals, databases from reputed healthcare series such as micromedx and ovid, IDIS etc and high-speed internet connection for web searching and access.

To widen its resources the PIC entered into an understanding with Drug Information Centre (DIC) at JSS College of pharmacy, Ooty and also with DIC, Karnataka State Pharmacy Council, Bangalore.

The trust had tie up with QMed services, Mumbai, for providing full text articles documents etc, from scientific journals, books etc, to the researchers in Chennai at a concessional rate.

With the advent of easy availability of internet and affordability to have Laptops, Desktops etc the activity of PIC has come down to reference of library books only.

Certificate Course for SSI's

A two day certificate course on **“Documentation and GMP”** on 8th & 9th of August 2008, to educate as well as update the knowledge of the technical personnel engaged in the pharmaceutical manufacturing companies, particularly for the small scale industries. The Trust subsidised the cost of the programme in order to benefit large number of SSI in Tamilnadu.

Pharma Web Newsletter

In order to improve the knowledge of professional skill and to achieve production of excellent quality medicines our Trust decided to publish a news letter in the name of “**Pharma Web**” newsletter, on 29th September 2008. The Council members of the Trust requested Mr. R. Narayanaswamy, joint Secretary of the Trust to be the chief editor of the newsletter and to publish the same on quarterly basis and circulate free of cost to all Pharmaceutical Industries, Pharmacy Colleges, professional associations and Drugs Control departments. The Council suggested names of eminent professionals like Dr. B. Suresh, Prof. K. Chinnaswamy, and Mr. J. Jayaseelan for the advisory and editorial board. The advisory board suggested publishing only the authentic news items and Mr. Jayaseelan made the design of the News letter cover page well appreciated by all readers.

The first issue of **Pharma Web** newsletter for the quarter oct—Dec2008 was released on 30th January 2009 by Mr. K. Sundaraswamy, the then Director of Drugs Control (i/c), Tamilnadu (chief guest of the function). The first copy was received by Mr. S. V. Veerramani, MD, M/s. Fourrts India Labs Pvt Ltd, Chennai. The first Pharma Web news letter covers an article about GMP – Non compliance by Mr. S. S. V. Krishnan, Reted Drugs Controller of Kerala, Gazette notification published by CDSCO and important events and Tamilnadu Pharmacy Colleges List, details of various councils and associations

In the subsequent issues, we covered important articles like Good pharmacy Educational practices, Requirement of controlled air system like HAVC for Pharma Industries, Natural products having medicinal properties, Good clinical practices including Clinical Research organization and clinical Trials of various phases and Good laboratory practices. Further various important Gazette notifications issued by Ministry of Health &family Welfare Govt of India pertaining to Drugs and Cosmetics Act & Rules, Parliament question & answers on Drugs & Pharmaceuticals in both Loksabha & Rajyasabha, information, and events conducted by various Associations and Pharmacy colleges and updated news from leading News papers like The Hindu, Times of India, Economic time etc on pharmaceutical industries are covered in our News letter. We also covered the important events like IPA convention held at Ramachandra University, Chennai and IPCA congress in Chennai. A special issue about new guidelines by NPPA on Drugs Price Control Order (DPCO) 2013 was also published with pricing of medicines covered under essential Drug list. Our newsletter covered the training programmes conducted by Pharma Knowledge and training Institute (Set up by our Trust) for fresh pharmacy graduates on Industrial orientation. The important notification like banning of Fixed Dose Combination (FDC) of Drug formulation containing more than 300 items and its implications through media are also published.

So far we have published nearly 29 issues since inception.(last 7years), All our news letters contain innumerable technical articles, regulatory norms and news items which can be considered as a bible for any Pharmacy professional. These news letters are archived in our Trust website (www.pictrust.com) as a ready reference to all readers for statistical purpose as well as to brush up the knowledge, with blessings of God, we were able to publish the news letter without any interruption . Hope our Pharma community utilizes this journal and give their valuable suggestion for future improvement.

The current issue is being released on 16th July 2016, at Hotel Le Meridian, at the “Silver Jubilee Celebrations” of the Trust.



B. Pharm – Essay Competition

In the year 2011, Tamilnadu Pharmaceutical Sciences Welfare trust initiated a new activity for the final year B. Pharm students studying in various Pharmacy colleges in Tamilnadu and Puducherry. Every year an essay competition is conducted on a topic relevant and important to the Pharmacy profession. Cash awards and certificates are given to the 3 best essays. These awards are sponsored by M/s. Pharm Products Pvt Ltd, Thanjavur self-confidence, self-esteem and be motivated to identify and work towards career goals.

Sr. No.	Year	No of appl Reced	Awarded	Amt. (Rs)			Total
				1 st	2nd	3 rd	
1	2011	34	3	10,000/-	5,000/-	3,000/-	18,000/-
2	2012	34	3	10,000/-	7,000/-	5,000/-	22,000/-
3	2013	42	4	8,000/-	7,000/-	5,000/- x 2	25,000/-
4	2014	22	3	10,000/-	8,000/-	6,000/-	24,000/-
5	2015	41	3	10,000/-	7,500/- x 2	*****	25,000/-



Soft Skills training for Pharma Students

To support the students in their quest to bridge the gap between college & corporate, the Trust conducted its 1st soft skill training programme for B. Pharmacy students in August 2012. The training programme titled **“Professional Communication and Soft Skill Training”** was conducted by a professional and experienced soft-skill trainer and behavioral analyst, was aimed to help the students to develop self-confidence, self-esteem and be motivated to identify and work towards career goals.

Pharma Knowledge and Training Institute (Finishing School)

The establishment of this Institute is the brain child of our Chairman Mr. S. V. Veerramani. As many of the fresh pharmacy graduates do not have exposure in Pharmaceutical Industry, it was decided by our Trust to establish an Institute in the name of **“Pharma Knowledge and Training Institute (Finishing School)”** in the year 2013. A team of council members consisting of Mr. R. Narayanaswamy, Mr. K. Prafulla Chandra and Mrs. Pratima Mathru visited Bangalore, where **Pharma Training Institute** is being run under the guidance of state IPA. The members studied the curriculum adopted by the institute for the training program. They have also gone through the various other activities and also facilities for conducting the training program. Dr. V. Ravichadran, was also inducted as the fourth member of the team.

The need of such training was also discussed with the heads of the Production & Quality assurance personnel of leading Pharmaceutical companies in Chennai. Based on the inputs received from them a complete structured program was prepared by the above expert group. Two programs Viz 1) **Industrial Orientation Training for Quality Management Personnel** 2) **Industrial Orientation Training for Production Management Personnel** were initially taken up for the training. The training program is for a duration of 4 weeks with 2 weeks of theoretical classes and 2 weeks of practical training in Industry. Senior management personnel from Quality Assurance, Quality control & Production departments of leading Pharma Industries located in Tamilnadu and Puduchery, Regulatory officials from state and central Drugs Control department and private consultants are invited to be the faculty for the training program. At the end of each training program placement interviews were held to absorb suitable trained candidates in to their organization.. The training is given to fresh Pharmacy graduates from Tamilnadu and Pondicherry.

The **“Pharma Knowledge and Training Institute (Finishing School)”** was inaugurated on 12th May 2014 at Hotel HABLIS, Guindy Chennai – 600032. Under the chairmanship Mr. S. V. Veerramani, Chairman & Managing Director, M/s. Fourrts (India) Laboratories Pvt Ltd., Chennai. . Mr. R. Anandarajashekar, Dean, Pharma Training Institute, Bangalore, Dr. B. R. Jagashetty, Former Drugs Controller of Karnataka, were present as special guests during the function. Mr. J. Jayaseelan, Managing Director of M/s. Delvin Formulations group of companies and Mr. R. Thiruvengadam, Joint Managing Director, M/s. Tablets (India) Ltd., felicitated the special guests and faculty.

Our Chairman Mr. S. V. Veerramani explained the objectives of the Institute, with a view to impart training to fresh B. Pharm and M. Pharm graduates coming out of the colleges and who aspire to make their career in Pharmaceutical Industry.

The first Training Program on the subject of “Industrial Orientation Training for Quality Management Personnel” was held between 12th May to 9th June 2014 in Chennai. About 15 students were trained in this program

The 2nd Training on the subject of “Industrial Orientation Training for Production Management Personnel” was held from 6th Oct to 9th Nov 2014. About 34 students were trained

The 3rd Training on “Industrial Orientation Training for Quality Management Personnel” was held between 18th Sep to 16th Oct 2015. About 60 students were trained.

There is a tremendous response from the Pharmacy colleges for such training. The training program is going to be an ongoing process. Mr. K. Saravana Kumar, from M/s. Fourrts India Labs Pvt Ltd, Chennai, Mr. R. Sabapathy and Mr. Sanjay Kumar Das Mohapatra, from M/s Medopharm, Mr. S. Jayakumar, from M/s Apex Lab Pvt Ltd,, Mr. J. Jayaseelan from M/s. Sai Mirra,, Mr. Sulaiman from M/s Madras Pharmaceuticals and Mr. R. Thiruvengadam from , M/s. Tablets (India) Ltd gave tremendous support for the success of the training program. We also thank the all the Pharma industries and other Technical Personnel for their support in imparting practical training to our trainees. Mr. S. P. Thiyagarajan, Dr. V. Manohar and their group from Indian Institute of Chromatography and Mass Spectrometry, Gunidy, Chennai were extremely helpful in providing lectures on Instrumentation and also making the trainees to visit their lab to practically see the latest equipments in use.



Inaugural Function of Pharma Knowledge and Training Institute (Finishing School)



Students attended the Training Programme



Inaugural address by Chairman of our Trust



Lecture by Dr. N. Murugesan, Director, CTDL, Chennai

University Merit Awards

The latest addition to the Trust activities is the University Merit awards initiated in year the 2015. The students securing top 3 ranks of B. Pharmacy from Dr. MGR Medical University, Chennai, are awarded cash prizes and certificates, sponsored by M/s. Fourrts India Labs Pvt Ltd, Chennai.

S. No.	Name	College	Prize Amount (Rs.)
1.	Rani. N	Jaya College of Pharmaceutical Sciences, Chennai	Rs. 7,500/-
2.	AfsanFathima C. A.	Aadhi Bhagavan College of Pharmaceutical Sciences, Cheyyar, Thiruvannamalai Dist	Rs. 7,500/-
3.	Sadhish. I.V.	Jaya College of Pharmaceutical Sciences, Chennai	Rs. 6,000/-
4.	Kanimozhi. T.	K. K. College of Pharmacy, Chennai	Rs. 4,000/-

The Trust also takes pride in taking active part in conducting Five Indian Pharmaceutical Congress Sessions and One Indian Pharmaceutical Convention



ARTICLES

THEORY OF CHROMATOGRAPHY – AN INTRODUCTION

By

Dr. V. Manohar,

Director, IICMS, Guindy, Chennai

(Lecture Delivered during the Training Program on
Quality Control, conducted by TNPST)

What will be covered ?

- Some of basic terms used in chromatography such as polarity, dipole moment, adsorption
- What is Chromatography about ?
- How does separation take place and classification?
- How will you explain the separation process ?
- What are the chromatographic parameters that define a separation ?
- How will you choose a column for analysis?

Before going to Chromatography,

Some of the terms, need to know are:

- ❖ Dipole moment
- ❖ Polarity
- ❖ Adsorption

Dipole moment and Polarity

“Charge distribution” of a molecule

- ❖ the **shape** of the molecule
- ❖ the **polarity** of the molecule

What is polar and non-polar molecule ?

Polar molecule

- The centre of overall negative charge **does not coincide** with that of positive charge
- Orientation of the molecule is such that one end has net positive charge and the other end has net negative charge, i.e., it has a **dipole**

Nonpolar molecule

- No charges on the opposite ends of the molecule
- Or, charges of the same sign on the opposite ends
- Molecule is **not** a dipole

- Polar molecules align themselves:

- in an electrical field
- with respect to one another
- with respect to ions

The degree of polarity of a molecule is described by its **Dipole moment**, $m = Q * r$, where

- Q equals the charge on either end of the dipole
- r is the distance between the charges

Electro negativity

It is the ability of an atom in a particular molecule to attract electron itself. It is a function of

- atom's ionisation energy (how strong atoms hold their own electrons)
- atom's electron affinity (how strong the atoms attracts other electrons)
- The greater the value, the greater the attractiveness for electrons
- **Electro negativity** is used to determine whether a given bond will be Nonpolar covalent, polar covalent or ionic

The general thumb rule for predicting the type of bond is

If the electronegativities are equal, the bond is non-polar covalent

- If the difference in electronegativities between the atoms is > 2.0 , the bond is polar covalent
- If the difference in electronegativities between the atoms is 2.0 , the bond is ionic.

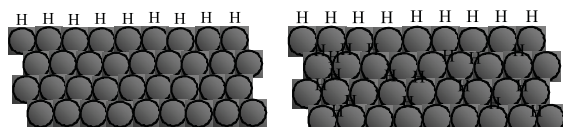
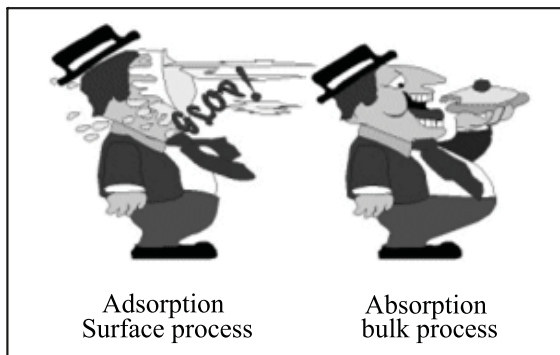
The thumb rule **to predict the molecular polarity** is

1. If all similar regions are not same, the chemical species is polar (unless symmetry takes precedence)
2. If all similar regions are the same, the chemical species is non polar

▼ **Bond polarity** is determined by electronegativity difference

▼ **Molecular polarity** is defined by the shape of the molecule

Adsorption versus Absorption



H₂ adsorption on palladium

H₂ absorption → palladium hydride

Molecular Adsorption

- Two types –
 - Physical adsorption (Physisorption)
 - Chemical adsorption (Chemisorption)

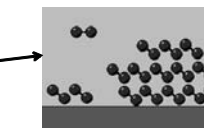
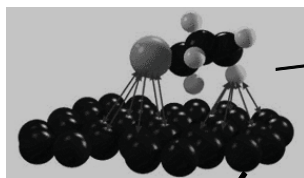
Physical adsorption:

The only bonding is weak Van der Waals - type forces. There is no significant redistribution of electron density in either the molecule or at the substrate surface

Chemical adsorption:

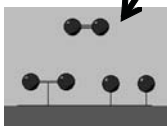
A chemical bond, involving substantial rearrangement of electron density, is formed between the adsorbate and the substrate. The nature of the bond will be anywhere between ionic or complete covalent character

Types of Adsorption Modes



Physical adsorption or physisorption

Bonding between molecules and surface is by weak van der Waals forces.

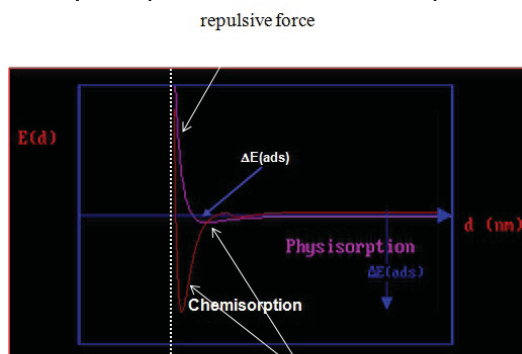


Chemical bond is formed between molecules and surface.

Chemical adsorption or chemisorption

Adsorption Energetics

Physisorption versus chemisorption



surface attractive forces

$\Delta E(\text{ads})_{\text{Physisorption}} < \Delta E(\text{ads})_{\text{Chemisorption}}$

small minima	large minima
weak Van der Waal attraction force	formation of surface chemical bonds

A brief History of Chromatography

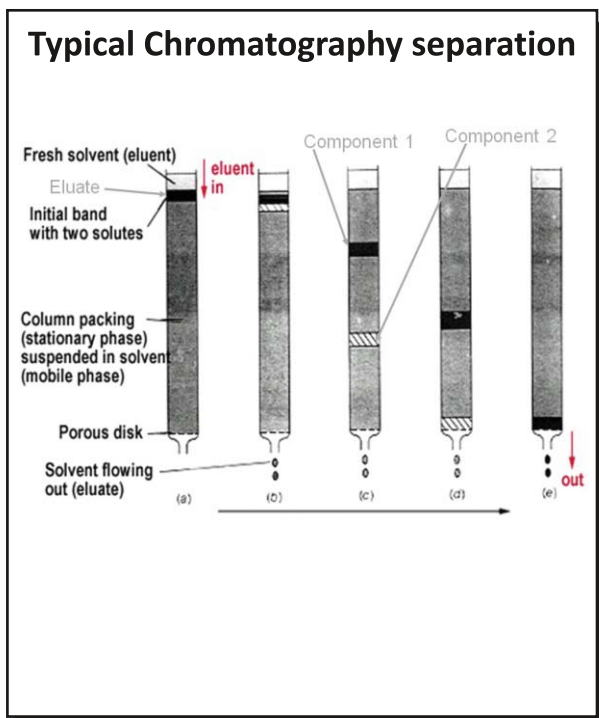
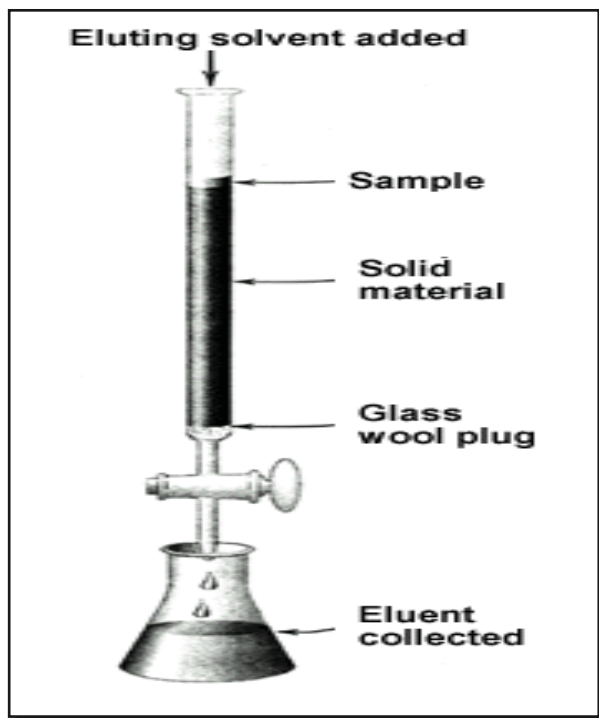
"Chromatography is a separation method in which a mixture is applied as a narrow initial zone to a stationary, porous sorbent and the components are caused to undergo differential migration by the flow of the mobile phase, liquid or gas"

-- H H Strain, Chromatographic Adsorption Analysis, Interscience Publishers, New York, 1945

- Originator of Chromatography is Michael Tswett, 1906
- Before him, in 1848, Way and Thompson recognized the phenomenon of ion exchange in solids
- Theory developed in early fifties by Martin and Synge, Lapidus and Admunson, Giddings, van Deemter 1956)

Some of the terms used in Chromatography are...

- Stationary phase
- Mobile phase - liquid or gas
- Elution - the process of separation
- Eluent - the mobile phase
- Eluate - the sample component being separated
- Retention - the extent to which the eluate is held up in the system



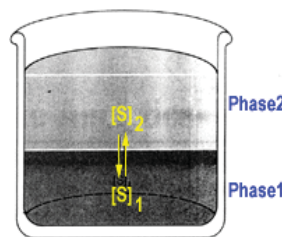
Distribution Ratio (K):

- Eluate (Solute) is transported by mobile phase over a stationary phase.
- There is a rate - competitive association and dissociation of the eluate species.
- This causes distribution of the eluates between the two phases
- The distribution can be defined as distribution ratio or partition ratio or partition coefficient

i.e. $K = A_s / A_m$ where

A_s is the concentration of A in a unit volume of the stationary phase

A_m is the concentration of A in a unit volume of the mobile phase



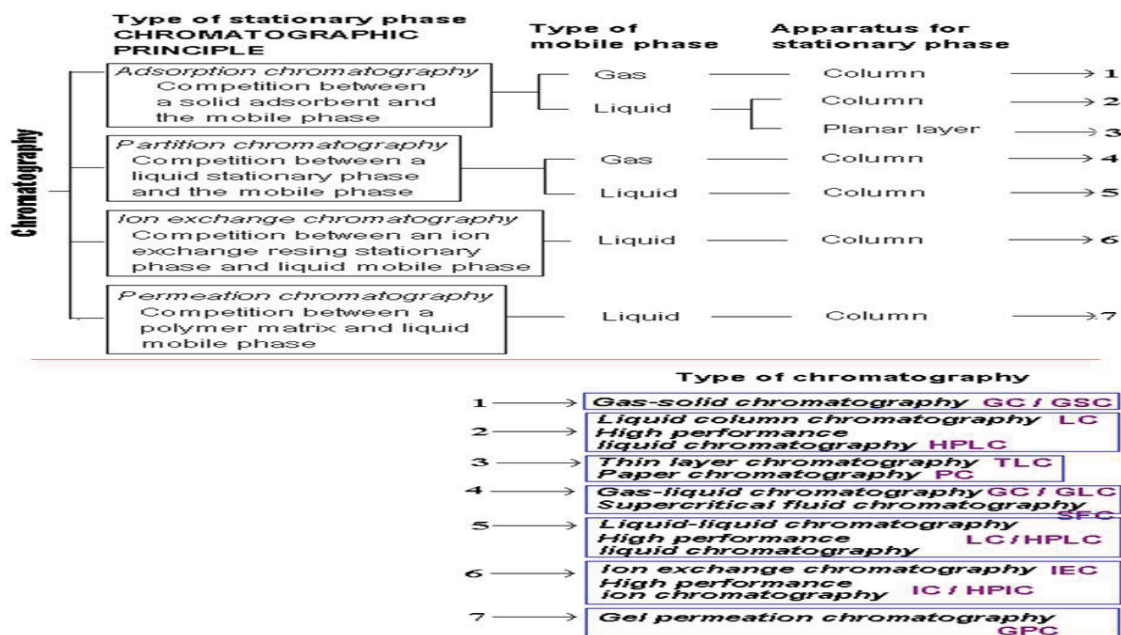
Eluate S is partitioned between two phases as S_1 and S_2

$$\text{i.e. } K = A_s / A_m$$

Based upon this simple process of separation and distribution ratio, chromatography process can be classified as follows:

- Adsorption Chromatography
- Partition Chromatography
- Ion exchange Chromatography
- Size Exclusion Chromatography
- Affinity Chromatography

These can be classified as



Factors that influence the separation

The retention behavior is determined by

- (1) distribution constant, K and
- (2) mobile phase flow rate

The magnitude of K, in turn, is determined by

- (1) physicochemical interaction such as hydrogen bonding, (dipole-dipole and dispersion forces, electrostatic (ionic) interaction and
 - (2) physical parameters such as temperature, viscosity and diffusion coefficient
- Eluent linear flow velocity (u)
 - Species with different K values have different migration velocities (v) with $v < u$

Zonal Elution

- Stationary phase volume places an upper limit on the amount of eluate
- Different K values - large sample volumes - displacement elution
- Similar K values - limited sample volumes - Zonal elution

Thin Layer Chromatography

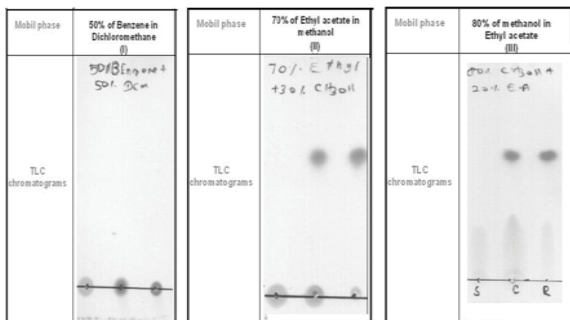


Plate Theory

Diffusion of solute (eluate) through the column leads to Fick's Second law of diffusion with effective diffusion coefficient D_e is given by

$$\frac{dC}{dt} = -v \frac{dC}{dx} + D_e \frac{d^2C}{dx^2}$$

$$C = \frac{M}{2\sqrt{\pi D_e t}} \exp \{-x^2 / 4D_e t\}$$

$$C = \frac{1}{\sigma\sqrt{2\pi}} \exp \{-(x/4\sigma)^2\}$$

$$\sigma^2 = 2D_e t$$

M of solute initially confined to a plane perpendicular to the direction of the flow

Effective zone migration can be given as

$$C_t = \frac{M}{F} \frac{1}{\sigma_t \sqrt{2\pi}} \exp \left\{ - (t_R - t)^2 / 2\sigma_t^2 \right\}$$

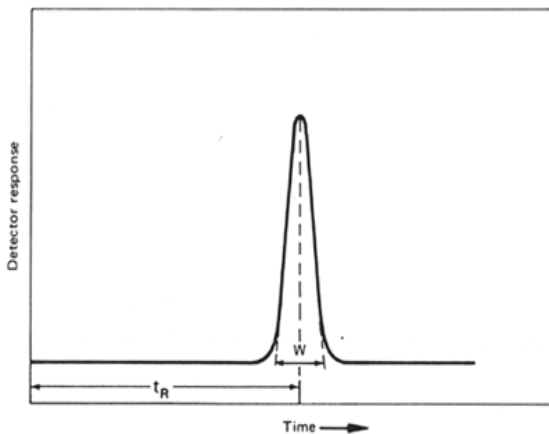
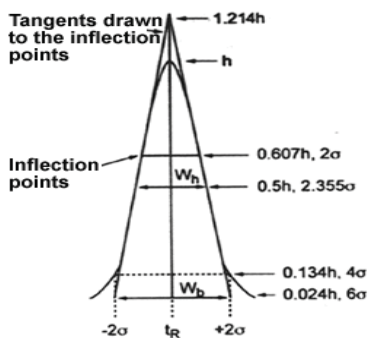
Where

M -- amount of solute initially confined to a plane $\perp$ to direction of flow

F -- Volumetric flow rate

σ_t - Gaussian with at time t

t_R -- Retention time



Connectivity between peak shape and column parameters

- Capacity factor (k')
- Selectivity factor (α)

Zone migration rate (v) is given by

$$v = u \times \frac{1}{1 + K \frac{V_s}{V_m}}$$

$$v = L / t_R$$

$$u = L / t_0 \quad k' = 1 + K \frac{V_s}{V_m}$$

Where

u - linear flow velocity of mobile phase

K - the distribution function

V_s - the volume of stationary phase

V_m - the volume of the mobile phase

$$k' = 1 + K \frac{V_s}{V_m}$$

This term is a measure of the extent to which the eluate is retained by the stationary phase, i.e., increasing t_R and decreasing u .

This is called s retention or capacity factor (k')

$$\text{i.e. } k' = (t_R - t_0) / t_0$$

Similarly the degree of retention of eluate A with respect to B is given by selectivity factor α

$$\alpha = \{(t_R)B - t_0\} / \{(t_R)A - t_0\}$$

Thus the physical parameters are related to the retention behavior

Plate theory

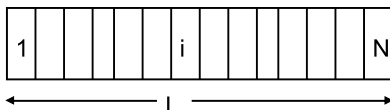
“Height Equivalent Theoretical Plate (HETP)”

It is similar to fractional distillation column

The column is divided into N segments, called plates.

It constitutes a certain length of column H

$$H = L/N$$



- The concentration of the solute in the mobile phase leaving that segment is in equilibrium with the average concentration of that species in the stationary phase.
- Assume that the equilibrium is rapid

The concentration at the N^{th} plate is given by

$$C_N = C_0 \exp(-av) \frac{(av)^{N-1}}{(N-1)!}$$

Where

C_N - concentration at N^{th} plate

C_0 - Initial concentration

$$a = (v_m + K v_s)^{-1}$$

v - total volume of the mobile phase passed through the first segment

This is a form Poisson distribution

It can be shown that the concentration distribution is related to standard deviation and hence H is related as

$$H = \sigma^2 / L$$

The limitation of this theory is the assumption that

- The concentration of the solute in the mobile phase leaving that segment is in equilibrium with the average concentration of that species in the stationary phase.
- Assume that the equilibrium is rapid

Rate theory

The Van Deemter Equation

$$H = A + \frac{B}{u} + Cu$$

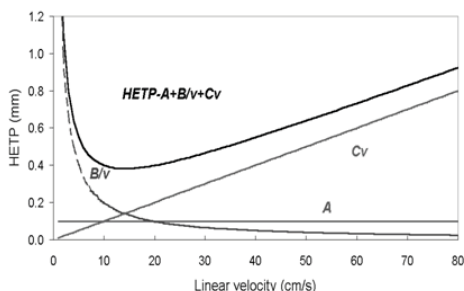
Where A , B , C are constants characteristics of the chromatographic system

A - multiple path factor for packed columns; different molecules follow different paths

B - Diffusion factor; molecules move from high to low concentration spontaneously

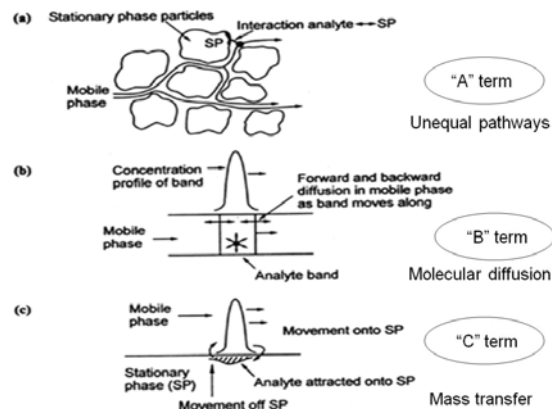
C - Mass Transfer; Different molecules enter and leave the stationary phase at different times

H should be made as small as possible



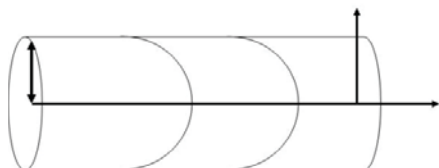
Difference between Plate and Rate theories

- **Plate theory** - assumes that the equilibrium is rapid
- **Rate theory** - considers that true equilibrium of the solute between the phases is never fully established throughout the column length or sample zone



"A" term: Different pathways

- It is called as eddy diffusion
- It is due to the variety of tortuous path available between the particles in the column
- It is independent of mobile phase velocity
- The flow velocity is parabolic in nature
- It is also a source of band broadening



"B" Term: Molecular Diffusion

- It is longitudinal or molecular diffusion of the sample components due to concentration gradient within the column
- The contribution to plate height is given by

$$H_{md} = \frac{2\gamma_m D_m}{u}$$

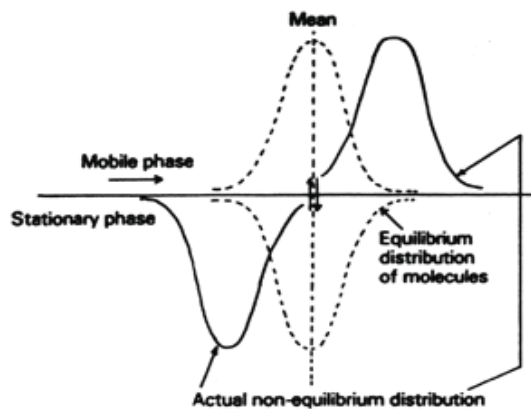
γ_m is obstruction factor 0.5- 1.0

D_m diffusion coefficient

u is the mobile phase velocity

"C" term: Mass transfer

- It is influenced by the partition coefficient
- It depends upon relative solubility of the sample in the stationary liquid phase
- It also depends upon adsorbability of the solute on the solid phase
- It depends upon temperature
- It not only recognizes the diffusion longitudinally but also axially
- There is a continual transfer of sample from both leading and trailing edge of sample zone
- It contribute for peak tailing and broadening



Column Resolution

Resolution R_s of a column provides a quantitative measurement of its ability to separate two analytes

It is proportional to the square root of number of theoretical plates and hence square root of length of column

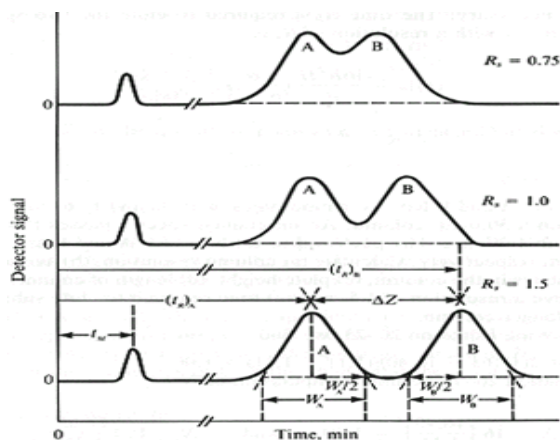
It is given by

$$R_s = 2\{(t_R)_B - (t_R)_A\} / (W_A + W_B) \text{ where}$$

$\{(t_R)_B - (t_R)_A\}$ is the difference in the retention times of two peaks A and B

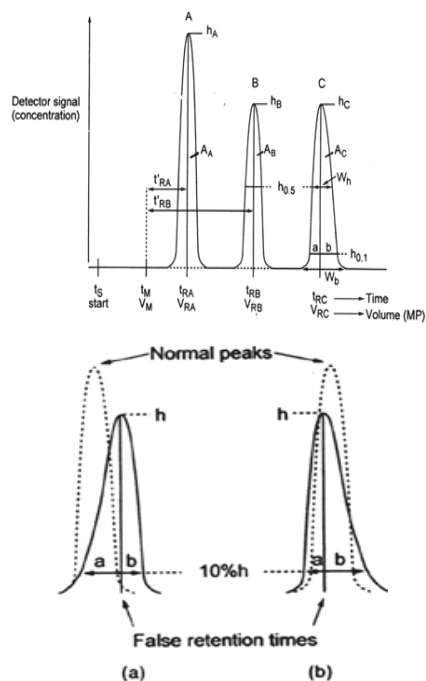
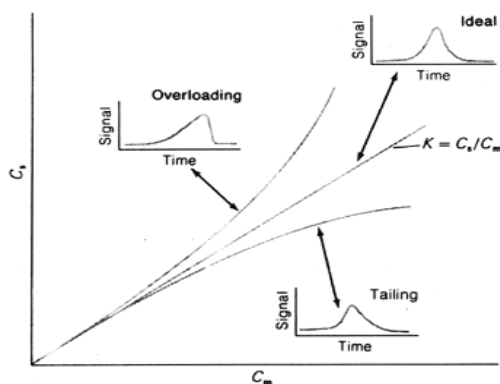
$(W_A + W_B)$ is the width of the peaks

Typical column resolution



Band shape / spreading / broadening

- Gaussian band shape results when the partition coefficient $K (=C_s / C_m)$ is constant
- A plot between C_s and C_m is called isotherm



Name	Symbol of Experimental Quantity	Determined From
Migration time, nonretained species	t_M	Chromatogram
Retention times, species A and B	$(t_R)_A, (t_R)_B$	Chromatogram
Adjusted retention time, species A	$(t'_R)_A$	$(t'_R)_A = (t_R)_A - t_M$
Peak widths, species A and B	W_A, W_B	Chromatogram
Length of column packing	L	Direct measurement
Flow rate	F	Direct measurement
Volume of stationary phase	V_S	Packing preparation data
Concentration of solute in mobile and stationary phases	c_M, c_S	Analysis and preparation data

Summary of chromatographic parameters

Name	Calculation of Derived Quantities	Relationship to Other Quantities
Linear mobile-phase velocity	$u = L/t_M$	
Volume of mobile phase	$V_M = t_M F$	
Capacity factor	$k' = (t_R - t_M)/t_M$	$k' = \frac{KV_S}{V_M}$
Partition coefficient	$K = \frac{k' V_M}{V_S}$	$K = \frac{c_S}{c_M}$
Selectivity factor	$\alpha = \frac{(t_R)_B - t_M}{(t_R)_A - t_M}$	$\alpha = \frac{k'_B}{k'_A} = \frac{K_B}{K_A}$
Resolution	$R_S = \frac{2[(t_R)_B - (t_R)_A]}{W_A + W_B}$	$R_S = \frac{\sqrt{N}}{4} \left(\frac{\alpha - 1}{\alpha} \right) \left(\frac{k'_B}{1 + k'_B} \right)$
Number of plates	$N = 16 \left(\frac{t_R}{W} \right)^2$	$N = 16 R_S^2 \left(\frac{\alpha}{\alpha - 1} \right)^2 \left(\frac{1 + k'_B}{k'_B} \right)^2$
Plate height	$H = L/N$	
Retention time	$(t_R)_B = \frac{16 R_S^2 H}{u} \left(\frac{\alpha}{\alpha - 1} \right)^2 \frac{(1 + k'_B)^3}{(k'_B)^2}$	

Column selection (GC)

- While selecting a GC column, the basic parameters are
 - Stationary phase
 - Column internal diameter
 - Film thickness
 - Column length

General Application Phase Selection Guide:

<u>Applications</u>	<u>Recommended Phase</u>
Alcohols	BPX5, Bp10, BP20
Alditol Acetates	BP225, BPX70
Alkaloids	BPX5, BP1
Amines	BP1, BPX5
Aromatic Hydrocarbons	BPX5, HT5
Aroclors	HT8, HT5, BPX5
Blood Alcohol	BP20
Carbohydrates	HT5, BPX70, BP225
Chiral Separations	Cydex-B
Chlorinated Organics	BPX5, BP10, BP624
Drugs/Pharmaceuticals	BP1, BPX5, BPX35
Fatty Acid Methyl Esters	BP1, BPX70
Flavours	BP1, BPX5, BP20, Bp21
General Purpose	BP1, BPX5
Herbicides	BPX5, BPX35
Hydrocarbons	BP1, HT5, BPX1, BPX5

Applications

Recommended Phase

Mono, Di and Triglycerides	BPX5, Ht5
Organic Acids (Free)	BP20, Bp21
Petroleum Products	BPX1, BPX5, PONA, HT5 PCBs Ht8
Pesticides (Organochlorine)	BPX5, BPX35, Bp5, BPX50, HT8
Pesticides (Organophosphorous)	BPX5, BPX50,
Phenols	BP1, BPX5, Bp20
Phthalate Esters	BPX5
Gasoline	BP1-PONA
Semivolatile Pollutants	BP5, BPX5
Simulated Distillation	HT5-SIM, BPX1-SimD
Solvents	BP1, BPX5, BP10, BP624, Bp20
Volatile Pollutants	BPX5, Bp624
Waxes	BP1, HT5, BPX5

GC Columns - a guide to polarity

Material	USP No.
Low Polarity Squalane	
HP-1, DB-1, BP-1, CP-Sil 5, Rtx-1	G1, G2, G38
DB-5, HP-5, BP-5, BPX-5, CP-Sil 8, Rtx-5	G27, G36
DB-1301, HP-1301, CP-1301, Rtx-1301	G43
DB-35, HP-35, BPX-35, Rtx-35	G42
DB-1701, HP-1701, BP-10, CP-19, Rtx-1701	
DB-17, HP-17, BP-50, CP-24, Rtx-50	G3
DB-225, BP-225, CP-Sil 43	G7, G19
DB-wax, HP-wax, BP-20, CP-wax52	G14, G15, G16, G20
DB-FFAP, BP-21, CP-wax58	G25, G35
DB-23, BPX-70, CP-Sil88	
High Polarity OV-275	

To summarize

- Some of basic terms used in chromatography such as polarity, dipole moment, adsorption
- What is Chromatography ?
- How does separation take place and classification?
- How will you explain the separation process ?
- What are the chromatographic parameters that define a separation ?
- Columns!!

--- Conclusion ---

Let us go to Gas Chromatography

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HIGH PERFORMANCE LIQUID CHROMATOGRAPHY (HPLC) – INSTRUMENTATION & COLUMNS

By

Mr. P. Raman,

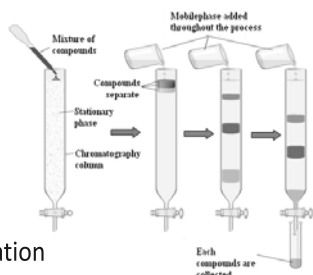
IICMS, Guindy, Chennai

(Lecture Delivered during the Training Program on
Quality Control, conducted by TNPSWT)

“Chromatography” meaning

The word “Chromatography”
is composed of two Greek roots

Chroma = Colour
Graphein = to write



And its verbatim translation
means **“Colour writing”**
which refers to visualizing
the separated **multicoloured ring**
on the column.

High Performance Liquid Chromatography



“ HPLC Principle”

- HPLC is a type of chromatographic technique used to separate, identify & quantify each component in a mixture
- Different Component in sample pass through the column & separated due to their adsorption & partition behaviour between mobile phase (liquid) and stationary phase (liquid coated on solid surface).

“ HPLC Principle”

Solvent Delivery system
(Pump)

Injector & Autosampler

Column compartment

Detector

Data Processor



Solvent Delivery System (Pump)

Pump is used to generate a specified flow rate of mobile phase from reservoir typically milliliters per minute.

Type -1 :Binary system (High pressure gradient system)

Type-2 :Quaternary system (Low pressure gradient system)



Binary system



Quaternary system

Types of possible configuration

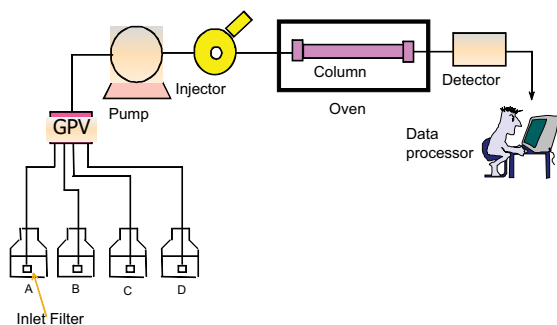
- ❖ Isocratic system
- ❖ Low-pressure gradient system
- ❖ High-pressure gradient system

Isocratic system

A chromatographic separation that occurs by using single solvent mixture of constant composition



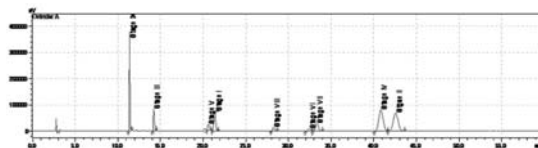
Low-pressure Gradient System



- o One pump used to control 4 reservoirs;
- o Mixing is done before pump by GPV valve
- o Ternary & quaternary gradient can be applied

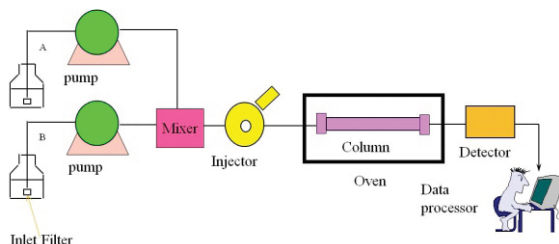
Low-pressure Gradient System

- Mobile phase A - 0.01M Ammonium formate pH 3.0 with formic acid
- Mobile phase B - Acetonitrile
- Run time - 60 minutes
- Column - Enable C8 (150 X 4.6 mm, 5 μ)



Peak	Retention time	Compound Name	Tailing factor	Resolution
1	11.38	Stage-IX	1.06	0.00
2	14.20	Stage-III	1.58	12.86
3	20.60	Stage-V	1.31	20.35
4	21.36	Stage-I	1.11	1.95
5	28.24	Stage-VIII	1.24	16.39
6	32.42	Stage-VI	1.05	7.92
7	33.33	Stage-VII	1.10	1.46
8	40.83	Stage-IV	1.07	9.36
9	42.56	Stage-II	1.06	1.73

High-pressure Gradient System



- o Excellent gradient accuracy.
- o High mixing efficiency
- o High Flow rates & fast gradients

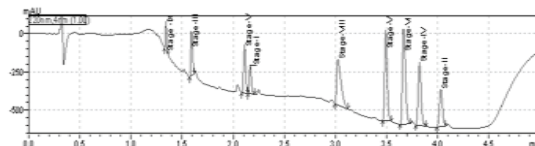
High-pressure Gradient System

Mobile phase A - 0.02M Ammonium formate pH 2.7 with formic acid

Mobile phase B - Acetonitrile

Run time - 5 minutes

Column - Eclipse plus (100 X 2.1 mm, 1.8 μ)



Peak	Retention time	Compound Name	Tailing factor	Resolution
1	1.34	Stage-IX	1.19	0.00
2	1.59	Stage-III	1.40	8.78
3	2.11	Stage-V	1.14	14.55
4	2.16	Stage-I	1.16	1.44
5	3.02	Stage-VIII	2.28	14.46
6	3.49	Stage-VI	1.23	7.30
7	3.66	Stage-VII	1.39	3.39
8	2.82	Stage-IV	1.18	2.86
9	4.03	Stage-II	1.12	3.82

Comparison of High Pressure & Low pressure gradient system

Low Pressure Gradient	High Pressure Gradient
Pump Backpressure – 5000 psi	Pump Backpressure -15000psi
Routine analysis purpose	R & D, NDD purpose
Analytical column with particle size more than 3 μ	Analytical column with particle size less than 3 μ
Fast Gradient is applicable with irregular retention time	Fast Gradient within 5.0min with reproducible result
Ternary & Quaternary solvent system also possible	Ternary & Quaternary solvent system cannot be introduced

Injector

Injector is used to introduce the sample in few microlitres into the continuously flowing mobile phase that carries sample into the column.

- Manual Injector (Rheodyne 9725i)
- Automated Injector (Autosampler)

Manual Injector



Autosampler



Injector

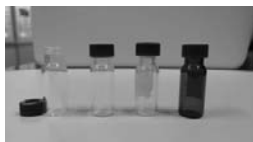
Manual Injector

Sample is injected in few microlitres into the continuously flowing mobile phase through certified glass syringe

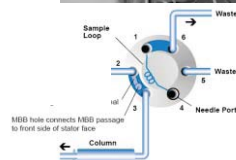


Automated Injector

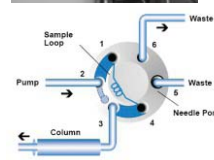
Sample is injected in few microlitres from HPLC vials with septa cap through automated injector into the continuously flowing mobile phase.



Manual Injector (Rheodyne 9725i)



Position 1 (LOAD)



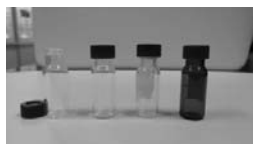
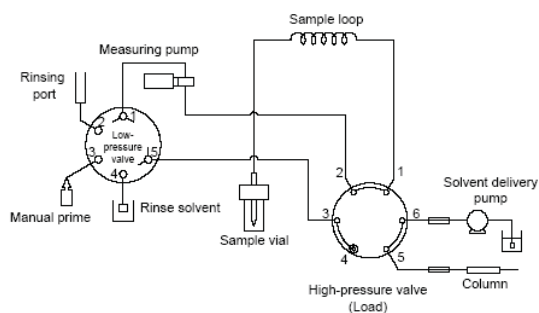
Position 2 (INJECT)

6 Port Valve System

Typical sample loop volume is 5-200 μ l

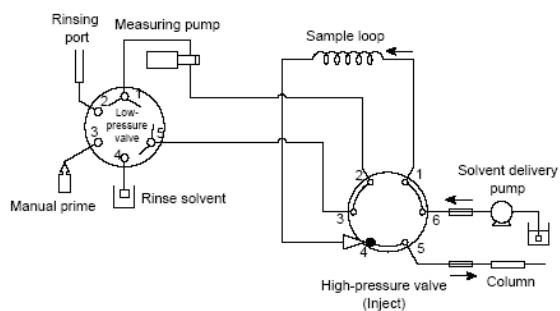
Automated Injector

Sample Loading Position



Automated Injector

Sample Injected Position



Comparison of Autosampler & Manual Injector

Autosampler	Manual Injector
Auto sampler Temp. 4°C-40°C	Room temperature
Auto-addition of compounds	Manual sample preparation
Conventional Injection volume from 0.1 µL to 100 µL	Conventional Injection volume from 5 µL to 20 µL
Injection carry over is 0.0025%	Manually sample loop to be flushed properly
Sample vial capacity-210 numbers	No vial Racks

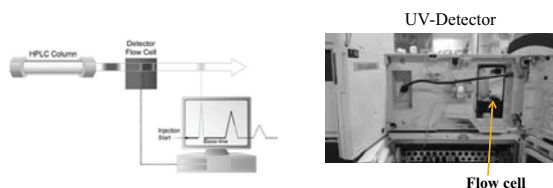
Comparison of Autosampler & Manual Injector

Column compartment

Column compartment provides stable column cooling 5°C & column heating upto 80°C to keep stationary phase (column) at stable environment for reproducible result.



Detector



Detector has ability to sense the presence of compound and send its corresponding electrical signal to computer data station.

Detector contains flow cell that detects each separated compound band against background of the mobile phase

Types of Detector

Detector selection based on the characteristics and concentration of the compound that needs to be identified.

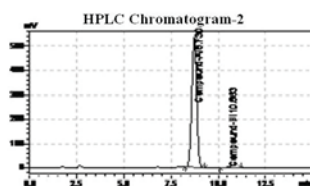
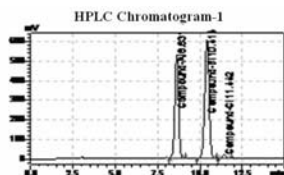
Types :

- ❖ UV-Visible detector (UV)
- ❖ Photo Diode Array detector (PDA)
- ❖ Refractive Index detector (RI)
- ❖ Fluorescence detector (RF)
- ❖ Evaporative Light Scattering detector (ELSD)
- ❖ Mass Detector

HPLC Chromatogram

HPLC chromatogram is an representation of the separation that has chromatographically occurred on the HPLC system.

Each peak corresponds to the detector response with respect to time for a different compound present in the sample mixture.



Column Chemistry



Stationary phase support in Chromatography

The major stationary phase support used in chromatography is Silica.

Stationary phase	Mode of Chromatography
Silica	Normal phase chromatography
Silica with chemical modification of the surface	Reversed -phase chromatography Normal phase chromatography Ion-exchange chromatography Size exclusion chromatography

Stationary phase support in Chromatography

Mode	Stationary phase
Normal Phase	Silica, Amino, Cyano, Diol
Reversed -phase	C18, C8, C6, C4, Cyano, Amino
Reversed -phase ion pair	C18, C8
Ion-exchange	Anion or Cation Exchange Resin
Size Exclusion	Polystyrene silica

Porous silica has a high surface area that leads to high efficiency column (through higher number of possible surface interactions – Theoretical plates)

Factors that are important in the manufacture of silica-based columns for HPLC

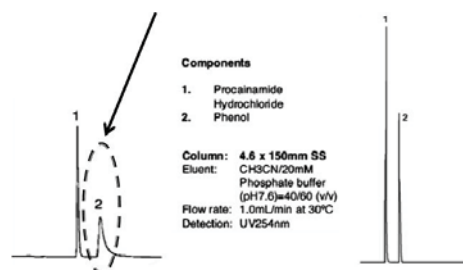
1. Purity (especially metal ion content)
2. Sol-gel or zero gel silica type
3. Shape (spherical or irregular)
4. Particle size and its distribution
5. Hybridization with alkyl groups
6. Deactivation / surface treatment

Metal ion content in Silica

The presence of metal ions within silica can cause peak tailing.

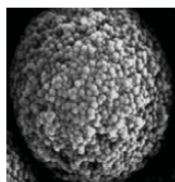
Analyte molecules *interact with metal* or silanol group on the silica surface and are **retained longer than the actual retention** of the analyte molecules.

The molecules undergoing this unwanted **secondary retention** causes the '**Tail**' of the peak.

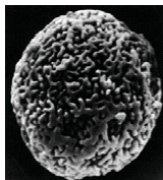


Particle Type

There are two types of silica particles widely used in modern HPLC

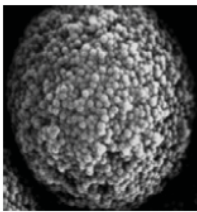
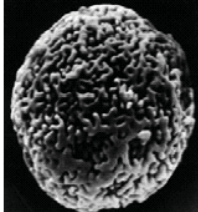


Silica Sol-gel



Silica Zero-gel

Comparison of Sol-gel and Zero-gel

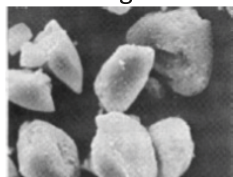
Sol-gel	Zero-gel
	
Less soluble at pH above 7 than silica gels.	Readily soluble at pH above 7
Particles have lower surface area, porosity and surface reactivity	Particles have higher surface area, porosity and surface reactivity

Silica gels - Manufacture vary from vendor to vendor with different
Shapes
Surface areas
Pore sizes and Surface chemistries

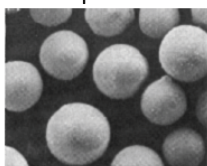
Particle Shape

There are two basic shapes of silica particles

1. Irregular



2. Spherical



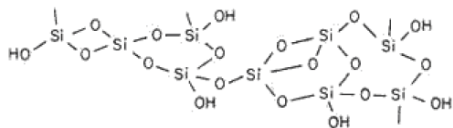
Milling of silica gels followed by sieving to obtain the appropriate particle size

Difference between Irregular and Spherical Shape particle

Irregular Shape	Spherical Shape
Less expensive	High expensive
Known to have poor efficiency	Known to have good efficiency
The use of high flow rate (pressure) can cause the irregular particles to sheer forming smaller sub-particles known as ' fines ' which may migrate and eventually block the outlet frit of the column	Spherical particles are not entertained this process of outlet frit block

Chemical Composition (Hybrid material)

The chemical structure of Silica particle is

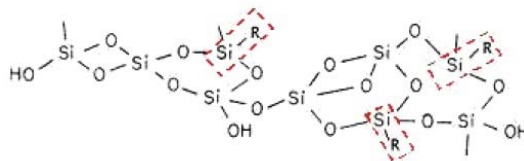


At high pH, the silica substrate used in HPLC column become susceptible to hydrolysis

When the **silica begins to degrade**, the symptoms include **rapid loss of efficiency** and an **increase in back pressure**.

Several manufacturers have now resorted to a new generation of support material that are generally referred to as **"Hybrid"** materials.

Chemical Composition (Hybrid material)



Chemical structure of hybridized Silica particle

These **hybrid silica** material show good stability at high pH as the surface is no longer with silanol and therefore not as susceptible to hydrolysis.

The reduction of silanol surface activity also ensure that the activity towards basic analyte is reduced and peak shape improves.

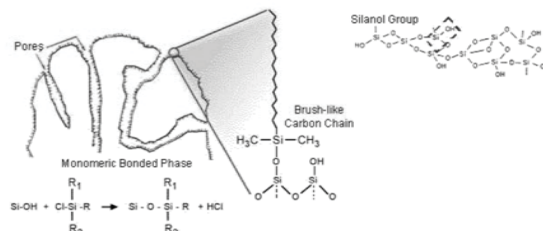
Chemically Bonded Phases

Typical bonded Phases are used to produce stationary phase with different selectivity

Bonded Phase
Trimethyl
Dimethyl-3-cyanopropyl
Dimethyl-n-butyl (C4)
Dimethyl-n-octyl (C8)
Dimethyl-n-octadecyl (C18)
Triisopropyl
Diisopropoyl-3-cyanopropyl
Diisopropoyl-n-octyl
Diisobutyl-n-octadecyl

Chemically Bonded Phases

C18 Reversed Phase column material

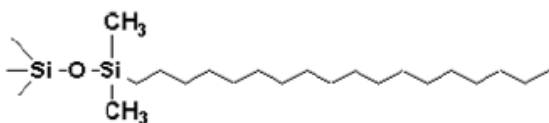


The fundamental composition of Silica chemically bonded

Reacting a **Chlorosilane** with the **surface silanol** groups of silica produces many useful stationary phases

Bonded phase silica support provide wide application in RP HPLC

C18 Stationary Phase



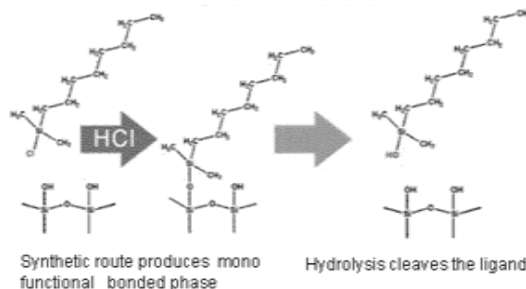
C18 is Octadecylsilyl

Highly robust hydrophobic phase, produce good retention with hydrophobic (non-polar) compounds

Can also be used for the separation of polar compounds when used with mobile phase additives.

Chemically Bonded Phases

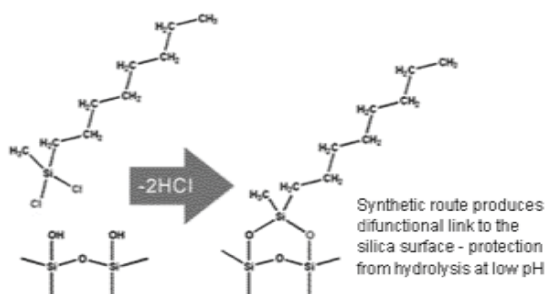
C8 monomeric bonded Reversed Phase column material



Monochlorosilanes produces monomeric packing materials that attach to the silica surface through a single bond (Called a silyl ether linkage)

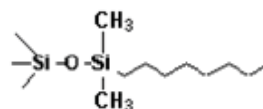
Chemically Bonded Phases

C8 with difunctional bonded Reversed Phase column material



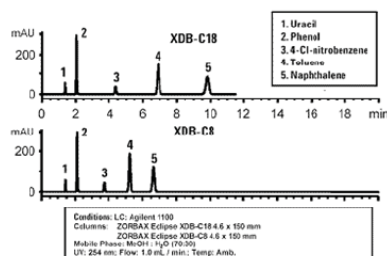
The choice of monomeric or polymeric phases with the extend of the bonding reaction can produce widely different stationary phase with different surface chemistry, thus changing the column selectivity.

C8 Stationary phase



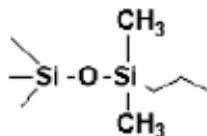
In general, shortening the alkyl chain will shorten the retention time of non-polar analyte

C8 is Octyl functional silica



There are only very slight selectivity differences between the C18 and C8 bonded phases.

C3 propyl functional silica phase



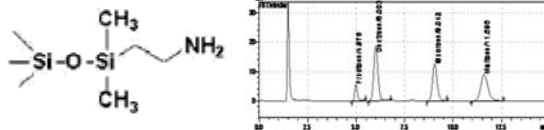
C3 is propyl functional silica

These C3 columns are having different selectivity due to the influence of the silanol surface with the short C3 ligand.

These C2 – C4 columns are often used for protein and peptide analysis.

These columns are not as chemically robust as their longer chain counterparts.

Aminopropyl Reversed-phase



Aminopropyl functional silica

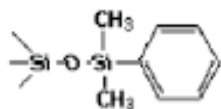
The use of more polar aminopropyl phases shows altered selectivity compared to the alkyl phases.

These phases are able to interact with polar analyte functional groups

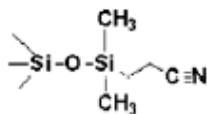
Amino columns are commonly used for the analysis of sugars, polysaccharides and organic ions.

Amino columns can be used in normal phase as well as reversed-phase

Phenyl and Nitrile functional silica



Phenyl functional silica



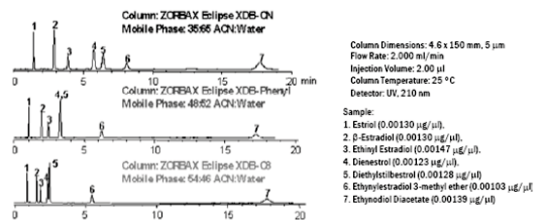
Nitrile functional silica

The use of more polar phenyl and cyano phases shows altered selectivity compared to the alkyl phases due to π -electron cloud.

These phases are able to interact with polar analyte functional groups.

Cyano columns can be used in normal phase as well as reversed-phase.

C8, Phenyl and Nitrile functional silica



Separation of estrogens in Cyano column is shows its selectivity in these class of compounds as compared to phenyl and C8 columns

Definition of Column - End Capping

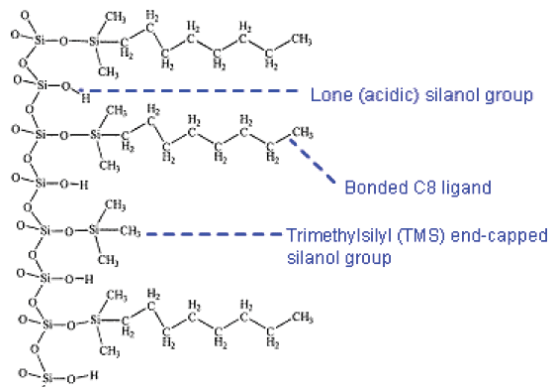
The surface of non-hybrid silica is covered with **silanol group** that are **left-out during the hybrid process** due to **steric effect**.

The highly reactive reagent like non-polar **trimethylsilyl groups** are used to react with **left-out silanol group to form 'end cap'** for the free silanol. (Column –End capping (or) Surface treatment –End capping)



Surface Treatment - End Capping

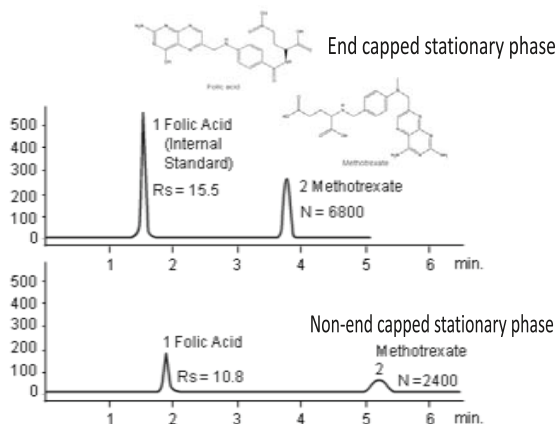
Typical surface chemistry of an end capped reversed phase stationary phase



The **left-out silanol** which involves in the **adsorption process** with analyte containing ionic or polar functional groups to give rise to **peak tailing**, through unwanted secondary interactions.

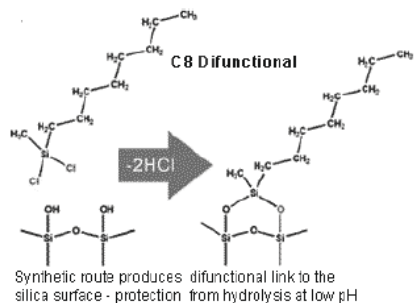
Surface Treatment - End Capping

Separation of basic compound using non-end capped and end capped column



Working at Low pH

2. Difunctional binding to the silica surface

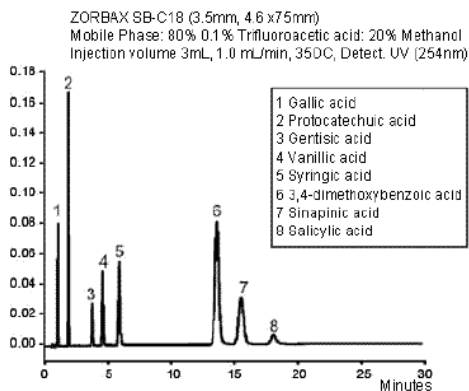


Difunctional ligands to protect silica from hydrolysis

It is noted that, the trifunctional bonding is very difficult. However, some manufacturer uses trifunctional ligand in order to increase the extent of difunctional bonding stability

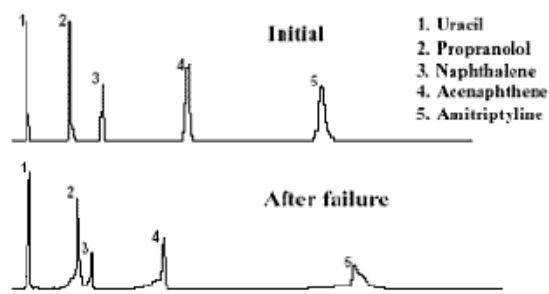
Working at Low pH

The use of bonded phase column in the separation of organic acids that is carried out with 0.1% TFA which adjusts the mobile phase to pH 2.1. At this pH all of the organic acids are in the non-ionic form resulting in improved peaks shape and retention.



Working at Low pH

Typical symptoms of column failure at low pH



The loss of efficiency and peak shape (including fronting as well as tailing) are symptoms of loss of bonded phases when working at mobile phase pH < 2.5.

Working at High pH

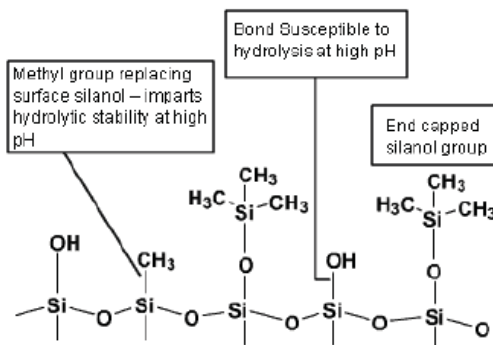
At higher pH, it is the silica surface that is most at risk from hydrolysis, primarily via the surface silanol species

At mobile phase pH above 7.0, traditional silica based packing material may begin to hydrolyze, leading eventually to the formation of small 'fines' which migrate to and block the outlet frit – leading to increased system back pressure. Also includes other earlier symptoms loss of peak shapes and efficiency.

Many approaches have been taken to protect stationary phases at higher pH.

Working at High pH

1. Using hybrid silica that contains less surface silanol groups



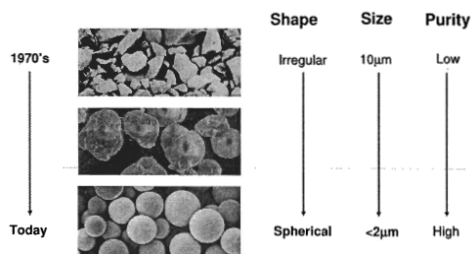
Hybrid silica shows greater high pH stability due to the reduced number of silanol groups at the silica surface that are susceptible to hydrolysis.

Typical Hybrid Silica Structure

Summarize

Column characteristics in order to make column choice for method development

- Efficiency
- Surface coverage
- Hydrophobicity
- Steric (shape) selectivity
- Hydrogen bonding capacity
(measure of available silanol)
- Ion exchange capacity at pH>7 and <3 (an identification of both total and lone silanol activity)



TARIFF FOR ADVERTISEMENTS

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Note: 20% discount on the above rates for four consecutive issues.

HPLC DETECTORS & IT'S APPLICATIONS

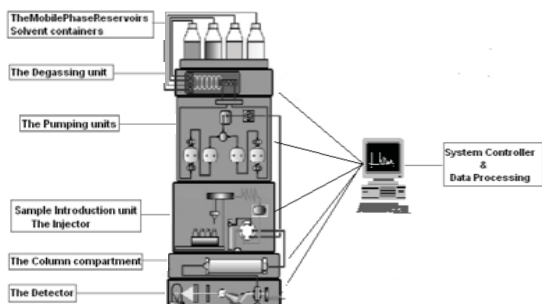
By

Ms. Rampriya Uthayakumar,

IICMS, Guindy, Chennai

(Lecture Delivered during the Training Program on
Quality Control, conducted by TNPSWT)

High performance liquid chromatography (HPLC)



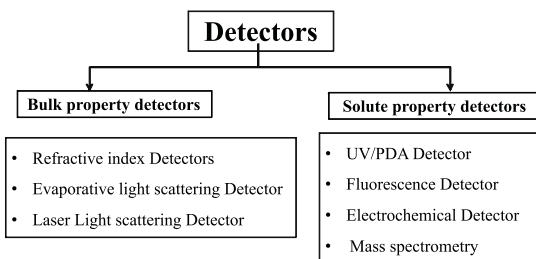
Detectors

- Integral part of the chromatographic system.
- “Eye” of the HPLC System.
- Detectors are **transducer**.
- Convert physical/chemical property of the analyte into an electrical signal.
- Signal is proportional to the analyte concentration.

Detector characteristics:

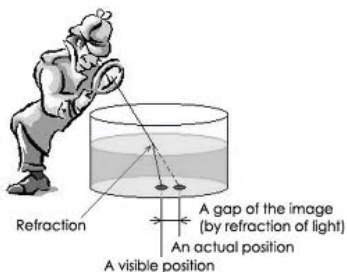
- High sensitivity.
- Respond to all solutes
- Responds independent of the mobile phase.
- Linear response
- Reliable and simple to use.
- Provide Qualitative & Quantitative information.

Types of Detectors

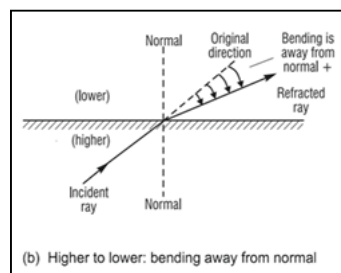
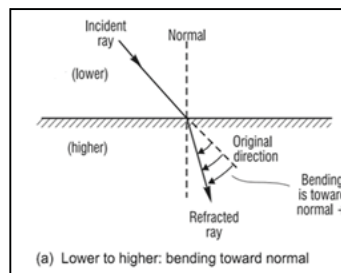


Refractive Index Detector

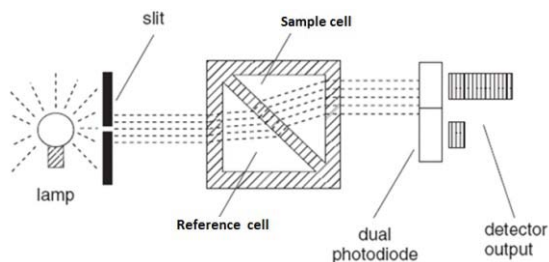
- Universal detector
- When a light passes from one medium to another medium, the direction of light changes. This is called **refraction**.
- Ratio of the speed of light in one medium to the speed of light in another medium is called **Refractive index**.



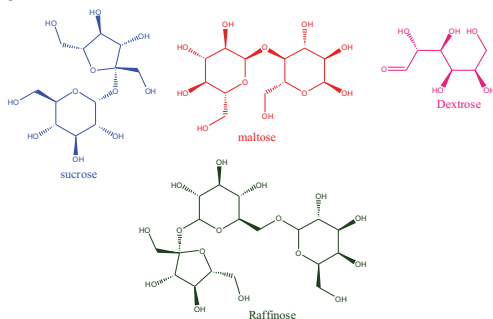
Refraction



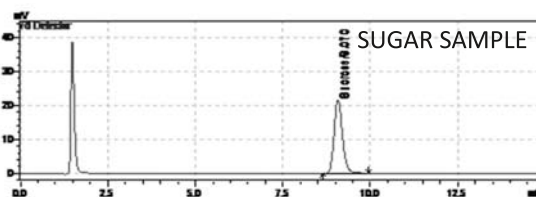
Refractive index detector



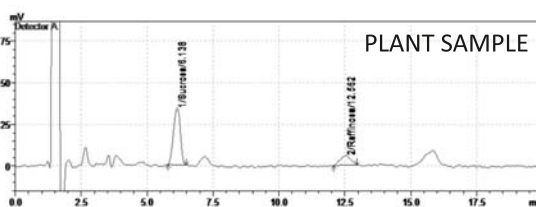
Applications:



Sugar sample analysed by RI Detector



Plant extract analysed by RI Detector



Limitations

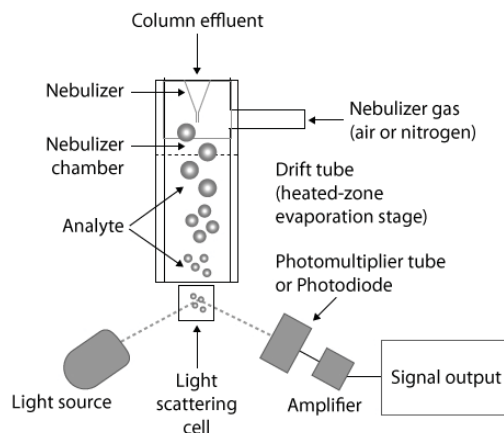
- Sensitivity is very low
- Gradient elution cannot be performed.
- Sensitive to temperature & flow.

Evaporative Light Scattering Detector

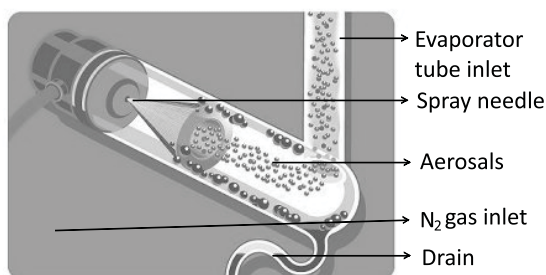
- Universal detector
- Based on the measurement of light scattered by particles after evaporation of mobile phase.
- Mainly used for non-volatile compounds.
- Mobile phase should be volatile.
- Sensitivity is high.
- Compatible with gradient elution.

Instrumentation

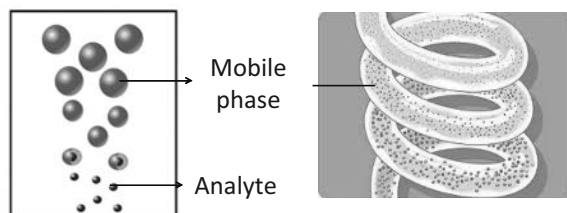
- Nebulizer
- Evaporator tube
- Light scattering cell



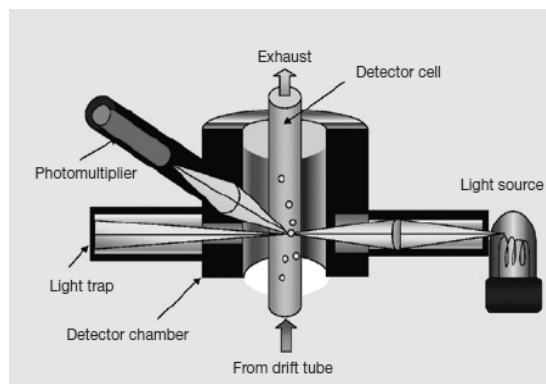
Nebulizer



Evaporator tube



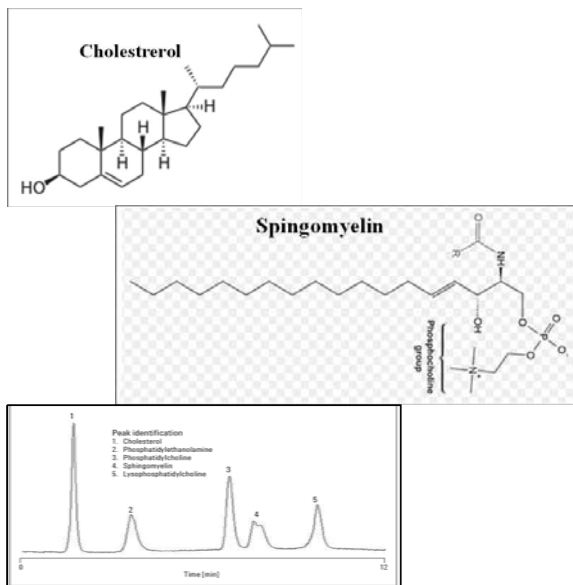
Light scattering cell



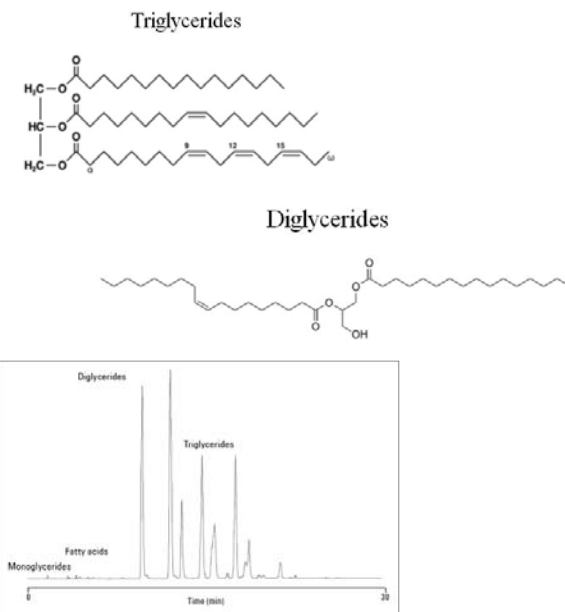
- Rayleigh scattering ($D/\lambda < 0.1$)
- Mie scattering ($D/\lambda > 0.1$)
- Reflection-Refraction ($D/\lambda > 1$)

Applications:

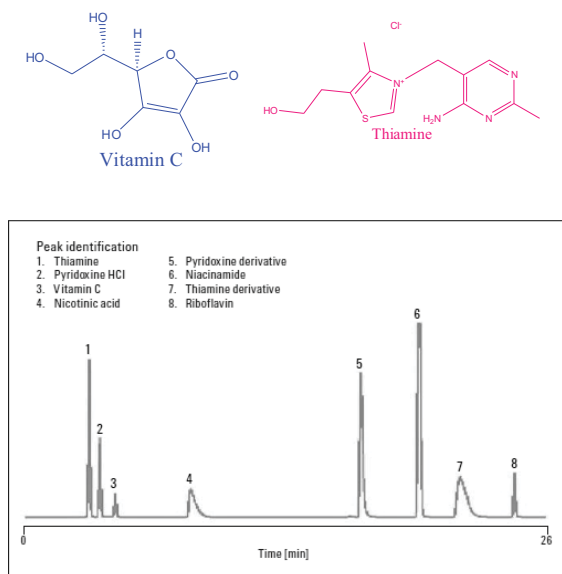
- Used to detect the phospholipids.



- Used to analyse the glycerides.



- Used to separate the vitamin mixtures.



Limitations:

- Only volatile mobile phase is used.
- Destructive
- Sample must be non-volatile.
- Highly pure gas and solvent.

Laser Light Scattering Detector

- Universal detector
- Multi-angle Laser Light Scattering Detector (MALLS)
- Determine the absolute molecular weight & size of the macromolecules
- Light interact with the sample and scatters in all directions.
- Scattered light is measured at different angles.
- Combined with size-exclusion chromatography (SEC)

Light scattering methods

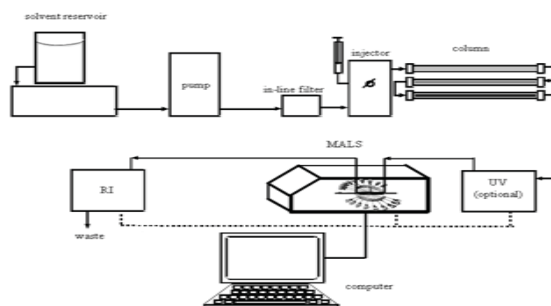
• Static light scattering

- Molecules are much smaller than the wavelength of the incident light.
- Determine the molecular weight of the macromolecules.

• Dynamic light scattering

- Molecules are larger than the wavelength of the incident light.
- Measure the particle size of the macromolecules.

MALLS Instrumentation



Components of MALLS

- Laser light
- Flow cell
- Photodiodes



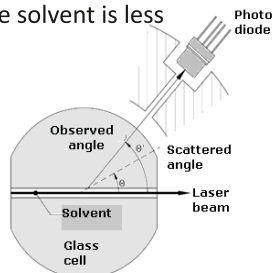
Components of MALLS

• Laser light

- Laser beam is used as a light source.
- It's provide high power density by a small beam diameter.
- Small beam diameter reduces the noise contribution.

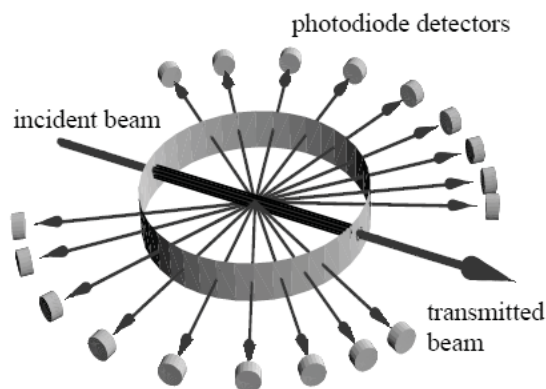
• Flow cell

- Heart of the MALLS Detector.
- Consist of cylindrical glass block.
- Refractive index of the solvent is less than flow cell.



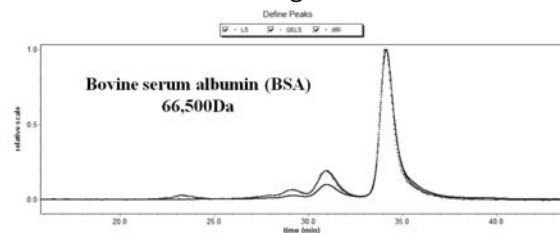
• Photodiodes

- 18 photodiodes positioned at fixed angles.
- 90° photodiode is calibrated.

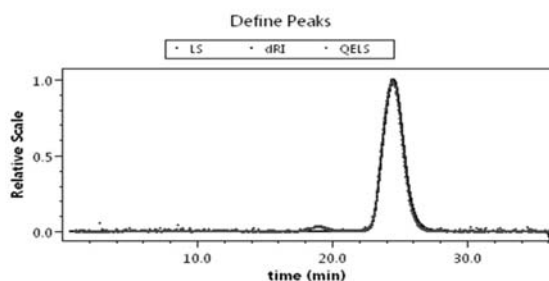


Applications

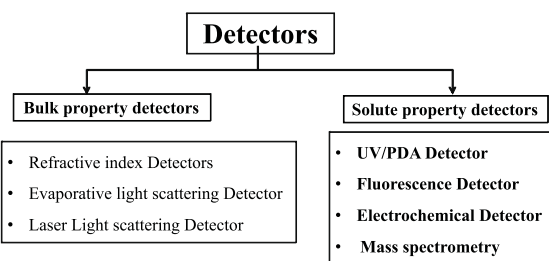
- Protein molecular weight is determined.



- Polymer molecular weight is determined



Types of Detectors



UV-VIS Detector

Absorption

When a photon of light interacts with a molecule to promote an electron from a lower to higher energy bound state.

Absorption is measured by Beer-Lambert law

$$A = \epsilon lc$$

ϵ = Molar absorptivity

l = Cell path length in cm

c = sample concentration

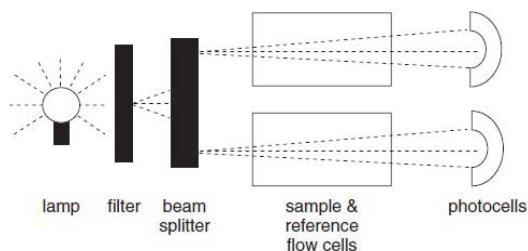
Types of UV-VIS Detector

- ✓ Fixed wavelength detector
- ✓ Variable Wavelength detector
- ✓ Diode array detector

Fixed wavelength detector

- Simple & Inexpensive
- Operates with a single wavelength
- Specific type of electric discharge lamp is used
 - Low-pressure mercury lamp - 254nm
 - Low-pressure cadmium lamp - 225nm
 - Low-pressure zinc lamp - 212 nm

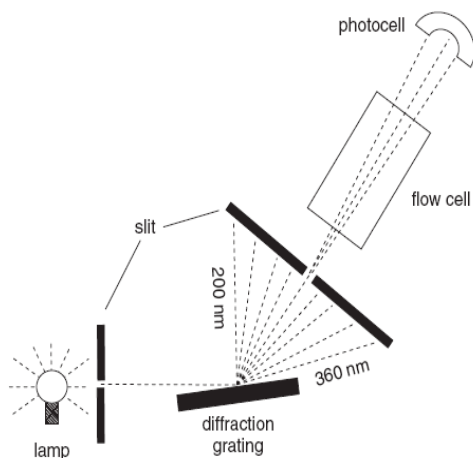
Fixed wavelength detector



Variable wavelength detector

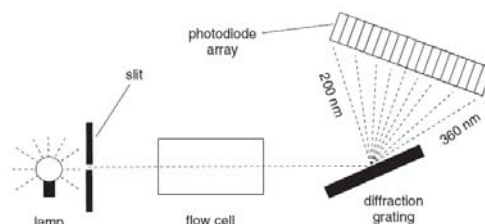
- Wide selection of UV and Visible wavelengths.
- Manually Change the detection wavelength.
- Deuterium lamp is used for UV region.
- Tungsten lamp is used for visible region.
- More expensive than fixed wavelength detector.

Variable wavelength detector



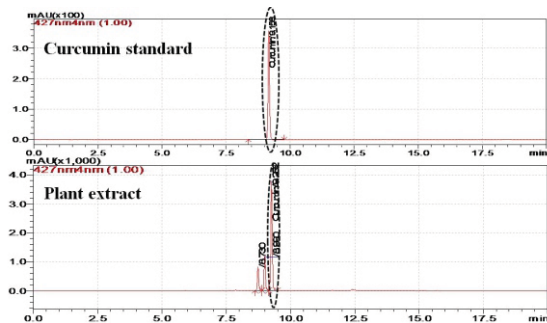
Diode array detector

- Detects the absorption in UV to visible region (190-800nm)
- Multiple photodiode arrays for obtain wide range of wavelength.
- 128 to more than 2000 diodes.
- Deuterium and Tungsten lamp is used.

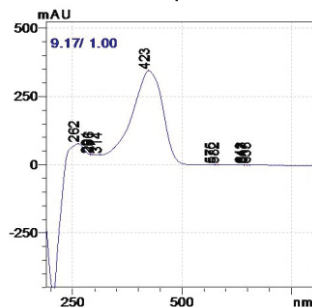


Applications

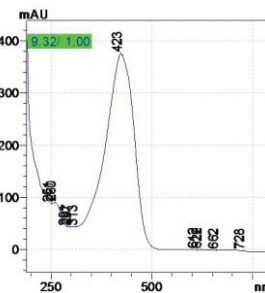
- Peak identification



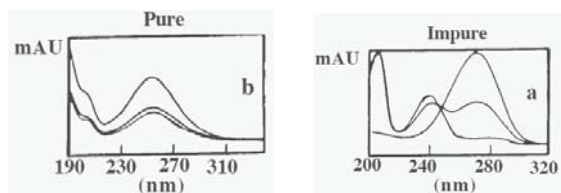
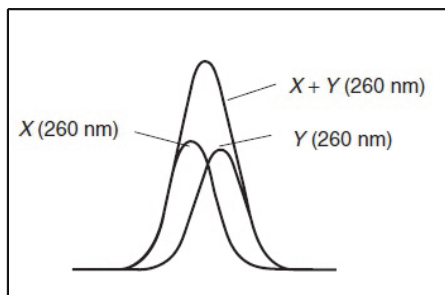
Standard UV Spectrum



Sample UV Spectrum



➤ Peak purity



Fluorescence Detector

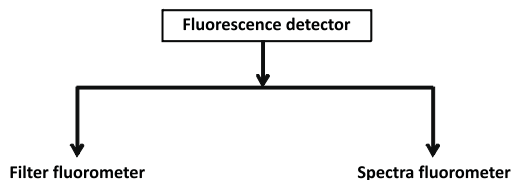
Fluorescence

When an atomic/molecular system is excited into higher energy state by absorption of energy, it returns back to lower energy state by emitting radiation of longer wavelength.

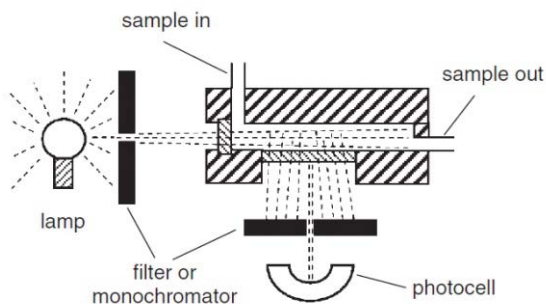
- Very rapid process (10-8 seconds).
- Sample must contain Fluorophores.
- Sensitivity is very high.
- Mercury or Xenon lamp is used.

Types of fluorescence detectors

Based on wavelength selection device:



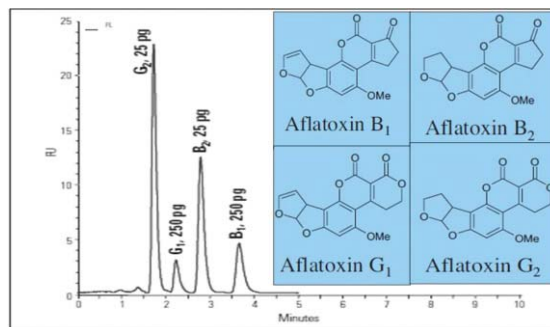
Fluorescence detector



Applications

- Nutritional supplement & Natural products (Tocopherols) are analysed.
- Phenolic anti-oxidants are analysed like Tert-Butylhydroquinone (TBHQ).
- Environmental pollutants like polycyclic aromatic hydrocarbons are analysed.

➤ Used to analysed the aflatoxins

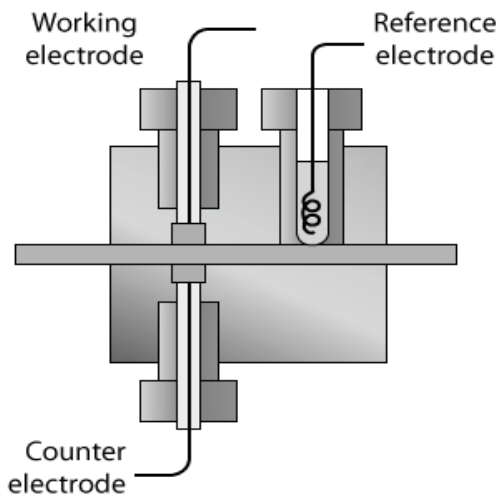


Electrochemical Detector

Amperometric detectors

- Measure the current from oxidation & reduction reaction in compounds.
- Current is directly proportional to the analyte concentration.
- Purity of mobile phase is very important.
- Three electrodes are used.
 - Working electrode
 - Reference electrode
 - Counter electrode

Electrochemical Detector



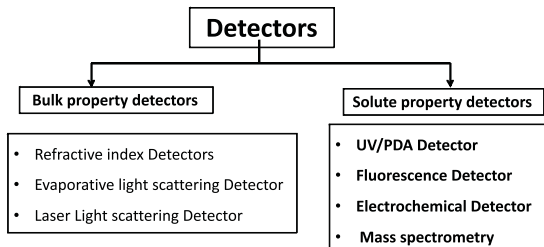
Applications

- Used for aromatic compounds (Catecholamines, phenols and anilines) & polar aliphatic compounds (Carbohydrates, amines & thio compounds).
- Mostly used for drug, pollutant and natural products sample analysis.

Limitations

- Ø Destructive
- Ø Not suitable for gradient
- Ø Mobile phase is electrical conductive

Summary



PHARMACIST ROLE : SAFETY FIRST WITH MEDICINES

By

**Mr. T. Senthamil Selvan,
J K K Nattaraja College of Pharmacy, Kumarapalayam**

Note: This article was awarded Second Prize in the Essay Competition conducted by our trust.

INTRODUCTION:

The Pharmacist is the person who plays a vital role in formulating, processing, manufacturing, dispensing of drugs and include the counseling process to patient. **Pharmacist also a member of health care profession who serves the people to improve their quality of healthy life.** Medicines are the agents which produce relief, quality health the people. But the medicines produce some effects and it leads to life threatening conditions, Pharmacy is an art to design and dispense the drug to the patients. The Pharmacist acts with honesty and integrity in professional relationships, which serves the individual community and social needs with respect to health care. Now a days the people have disease they are taking the multiple drug therapy, they leads to an adverse effects and produce some unwanted effects or disturbances. So it is the duty of pharmacist to make awareness about the medication and the drug usage.

In recent years the pharmacist role has developed to **elevate the public health and secure their life.**

PHARMACIST ROLE IN HANDLING OF MEDICINES:

Pharmacist while dealing with OTC drugs, psychotropic, narcotic drugs he should have a sound knowledge in pharmacology, pharmacotherapy and pharmaceutics and should be aware while dispensing the drugs with proper dose and dosage form.

Pharmacist should minimize the irrational drug therapy to avoid the maximum toxicity or incompatibility of drugs.

Pharmacist plays a major role in patient counseling. He is involved in following works

- a) To maintain the prescription reading without error or doubtful.

- b) **To provide the knowledge** about dose, dosage, route of administration, side-effects and ADR.
- c) **To educate the public** how to avoid the disease conditions, disease causing agents like the dengue fever caused by mosquito named as Aedes, so we want to avoid the mosquito growth in unsanitary conditions and near the household.
- d) Then the patient should advise to consume the drug properly with prescribed time to **avoid the missing dose of drug**.
- e) In developing countries the patients are suffered in hospitals is higher than in industrialized nations. In developing countries the medical equipment is not used or **partly usable due to the lack of skills** and commodities.
- f) Check the name of the medicine and dosage against a previous refill to **ensure that patient has the correct medication**.
- g) When filling a prescription, be sure to **check patient name and address** to make sure you are receiving the medicine that is meant for particular patient.
- h) Always safely discard any leftover medications that you are no longer using, as well as **any medicines that are out of date**.
- i) To act as a vital link in chain of health professionals dedicated to the care of patients.
- j) The **counseling process should be in local language** because the patients can easily understand the details.

PHARMACIST ROLE IN HANDLING OF NON- PRESCRIPTION MEDICINES:

Non –prescription drugs need some labels that will explain the “drugs fact” like its benefits and risks and how to use correctly. However all medicines have some benefits and risks there may be tolerated if people are to receive a drugs action. Use non-prescription products only for minor health problems on a short-term basis.

PHARMACIST ROLE IN INJECTION SAFETY:

The WHO estimates the developing countries are consumed average of 16 billion health care injections per year (3.4 inj/person). It indicates the inappropriate usages of injections are leads to over usage as mean the unsafe procedure cause infections. The misuse or over usages of medicines harm the community large when health care facilities. The discipline of pharmacist in patient safety is co-ordinate efforts prevent harm to patients while administer the medicines.

**“While increasing the safety with medicine.
It reduce the harmful sign”**

PHARMACIST ROLE IN MEDICINE STORAGE:

Pharmacist also plays in the medicine storage department. The Pharmacist only knows about the drugs clearly and they have sound knowledge about drug storage. If the drug doesn't stored in proper condition causes the unexpected reaction. So the pharmacist secure the public health when admit to the medicine storage section. For example we consider the medicines are stored under following conditions;

At room temperature- 15-250c

Cool condition- 8-150c

Cold condition-2-80c

Frozen condition= -200c

While dispensing the drugs the pharmacist should inform the storage condition to the patient, to maintain the medicine as effective.

PHARMACIST ROLE IN PATIENT COMPLIANCE:

Patient compliance is a process of undergone the patient rules and regulations of people made by pharmacist or any other health care professionals. the objective of prescribed therapy is to achieve the patients health safety and management of the diseases. the pharmacist role in patient compliance is followed by;

- a) Identification of **risk factor**
- b) To **develop the treatment plan**
- c) Patient education such as oral communication or verbal communication.
- d) They also play is **patient motivation process**.
- e) The patient should inform the any abnormal condition occur due to medicine they may be rectified by the healthcare team members.
- f) **Ask your doctor or pharmacist** about drug benefits that may be available to people in your age or income range.

CONCLUSION:

Pharmacist act as a link or bridge between the physician and patient to maximise the public health. The medicines are administered to the patients only to improve their health not to be ruin their health . So the pharmacist should know all of the effects and patient safety because he/she is only responsible for the patient health. So the patient should follow the pharmacist advise and the instructions about medicines, because pharmacist only responsible for the patient health.

**“Medicines are also a sharp knife
While taking care it saves you
If you plays you may loss life”**

While misuse or wrong medication may leads to the life threatening conditions.

So medicines are used only to save the life not lose the life.try to avoid misuse or self medication without consult of your doctor and pharmacist.



INFORMATION

M. PHARM & PHARM D SCHOLARSHIPS 2015-16 AWARDED BY TNPSWT

Profile of 2nd Rank Projects

PHARMACEUTICS

Name: Mr. Sanjay
Project Title: "Formulation & Evaluation of nanogel for anti-glaucoma agent"
College: SRM College of Pharmacy, SRM University, Kattankulattur
Guide's Name: Dr. M. Motilal

PHARMACEUTICAL CHEMISTRY

Name: Ms. Niladri Saha
Project Title: Design, synthesis and 3D-QSAR study of novel antibacterial agents targeting Alanine racemase enzyme.
College: JSS College of Pharmacy, Ooty
Guide's Name: Dr. Md. Afzal Azam

PHARMACEUTICAL ANALYSIS

Name: Mr. E. Balapriyan
Project Title: QbD Approach for Validated Spectrophotometric, RP-HPLC & HPTLC Method for the simultaneous estimation of Abacavir, Dolutegravir and Lamivudine in bulk and its tablet dosage form
College: Adhiparasakthi College of Pharmacy, Melmaruvathur
Guide's Name: Dr. J. Saminathan

PHARMACOLOGY

Name: Mr. R. V. Venkataramanan
Project Title: Appraisal of hydro alcoholic leaves extract of Smilax zylénica against type II collagen induced arthritis Mediated diabetes in Rodents
College: SRM College of Pharmacy, SRM University, Kattankulattur
Guide's Name: Mrs. M. Sumithra

PHARMACOGNOSY

Name: Ms. T. Velvizhi Thilagam
Project Title: A comparative Pharmacognostic evaluation, in vitro anti-tumor and anti mutagenic properties of Karumboolam and Rakthaboolam the two indigenous varieties of Aloe plant
College: Mother Theresa Post Graduate & Research Institute of Health Sciences, Puducherry
Guide's Name: Prof. Dr. V. Gopal

PHARMACY PRACTICE

Name: Ms. Deepthi Merin Raju
Project Title: Effect of yoga on depression and glycemic control in type 2 Diabetes mellitus
College: JSS College of Pharmacy, Ooty
Guide's Name: Dr. D. Raja

PHARM D- PHARMACY PRACTICE

Name: Mr. Aswin R, Ms. Benzy Susan Joseph,
Ms. Dona Maria Jetto, Ms. Elisabeth Saji Cherian
Project Title: "Assessment of severity of hepatic dysfunction and dosage individualization in patients with hepatic function impairment"
College: Sri Ramakrishna Institute of Paramedical Sciences, Coimbatore
Guide's Name: Dr. Manjula Devi A.S

PHARM D- CLINICAL PHARMACY

Name: Dhanalakshmi. K, Ms. Dhanuja Bhowmick, Ms. Divya. A, Ms. Divyasree .R. K
Project Title: To study the control of Hypertension, incidence of Microalbuminuria and their relation to patient adherence in type 2 Diabetes Mellitus
College: College of Pharmacy, Sri Ramachandra University, Chennai
Guide's Name: Dr. P. Seenivasan



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Tenders / Institution supplies

Contract manufacturing

Joint venture

Distribution Channel

Strategic Alliance

VARIOUS ACCREDITATIONS

- NAFDAC NIGERIA
- FDA - GHANA
- IVORY COAST -GMP
- MOH - CAMBODIA
- CDDA SRILANKA
- CONGO - GMP
- MOH - LIBYA
- PPB – KENYA
- PMPB – MALAWI
- ISO 9001 – 2008 CERTIFICATION
- PEPSICO, AUSTRALIA HAS APPROVED OUR FACILITY

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EVENTS

Sugam - Online Portal of CDSCO - Orientation & Facilitation Meet

The South Zone CDSCO headed by DDC Dr. S. Manivannan organized a meeting for all stake holders on the E-Governance Portal of CDSCO; Sugam. The meeting was addressed by Shri. R. Chandrasekar, DDC, CDSCO HQ.

Shri. R. Chandrasekar in his presentation illustrated the various advantages, the Sugam portal offers for patients (about drug & device approvals), for Industry (about guidance, registration & listing), for the CDSCO officials & for the consumers.

He further went into the stakeholders specific live pages on how an applicant can apply for permission (Import & Registration / Medical Devices & Diagnostics / Test License / Cosmetics), track the status of submitted application, answer back to the raised queries, to upload essential documents for registration Certificate, Import Licence and other related activities.

Recently the online issue of Form-12 (grant of licence to import drugs for the purpose of examination, test or analysis) was also made mandatory with effect from 15.06.2016. This is to be issued online by the DDC at the Zonal CDSCO offices. With its effect, in just 1 day, South Zone CDSCO headed by DDC Dr. S. Manivannan processed the online Form-12 & issued the first approval in the country in a days time to a stake holder. This is a major initiative of CDSCO & in particular the south zone CDSCO, which was the highlight of the program.

The program was attended by more than 100 stake holders & majorly IDMA member companies. On behalf on IDMA TNPBSB Chairman Shri.J.Jayaseelan felicitated DDC Dr.Manivanan, DDC Mr. R. Chandrasekar & IDMA TNPBSB Hony. Secretary Shri. T. Sathish proposed the vote of thanks.



R to L : IDMA TNPBSB Chairman Shri.J.Jayaseelan, DDC Mr. R. Chandrasekar, DDC Dr.Manivanan, & IDMA TNPBSB Hony. Secretary Shri. T. Sathish

INTERNATIONAL WOMEN'S HEALTH DAY AT PCPS!



On the eve of International Women's Health day (28th May), Periyar Health Club of Periyar College of Pharmaceutical Sciences, Tiruchirappalli organized a guest lecture on 22nd June 2016 at the institution. Dr. T. Shri Vijaya Kirubha, Secretary, Periyar Health Club, welcomed the gathering. Dr. S. Munavar Sultana, Medical Officer, Periyar Maniammai Dispensary, Trichy delivered an awareness lecture on Women's health. She enunciated on the main issues regarding women's health to enshrine their wellbeing. She deliberated on many health concerns that are unique to women at different stages of their lives starting from pre menstrual to post menopausal stage in a lucid manner. She added that the biggest challenges women face is learning how to care for themselves while caring for others and concluded that it is possible for all women to adopt a healthy lifestyle, exercising regularly and eating right amidst their busy schedule, and cultivate the right mindset and build a supportive network to keep them on track. Prof. Dr. R. Senthamarai, Principal presided over the function. Mr. G. Sebastian, Correspondent, Dr. A.M. Ismail, Professor and Dr. G. Krishnamoorthy, Vice Principal graced the programme. Staff of Periyar Centenary Educational Complex and Faculty & Students of the institution attended the programme. Ms. S. Shamalar, Asst. Professor proposed vote of thanks.



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HIV Cure Closer After Gene Editing Breakthrough

American scientists have made huge strides towards finding a cure for HIV using pioneering 'gene editing' techniques. A team from Temple University, Pennsylvania used the technique to successfully remove HIV DNA from normal human cells. The team is confident the treatment could be tried on humans within three years.

In a lab, they 'edited' HIV DNA from infected T-cells (which play a major role in the immune system) in a more accurate simulation of how the virus would be treated inside patients' bodies. The team drew blood from people living with HIV; their T-cells were cultured in the lab, and then treated with the CrisprCas9 gene editing system, in which a targeted protein uses enzymes to remove genetic sequences (in this case, HIV DNA) from cells. Their results proved it is possible to eliminate the virus and prevent it from re-infecting cells.

Gene editing is an important medical field, but there are fears that the process could have negative effects beyond the boundaries of the cells, resulting in further health problems. However, using highly-detailed genome sequencing to analyse the treated cells, the scientists found they continued to grow and function normally, and didn't appear to be suffering from side-effects.

According to Kamel Khalili, leader of the study: "The findings are important because they demonstrate the effectiveness of our gene editing system in eliminating HIV from the DNA of T-cells and, by introducing mutations into the viral genome, permanently inactivating viral replication."

Source: *The Times of India*, 3rd April 2016



Non-FDA Triggers key to Gradual Pharma Recovery

Indian Pharma companies are paying the price for becoming significant players in the US drug market. The out performance of drug companies has been blunted in the past one year — thanks to regulatory headwinds as well as intensifying competition — both in the US and in local markets. After hitting record highs on the bourses in 2015, Pharma stocks have taken a beating with valuations having rationalised - coming off from the peak valuations of their heydays.

USFDA warning letters have become a key reason for increasing the risk profile of the sector, otherwise perceived to be defensive. Credit rating agency ICRA finds 143% increase in such notices in 2015 over the previous year. Most Pharma firms have borne the brunt of FDA action.

According to Credit Suisse, FDA related pain is likely to last another year and should lessen in the next round of inspections as firms upgrade their systems and practices.

In the domestic market, the increase in number of drugs under price control and banning of 344 fixed dose combination drugs are likely to intensify pressure on the companies. At such a time, Aurobindo Pharma, the fifth largest Pharma company by revenues, has made an entry into the benchmark Nifty Index from April 1. The 50-member index now has five Pharma companies having a cumulative weight of 7.5%.

As regulatory overhang has cooled down the valuations, non-FDA triggers are likely to result in a gradual recovery in these stocks. A pickup in the pace of drug approvals by the USFDA unveils product-specific gains to companies. Besides, recent buyouts, especially in the US, by companies like Lupin, Cipla and Sun Pharma, are slated to enhance their drug pipelines. Lupin on Tuesday launched its first product from Gavis.

The sustained push in the US for bringing down cost of medication remains a secular positive factor. For investors keen to partake in the Pharma growth story, the recent correction could be a blessing in disguise.

Source: *The Economic Times*, 8th April 2016



Soon you may Get Vegetarian Capsules

our neighborhood chemist could soon offer you a vegetarian capsule. The country's top drug regulator is evaluating a proposal to introduce plant cellulose-based capsules to replace those made of gelatin. "A proposal has been received for plant cellulose-based capsules which are also safer for use than animal-based gelatin ones," drug controller general of India G N Singh said. Gelatin is manufactured from processed bones, skin and tissue of cattle, pigs and other animals.

The regulator sought suggestions from stakeholders, including the pharmaceutical industry and consumers, to take what it says is a considered decision on the proposal. Regulatory sources said a final decision is likely by end of May. The proposal has the support of various quarters in government. Besides, it is also considered safer than gelatin because it's plants sourced. However, more scientific evaluation is needed before taking a final call," an official source said.

As of now the Bureau of Indian Standards has already framed standards, norms and guidelines for manufacturing vegetarian capsules based on cellulose.

The over Rs 1 lakh crore Indian pharmaceutical industry extensively depends on gelatin. According to a senior industry executive, almost 80% of any pharmaceutical company's products are either capsules or tablets. Though tablets are a bigger share, capsules make up at least 40% of the total.

While some in the industry and medical fraternity feel switching to cellulose may impact the cost of medicines as cellulose coating is more expensive than gelatin, many believe the difference may not be significant with easily available technology and expertise. Also, it would be adding to the choice available for consumers.

A proposal to switch to cellulose was discussed in the past as well. However, regulatory agencies and the government have so far failed to provide vegetarians with this option, primarily because of opposition from the industry so far.

According to the regulatory source, some scientific papers claim cross linking of gelatin and drug incompatibilities.

Source: *The Times of India*, 10th April 2016



Sick? Go Easy on the Antibiotics

A young man barges into the air-conditioned pharmacy nearly sneezing his nose off. “Give me something for a headache/cold,” he tells the Pharmacist as he wipes his runny nose on his sleeve.

“Do you have fever?” the pharmacist asks.

“No,” he replies.

After a brief conversation — one that you might have expected the young Turk to have had with his GP — the Pharmacist gives him a long list of antibiotics, an antihistamine and a blister pack of antacids. He pays, gets a glass of water from the kind Pharmacist, pops a tablet of each drug into his mouth, gulps them down and walks out, wiping his face on his sleeve again.

You could wish and hope that this is a rare scenario, but the truth is that it's pretty common across the country. The Pharmacists, oh well, the folks who man the Pharmacy — with or without a qualifying degree — are, verily, doctors, dispensing advice and medicines with equal glee. The first rule of antibiotic use is that they are used to fight bacterial infections and they don't work on viruses. A common cold or cough is most likely caused by a viral infection. In the young man's case, a course of antibiotics has been used in vain.

Reality of AMR

It is precisely this kind of carpet-bombing of the community with antibiotics that is responsible for the alarming increase in antimicrobial resistance (AMR) in the country. Irrational use of drugs, overdosing or under-dosing, self-medication, misuse of drugs, and the inappropriate use of antimicrobials in a hospital setting are all cause for alarm.

Dr. Abdul Ghafur, Consultant, Infectious Diseases and Clinical Microbiology, Apollo Hospitals, Chennai, was in the small team of professionals who put together the “Chennai Declaration”, which has come to be recognised as a sort of milestone for activities against antimicrobial resistance in India.

Growing antibiotic resistance has been well-documented in the recently released National Treatment Guidelines for Antimicrobial Use in Infectious Diseases (for medical professionals) that the Centre drew up. The report articulates the urgent need to follow guidelines: “Antimicrobial resistance in disease pathogens has become a matter of great public health concern globally.” Attributing it to the widespread use and availability of practically all antimicrobials across the counter for human and animal consumption, it sets out clear dividing lines for doctors to follow.

“The 'Chennai Declaration' created awareness among the medical fraternity about the need to control antibiotic usage. Of course, it could be argued that we should have taken action on this at least a decade earlier,” says Dr. R. Ramasubramanian, consultant, Infectious Diseases, and Director, Immune boosters, Adult Immunisation clinic at Apollo Hospitals, Chennai. The NDM-1 superbug scare played a key role in getting at least hospitals to wake up to the issue. However, he points out, the thing about this is that it is not rocket science, and only requires a change in mindset, among doctors and patients. Prescribing antibiotics for common viral infections, pharmacists selling antibiotics over the counter and a few precautions for hospital-based workers — using a hand rub before and after examining the patient, for instance — will go a long way in controlling the spread of resistant bugs, as well as hospital-acquired infections.

Measuring load

Giridhar Gyani, founder Director General of the newly constituted Association of Healthcare Providers (India), was earlier involved with hospital standards in his avatar as the secretary general, Quality Council of India. He suggests that measuring the antimicrobial load of every State is the way ahead. “While Kerala has already made some headway in this, once each State starts measuring the load then there is no escaping the reality of AMR.”

But headway seems to have been made on that front. Recently, the Union Health Ministry launched the National Programme for AMR Containment. Among its key tasks is to conduct AMR surveillance with a network of 10 laboratories across the country. It has begun to generate data from various sites. In fact, it is this data that helped form the guidelines for treatment, Dr. Ghafur explains. Which is why the guidelines will be constantly evolving? They will take into account the latest trends and data to indicate better treatment for various infections, he adds.

But what does a person keen on avoiding developing bacterial resistance do? Is it even possible for an individual to take on the big bugs' resistance and emerge unscathed? Guidelines are for the professionals, anyway.

“Basic information that antibiotics are effective only with the bacterial infections should help,” he says. This knowledge will make an informed, if, at times, pesky patient. Checking with the physician if the antibiotic is absolutely essential, and not buying drugs without prescriptions are some of the tricks patients can learn, even as they defer to the superior knowledge of the doctor involved.

In food chain

Even if the utmost care is taken to keep off unnecessary antibiotics, Dr. Ramasubramanian points out the enormity of use in non-human subjects, animals and poultry. In terms of tonnage, human use versus animal use of antibiotics is nearly 1:5. When you eat chicken dosed in this way with antibiotics, it fills your gut and colonises it, leaving you vulnerable when you are actually ill and need to take drugs to counter an infection. In other words, you have turned resistant to certain drugs, thanks to the consumption of chicken dosed with antibiotics.

Dr. Ghafur explains that antibiotics are used to “wash out” livestock of any kind of bacteria, not only to treat diseases but also to prevent them, and in the process spur faster growth. The tough part is that the practice is rather widespread across the world, and it has actually become tough to touch animal products that are “safe”. There are, however, free-range animal products that claim to be free of antibiotics, but are difficult to verify, and are expensive too.

During the first World Antibiotic Awareness Week (WAAW) in November last, Danilo Lo Fo Wong, Programme Manager for Antibiotic Resistance at WHO/Europe, said, “What we must do — as policy-makers, health-care workers, patients and farmers — is to ensure effective treatment for as long as possible through the rational use of antibiotics.”

Source: *The Hindu*, 10th April 2016



Supply of Look Alike Drugs in Kerala Hospitals to End

The Kerala Medical Services Corporation Limited (KMSCL) will no longer supply look-alike medicines to government hospitals and dispensaries in the State.

KMSCL has initiated measures to stop the procurement of look-alike medicines in the wake of complaints of wrong usage and confusion, reported from different parts of the State. Several medicines meant for critical health issues were wrongly administered to other patients as the medicines looked similar.

The Kerala Government Medical Officers' Association (KGMOA) had raised concerns over the situation that put the lives of people, including children, at risk in the State. The doctors had demanded withdrawal of all look-alike medicines.

In a case reported from Cheruthuruthy, Glimepride tablets meant for diabetes were wrongly given to children for cold and fever. "This is dangerous. It happened because the labels of both medicines looked similar," said A.K. Raoof, KGMOA general secretary.

Dr. Raoof said wrong dispensation of medicines could be dangerous for patients. Heparin and Midazolam injections, for example, look alike and run the chances of wrong administration in a critical care unit. While Heparin, an anti-coagulant, is used to prevent the clotting of blood, Midazolam is used for sedation. Both of them are widely used in operation theatres.

KMSCL, the government company that procures all essential medicines for government hospitals, will no longer accept medicines with the same label.

Following complaints from doctors, the company included a clause in its tender which says labels and colours of all medicines should be different. Manufacturers failing to comply with this will invite a penalty of five per cent of the total value of the drugs in question and its rejection too.

Source: The Hindu, 10th April 2016



In Saga of Indian Drug Approvals, US FDA isn't Villain of the Piece

Amid the noise about American regulator's rap for desicos, annual report from Office of Generic Drugs shows Indian cos won key approvals in 2015.

While Indian companies have been getting the rough end of the stick from the US Food & Drug Administration (FDA) with a plethora of inspections and warning letters, the run of bad news may have drowned out some of the more positive developments.

The annual report released by the FDA's Office of Generic Drugs (OGD) shows Indian companies have won some key approvals in the world biggest pharmaceuticals market.

Of 90 first time generic drug approvals in 2015, as many as 14 were won by Indian drug companies, most of which belonged to specialized treatments. Companies such as Glenmark, SunPharma, Torrent, Hetero, Lupin are some of the companies that are in the list of "notable approvals".

Generic drugs now account for 88% of prescriptions dispensed in the US and saved the US health system \$1.68 trillion from 2005 to 2015, "OGD director Kathleen Cook wrote in an April 13 blog post.

Cook said that 2015 was a record year for approvals and tentative approvals by her office a total of 700.

Some of the high value approvals that Indian companies received were for generic versions of Otsuka's Ability (aripiprazole), used for treating schizophrenia; Vigamox (moxifloxacin), a conjunctivitis drug made by Novartis company Alcon; Zetia (ezetimibe), a drug prescribed for treating hypertension made by MSD, and anti-cancer drug Gleevec (imatinib) made by Novartis.

The faster turnaround of approvals is also the result of the Generic Drug User Fee Act (GDUFA), according to the FDA which has helped it to clear almost 90% of the approvals backlog. Under GDUFA, the industry agreed to pay approximately \$ 300 million in fees for each year of the five year program said Cook in her note.

Source: *The Economic Times, 15th April 2016*



New FDI norms to Boost Pharma Sector

The easing of foreign direct investment (FDI) policy norms for the Pharma sector should help in reducing timelines for deals as well as result in more funds being pumped into the sector, according to analysts.

As part of a second wave of big bang reforms, the government on Monday approved 74% FDI in brown field Pharma and 100% FDI in green field projects, both under the automatic route. The first set of big ticket reforms were announced in November 2015. Analysts say that the move may lead to more deals in a sector which shows a robust double-digit growth year-on-year and outperforms the sensx. Industry experts say the move will allow promoters to monetize part of their shareholding easily, should they choose to do so. The FIPB process used to add to timelines, and deals will close much quicker, they add.

"This change will benefit financial investors as they would generally pick up only minority stakes. As a result, investments and exits will both become quicker," Bhavik Narsana, partner in law firm Khaitan & Co, said. Kalpesh Maroo, partner in BMR & Associates, said, "The Pharma sector has been witnessing heightened activity in the recent past and this change should help in reducing timelines for deals involving FDI of less than 74% equity stake."

However, there is not much clarity on certain aspects in deals. "A sticky issue for M&A deals has been the non-compete issue as Non-compete proposals were not permitted without approval. The press release is silent, but one would hope that every aspect of the deal, including non-compete clauses, should be under the automatic route so long as the investment is 74% or below," Rajat Mukherjee, partner at Khaitan & Co, said.

Source: *The Times of India, 21st June 2016.*



Alkem Fudged Trial Data, says German Regulator

India's Alkem Labs has been accused by Germany's health regulator of fudging data on clinical trials of an antibiotic and brain disorder drug becoming the third Indian firm to be scrutinized since 2014 for suspected manipulation of trial data.

The medicines are now being reviewed by the European Medicines Agency (EMA) on the recommendation of the German regulator which inspected Alkem's Taloja plant near Mumbai last March.

Alkem was found to have engaged in "intentional misrepresentation" of data and duplicated results of electrocardiogram (ECG) readings of patients in trials, the German regulator said in a notice sent to the EMA on March 24, 2016.

The notice on the review dated April 1 was seen by Reuters on the EMA website on Friday.

The drugs include the antibiotic cefuroxime and rulizole, used to treat the neurological disorder amyotrophic lateral sclerosis, sold both by Alkem and Slovenia's Krka, the EMA said. Alkem was conducting trials on the drugs for Krka.

The German regulator made Alkem aware of its findings on September 8, 2015, according to the notice. Alkem did not reply to requests for comment on Friday.

Source: *The Times of India*, 16th April 2016



US Drug Spend to Hit \$ 400b a Year

U.S. annual spending on prescription medicines will increase 22 percent over the next five years, climbing as high as \$400 billion in 2020, according to a report released by health care information company IMS Health Holdings Inc on Thursday.

Those figures, which take into account anticipated discounts, rebates and other price concessions that have become common, represent an annual growth rate of 4 percent to 7 percent through 2020, according to the report.

Using wholesale prices, IMS sees U.S. spending rising 46 percent to as high as \$640 billion in 2020.

The average net price increase for branded drugs was just 2.8 percent in 2015, according to IMS, versus 12.4 percent using wholesale prices.

Source: *The Economic Times*, 16th April 2016



Alkem to Submit Clarification to EMA on Clinical Study Data

Drug maker Alkem Laboratories today said it will submit 'suitable clarifications' to the European Medicines Agency (EMA) over a decision by the drug regulator to review two drugs for which clinical trial studies were conducted by the Mumbai-based firm. "We will be submitting suitable clarifications to the EMA within the stipulated timelines to enable the Committee for Medicinal Products for Human Use (CHMP) take a balanced risk-benefit view with respect to these two products," Alkem Laboratories said

Source: *The Hindu*, 17th April 2016



E-Pharmacy co 1mg Gets Fund Booster Shot

S-based investment fund Maverick Capital Ventures is leading a Rs 100-crore financing round in 1mg, formerly Health Kart Plus, as investors continue to be bullish on the huge potential of online pharmacy startups. The Sequoia Capital-backed 1mg had spun off last year from its parent Health Kart and raised \$6 million in capital separately. With the new funds, 1mg plans to expand its marketplace platform to 30 cities from the present 12, and strengthen new lines of businesses.

In the past few months, a spate of e-pharmacy ventures like Netmeds, Phaneesh Murthy-led Ziggy and Matrix Partners-backed Myra has scooped up early-stage funding from investors who are tracking the healthcare sector in India.

Talking to TOI, Prashant Tandon, CEO & co-founder, 1mg, said the company was looking to go beyond delivering medicines and becoming a complete healthcare platform. "Although e-pharmacy is still the big chunk of our revenues, we will be pushing two verticals — e-diagnostic services and ayurvedic medicines," Tandon said.

For now, the Gurgaon-based 1mg will stick to being a marketplace for pharmacists and not adopt the inventory model. Tandon claimed fulfillment was not an issue and that 90% of its orders were being shipped the same day. "We do three levels of prescription verification and still manage to make deliveries in a day's time," he said.

1mg is the second investment by Maverick Capital Ventures, the VC fund affiliate of hedge fund Maverick Capital, in an Indian tech company after backing mobile advertising and commerce player Vserv. Maverick Capital manages \$10 billion in assets. 1mg previously raised money from Sequoia India, Omidyar Network, Kae Capital and Intel Capital as part of HealthKart before it spun off in February last year. HealthKart.com now focuses on selling products in the fitness and nutrition space. Mumbai-based investment bank, The Rainmaker Group, was the sole adviser to the deal.

As many as 60 online pharmacy delivery startups have mushroomed over the past two years in India, according to startup data collector Tracxn.

Source: The Times of India, 20th April 2016



Cancer Drugs can Stop Progression of Alzheimer's, Parkinson's

In a breakthrough, researchers from the University of Delhi found that the progression of Alzheimer's and Parkinson's diseases can be suppressed or stopped by down regulating the expression level of d-myc in Drosophila (fruit fly). Since d-myc is an evolutionarily conserved human homolog of c-myc proto-oncogene, the findings in fruit fly may be applicable to humans as well.

Results of a study were published on March 21 in the journal Molecular Neurobiology.

Alzheimer's and Parkinson's diseases occur due to accumulation of abnormal clumps of proteins in neuronal cells. The abnormal clumps are formed when a mutation to tau protein acts as a trigger and causes the addition of more phosphate group to the tau protein.

The addition of more phosphate group (phosphorylation) to the tau protein causes it to fold into the wrong shape and stick together to form fibre-like structure, which eventually bundle up to form clumps (neurofibrillary tangles) of proteins in the affected brain cells.

“Our team focused on finding an appropriate gene/protein which can be utilized as an effective drug target to suppress or stop the pathogenesis and manifestation of Alzheimer's and Parkinson's diseases by reducing or preventing protein clumps from being formed in the brain cells,” said Dr. Surajit Sarkar from the Department of Genetics, University of Delhi. “We screened over 1,000 genes in *Drosophila* and found d-myc as a candidate gene that was restricting the pathogenesis of Alzheimer's and Parkinson's diseases.”

Most of the attempts at drug development have failed in the past, in part, because of the difficulties in finding an appropriate target gene or protein to act upon. Not anymore. Dr. Sarkar's team has successfully zeroed in on d-myc in fruit flies (c-myc proto-oncogene in humans) as a possible target gene.

The c-myc proto-oncogene in humans is a global regulator of gene expression. When this gene is down regulated, it prevents other genes from enabling more phosphate group to get added to the tau protein, thereby restricting/stopping the progression of disease.

Since a majority of anti-cancer drugs attempt to regulate c-myc proto-oncogene expression, the use of such drugs in people with early stages of Alzheimer's and Parkinson's disease can help in stopping the progression of the disease.

“Our study demonstrates for the first time that a common drug target c-myc proto-oncogene can be used to treat two most devastating human disorders — cancer, and Alzheimer's and Parkinson's diseases,” Dr. Sarkar said.

Interestingly, several reports of successful clinical trials using certain anti-cancer drugs to treat Alzheimer's and Parkinson's appeared just as his team concluded the experimental work. “These scientists used anti-cancer drugs without knowing how and why the drugs were effective. Now, our study shows why the drugs helped in treating Alzheimer's and Parkinson's diseases,” he said.

Cellular and molecular investigations were carried out in fruit fly as undertaking such studies on human subjects is unethical. Also, brain tissues are completely degenerated in people with Alzheimer's who have died.

The fruit fly was genetically programmed to develop symptoms of Alzheimer's and Parkinson's disease. Interestingly, expression of human's Alzheimer's or Parkinson's disease causing gene in fruit flies shows symptoms similar to human Alzheimer's or Parkinson's — death of brain cells, memory loss, disability in movement, early death.

Source: *The Hindu*, 25th April 2016



India Eyes Oil-for-Drugs Deal with Venezuela to Recoup Pharma Cash

Indian officials say they have proposed an oil-for-drugs barter plan with cash-strapped Venezuela to recoup millions of dollars in payments owed to some of India's largest pharmaceutical companies.

Several of India's generics producers, led by the country's second-largest player Dr Reddy's Laboratories Ltd, bet heavily on Venezuela as they sought emerging market alternatives to slower-growing economies such as the United States.

But the unraveling of Venezuela's socialist economy amid a fall in oil prices has triggered triple-digit inflation and a full-blown political and financial crisis. Unable to pay its bills, the country is facing severe shortages of even basic supplies such as food, water and medicines.

Dr Reddy's wrote off \$65 million in the March quarter, which it said was almost all the money it was owed from Venezuela. Rival Glenmark Pharmaceuticals Inc, another major investor, says it is due \$45 million.

"The situation in Venezuela is very precarious the government knows it needs to do something about the medicine shortage, that's why it is willing to discuss such a deal," one Indian official told Reuters.

"At this point, even if our companies get back 5 or 10 percent of the payment they are owed, they would be satisfied."

Venezuela's Health Ministry did not immediately respond to a request for comment.

Like pharmaceutical companies globally - which used to enjoy a preferential exchange rate in Venezuela - Indian producers have been left badly stung by the collapse of the Bolivar currency.

PAYMENT PLAN

The Indian officials, who could not be named as they are not allowed to speak to the media, said the trade ministry had proposed a payment mechanism that would allow Venezuela to repay some of the amount owed with oil.

The proposal, seen by Reuters, would use the State Bank of India to mediate the transfer. The plan is now awaiting approval on the Indian side from the finance ministry and the central bank, which regulates such payments.

India, one of the world's biggest oil importers along with the United States and China, had similarly elaborate barter deals with Iran, swapping rice and wheat for oil.

The officials said Venezuela had been receptive to the plan "in principle", but not made any concrete commitments yet.

Indian officials said a "high level" meeting with Venezuela was due in the coming months to discuss the proposed deal.

"The finance ministry has assured us that the government is fully committed to it, but it will take time," said P.V. Appaji, Director General of the Pharmaceutical Export Promotion Council of India, a body under the country's commerce ministry.

India's exports to Venezuela between April 2015 and February 2016 almost halved year-on-year to \$125.5 million, compared with a year earlier. Most of that was Pharmaceutical products.

SOCIAL UNREST

The amount owed to Indian companies is modest on a global scale - Novartis AG, Bayer AG and Sanofi SA took heavier hits when they agreed to take bonds from state-owned oil company PDVSA in lieu of cash, sold at a deep discount.

But Venezuela is India's largest trade partner in Latin America and one of its key suppliers of oil.

A deal could also revive sales, albeit at a reduced level, at a time when Venezuela is desperately short of medical supplies, lacking as much as 80 percent of what it needs to treat its population, according to a Venezuelan industry body.

Of course, many other providers in the oil, food and trade sector are pressuring Venezuela to pay its debts at a time when the cash-strapped government is facing growing social unrest. The OPEC country's oil production is also expected to fall this year due to a lack of resources, a power crunch and maintenance problems, likely leaving it with less crude for export.

Both Dr Reddy's and Glenmark have now stopped shipping to Venezuela. But, neither have said they would pull out yet, as they continue to bet on the market's future potential.

Per capita consumption of medicines in Venezuela is high, and its healthcare market was growing at a rate of about 20 percent a year until 2014, when the economic crisis began.

Dr Reddy's Chief Operating Officer Abhijit Mukherjee said last week that Dr Reddy's remained "very focused" on Venezuela, where it has signed deals with two government organisations.

"Only condition to the contract is that we will dispatch (products) only when we get either the LC (licensing certificate) or some advance," he said.

Glenmark said it was evaluating its operations in Venezuela on a month-by-month basis.

"We are extremely encouraged that the Indian government is taking constructive steps to recover our money that is stuck in our own Venezuela subsidiary," said Chairman and Managing Director Glenn Saldanha in an emailed statement.

Source: *The Times of India*, 18th May 2016



Congratulation to CDSCO, South Zone on ISO 9001:2008 Certification

TNPST has congratulated Dr. S. Manivannan, Dy Drugs Controller (India), CDSCO, South Zone, Chennai on receiving the ISO 9001:2008 Certification vide Certificate No. 15 QMS 5905 valid from 30/11/2015 to 14/09/2018.

On behalf of our Chairman Mr. S. V. Veerramani, and members of the Executive Committee, we take this opportunity to congratulate you for this excellent achievement. This will certainly go a long way in developing and maintaining the image of the Regulatory authorities in India. Kindly Convey our best wished to your entire staff and we are sure under your stewardship CDSCO Zonal Office (South Zone) will reach greater heights.

We will certainly continue working together with you in the interest of the patients and the Pharma Industry in India.



Dr. S. Manivannan
Deputy Drugs Controller (India)
CDSCO, South Zone

Turmeric is Effective in Treating Breast & Ovarian Cancer

Curcuma longa, also known as turmeric, is effective in the treatment of various types of cancer, including breast and ovarian cancer, which has risen 30 percent among women in the last one decade, says a study.

Turmeric has nearly 20 molecules with antibiotic property, 14 molecules with cancer preventive potential, 12 with anti-tumor effect, says the study conducted by B.L. Kapoor Memorial Hospital here.

"At least 12 molecules in it have anti-cancer effect while 10. have anti-oxidant features. Overall, turmeric is known for it's antibiotic, antiseptic, anti-cancer and anti-oxidant property. It is known to be a good digestive substance," said the study.

According to the study, turmeric contains curcuminoids which are the main component found to be effective in cancer treatment.

"Curcumin, the principal curcuminoid of turmeric, has been intensely studied as a cancer protective agent. Its potential has been tapped in head and neck cancers, breast, lung, gastro-intestinal cancer, ovarian cancer, melanoma, neurological cancers, sarcoma, leukemias and lymphoma," said the study.

Tapaswini Sharma, Senior Consultant (Surgical Oncology) at B.L. Kapoor Memorial Hospital, said: "Curcumin suppresses all three stages of carcinogenesis: initiation, promotion and progression. It also has a role in neutralising substances and conditions which lead to cancer."

"By inhibiting the enzyme Topoisomerases, which is required for multiplication of cancer cells, it is able to arrest the growth of these cells," said Sharma.

With time, cancers cells tend to become resistant to chemotherapy and radiotherapy, Sharma observed.

Curcumin, on the other hand, when consumed in therapeutic doses, targets several cancer pathways and sensitizes the cancer cells to chemotherapy drugs by increasing the pace of death of the cancer cells, she said.

"Studies in advanced breast cancer have also shown that curcumin increases the effect of chemotherapy and prevents the spread of cancer cells to the lung," she said.

"In lung carcinoma, when curcumin is added to the chemotherapeutic drug, it increases the effectiveness of the drug by promoting cell death of cancer cells. The efficacy of it has also been seen in the brain tumors where it sensitises the tumor cells to the cancer drugs," said Sharma.

According to the study, curcumin enhanced the effect of radiotherapy by inhibiting tumor re growth per se, and also by suppressing new vessel formation.

Being a powerful anti-oxidant it scavenges all the harmful free radicals induced by radiation exposure of the cells, thereby reducing the side effects of radiotherapy.

Source: *The Economic Times*, 10th June 2016.



Nation's First Medical SEZ Struggles in ICU, Awaits Lifeline

IT was billed as India's first Medical Special Economic Zone (SEZ) and launched with great fanfare seven years ago. Unfortunately it has landed in the financial ICU. In 2009, when Mediville project of Frontier Lifeline at Elavur village near Gummidipoondi was accorded the SEZ status, hopes were high among the healthcare fraternity that it would usher in indigenous development of new technologies and pre-clinical animal trials.

However, that seems to have been just a mirage. Despite having the potential to become a major player medical R&D with its world-class facilities, the project has been burdened by cost overruns and project delays.

The creditors are exploring options to auction the assets to recover outstanding loans. State Bank of India, one of main lenders, has classified it as a non-performing asset (NPA).

Acknowledging the problem, Dr KM Cherian, Founder Chairman, Frontier Mediville, told Express that he was helpless.

"I chose to return to India, leaving a lucrative career in Australia and the US, to do something for the country. Today, I stand disappointed. I want to put India on the map as a global player of high end medical products, thereby greatly reducing the cost of healthcare in India. But the complex bureaucratic system has derailed my dream. It took us six years to build the facility, now we are facing the uphill challenge of getting permissions for the research projects," he rued.

Though several domestic and international research institutes are queuing-up to collaborate with Mediville, he said research projects are not materializing due to delay in getting approvals from multiple departments.

According to him Mediville has lost revenue of \$3.5 million last year alone. Five Indian companies showed interest in conducting pre-clinical trials at Mediville and later approached facilities in China and Singapore. Documents available show the world's leading medical device company, Medtronic, headquartered in Dublin, Ireland, had envisaged interest to collaborate and so had Argentina.

Clients can't wait for 1-2 years to start work. In China, approvals can be obtained in 10 days and in Singapore, it takes maximum three weeks. Here, government agencies like committee for the purpose of control and supervision of experiments on animals (CPCSEA), central drugs standard control organisation and Indian council for medical research take ages to give approval.

For instance, Mediville had applied for approval to conduct phase III clinical trial to determine the efficacy, safety and tolerability of tissue engineered xenograft valves in patients with structural heart disease and pulmonary stenosis. The six-member panel headed by Dr. Soumya Swaminathan, secretary, Department of Health Research and Director General, ICMR, has been sitting on the project for the past two months.

The Union health Ministry and Central Drugs Standard Control Organisation have forwarded the proposal. The well documented phase II trials were recognised by the international community. "Now, my question is why the unnecessary delay. Our phase III trials involved biological and bio prosthetic valves, which are more desirable than current mechanical valves. Once commercial manufacturing gets started, costs will get cut down by 50 per cent. Ultimately, people of our country are benefited, but the government does not understand this," Dr. Cherian said, adding that he had even met PM Narendra Modi, taking 30 minutes to explain the issues.

On current projects, Dr Cherian said CPCSEA has approved pre-clinical animal trials to be conducted on 16 male pigs and 8 beagles, for an instrument called Hemostat.

Mediville signed a MoU with a Russian manufacturer to make artificial hearts, and may land in trouble if the State doesn't extend financial assistance.

Dr Cherian said considering the huge cost in the manufacture of Heart Mate, Mediville had proposed to carry out the project under public private partnership with the TN government. CM Jayalalithaa was instrumental in identifying the land for Mediville during its inception stage, he said, pinning all hopes on her.

I chose to return to India, leaving a lucrative career in Australia and the United States, to do something for the country. Today, I stand disappointed. I want to put India on the map as a global player of high end medical products, thereby greatly reducing the cost of healthcare in India. But the complex bureaucratic system has derailed my dream. It took us six years to build the facility, now we are facing the uphill challenge of getting permissions for the research projects Dr KM Cherian, Founder Chairman of Frontier Mediville

Source: *The New Indian Express, 12th June 2016* pigs and 8 beagles, for an instrument called Hemostat.



Now, Diabetics to get Tested for TB

Patients who test positive for diabetes at government facilities will now also be referred to undergo examination for tuberculosis.

The new guideline was recently framed by the central TB division after studies showed that people with diabetes have 2-3 times higher risk of contracting TB. At present, under the revised national tuberculosis control program (RNTCP), TB patients are asked to check their sugar levels too. Through the new framework, health officials hope to detect more TB cases.

"Our estimation of people suffering from the bacterial infection is 22 lakh, but we are able to reach only 14 lakh patients. We don't know if the 'missing' population is getting the right diagnosis and treatment," said Dr Sunil D Khaparde, deputy director general in the ministry of health and family welfare, who also heads the central TB division. As a pilot project, the new framework was implemented in 100 districts across India.

Dr Khaparde, who was in the city to deliver the 31st edition of Professor Viswanathan Medical Oration on Sunday, said the guidelines will be followed by all government facilities with the RNTCP setup. A recent study by Dr Vijay Viswanathan, chief diabetologist at M V Hospital for diabetes, and University of Massachusetts Medical School, found that 54.1% of the 209 patients they surveyed with pulmonary tuberculosis were diabetic, while 21% were pre diabetic.

"According to data, every fourth person has latent TB, which surfaces when the immune system is weak," said Dr Viswanathan. Diabetes, he explained, increases the risk of progression to active TB disease in people infected with *Mycobacterium tuberculosis*, the bacteria that causes TB. Conversely, TB has an effect on diabetes. It can not only worsen blood sugar control but also complicate clinical management of diabetes.

Dr Khaparde said earlier studies had shown that treatment failure rates of tuberculosis patients were higher if they had poorly-controlled diabetes. Chennai is estimated to have a diabetes prevalence of 18.5%, and TB prevalence of 0.25 %. "Although the evidence on the link between TB and diabetes has been around for a while now, it has been assessed and consolidated only recently. Now we have compiled enough evidence, and need to act fast and implement bidirectional screening," said Dr Khaparde.

Source: *The Times of India*, 20th June 2016



Higher Cap in Pharma Sector Raises Questions

The move to relax FDI in Pharma up to 74% would have met with greater approval if the Centre explained the rationale

In 2010, alarm bells went off when the government found that the pharmaceutical industry had witnessed about six local acquisitions by foreign drug makers in just five years.

Ministries like Commerce and Health started wondering aloud if investment caps were required in a sector that was integral to keeping the "health security" of the country.

In fact, multiple departments evaluated these concerns, including the DIPP (Department of Industrial Policy and Promotion), the Arun Maira committee and a Parliamentary Committee on Foreign Direct Investment (FDI) in the pharmaceutical sector. The resounding view was that new or green field projects could attract 100 per cent FDI, while brown field investments (into existing operations) would go through a gate-keeper, a task bestowed on the FIPB (Foreign Investment Promotion Board), again after much discussion.

This being the backdrop, the Centre's latest move to relax foreign investments in domestic pharmaceutical operations up to 74 per cent has raised the question as to what gave confidence for such a decision, and whether concerns raised by several agencies in the past have been allayed. The move would have met with greater approval if the Centre was transparent with the rationale behind the decision.

Stable policies

But not everyone is worried that a domestic sell-out is imminent. Hitesh Sharma, EY's Partner and National Head (Life Sciences), observes the move may not be a "game-changer", though it does reduce the uncertainty and waiting period of three-six months that every deal took while being reviewed by the FIPB.

Beyond the 74 per cent cut-off, a buy-out deal will be put through checks on its overall size and the impact on market share, etc, he points out, referring to concerns on whether the latest move would change the ability of local drug makers to make medicines.

In fact, he adds, the FDI breather, in isolation, would not see foreign drug makers line-up to buy operations in India, until greater stability comes into the local environment in terms of clinical trial norms, intellectual property protection, and medicine price control. Indian Pharmaceutical Alliance's DG Shah feels the "acid test" for the government is in how the pharmaceutical landscape fares over the next three years. It will show up whether investments come into small drug companies making generic medicines, or into those making specialty products like injectables, vaccines, and biotech products, he says.

A similar concern had been raised in the Parliamentary committee report on the subject, that found FDI went largely into brown field projects.

The concern of “family silver” leaving the country had reached a shrill pitch when big-guns in the industry like Ranbaxy sold out to Daiichi Sankyo and Piramal Healthcare sold domestic operations to Abbott.

The Parliamentary report also stated that investments needed to go into segments like Active Pharmaceutical Ingredients (bulk drugs), etc.

Source: *Business Line*, 21st June 2016



Cipla & Pfizer Among 200 Under Lens for Poor Drugs

After regulatory ban on fixed dose combination (FDC) drugs, the Drug Controller General of India has now launched inspections against 200 drug makers for allegedly selling poor quality medicines and noncompliance to manufacturing norms. The drug makers include big Pharma companies - Cipla and Pfizer.

Mynahcare.com sent mails to Cipla and Pfizer for their versions. While Pfizer did not respond, Cipla maintained that none of the Cipla's own manufacturing units have received any inspection notices.

200 companies listed on three criterion

The 200 companies, where “risk-based inspections” are being carried out, have been listed based on three criterion. “We have analysed regulatory data for last five years and listed companies where violations were reported regularly. Besides, complaints from international agencies and importers of medicines from Indian plants have been considered,” an official said. The regulator has also drawn drug samples from the market through surveys and gathered inputs from state authorities to identify the firms.

Already inspected 36 drug manufacturer plants

This is for the first time inspections on this scale have been undertaken by the domestic regulator. “We have already inspected 36 drug manufacturing plants based in Tamil Nadu, Uttarakhand, Maharashtra and Himachal Pradesh over last three months. In the second phase, starting from Monday, we will conduct inspections in 20 more facilities. The health ministry had organised special training programs for drug inspectors to ensure objectivity and transparency.

Notices to Cipla, Pfizer

According to a source, notices have been issued recently to Cipla and Pfizer informing them of the upcoming inspection as well as violations found in their products. Indian pharmaceutical manufacturing plants have been on the radar of international agencies. Ranbaxy Laboratories, now part of Sun Pharma, had to stop supplies after the US FDA pointed out major violations. Pharmaceutical exports are expected to cross \$20 billion by 2020 from \$14 billion in 2016.

Source: *Health World*, 21st June 2016



Docs Find Low Vitamin-D in Diabetics

While the spiral in diabetes cases remains a cause of concern, researcher have now found high prevalence of vitamin D deficiency in those suffering from the metabolic disorder.

A study undertaken by M V Diabetes Research Centre, covering 4,600 patients with type-2 diabetes in Chennai, found that more than 70% of them had deficient and 15% had insufficient vitamin D. Vitamin D plays a major role in bone metabolism and in the regulation of intestinal absorption of minerals such as calcium and phosphorous. Deficiency of the vitamin has been linked to chronic diseases like hypertension and cardiovascular diseases.

Chief dialectologist Dr Vijay Viswanathan, who was part of the research team, said the findings were significant as studies in the past have identified lack of vitamin D as one of the contributing factors for diabetes. "Although the prevalence of vitamin D deficiency is high in the general population, we wanted to find if it was high among those with diabetes too as there are theories that lack of the vitamin can impact glucose metabolism," said Dr Viswanathan. The researchers didn't just find that prevalence was high among the diabetic population; the study threw a surprise: the highest occurrence of Vitamin-D deficiency was in the 30-50 years age group at 76.2%. The figure for the same among the 50-70 age group was 70% and the least among those above the age of 70 at 66.5%.

Researchers said the study highlighted the need for including Vitamin-D tests as part of the routine examination for sugar levels. "As of now, we just check cholesterol, creatinine level (which indicates the kidney function) and blood urea nitrogen. Vitamin-D is rarely considered as the tests are also quite expensive," said Dr Viswanathan, adding those with borderline diabetes should also get themselves examined as lack of the vitamin can push up sugar levels.

"But we still need to conduct further investigations to establish the exact association between Vitamin-D levels and risk of developing type-2 diabetes," he added.

Type 2 diabetes occurs when the body doesn't produce enough insulin to function properly, or the body's cells don't react to insulin. This means that glucose stays in the blood and isn't used as fuel for energy.

Latest Comment

Every report like this one, just creates fear with facts. But none of them provide a solution .Kailash K

Vitamin D deficiency, on the other hand, has been traditionally associated with rickets and other ailments related to the bone. However, increasingly , research has revealed the importance of the vitamin in protecting against a host of health problems, including diabetes.

The present study , which was published in the International Journal of Diabetes in Developing Countries, also found high calcium deficiency in those lacking the vitamin.

Doctors say although the deficiency of both may not directly impact the current treatment, it could cause complications in some patients.

Source: *The Times of India*, 21st June 2016



2,839 Bottles Made by Sun Pharma Inc being Recalled in US

As many as 2,839 bottles of anti-bacterial medicine Nitrofurantoin Oral Suspension manufactured by Sun Pharmaceutical Industries are being recalled in the US market on account of failed dissolution specifications.

The ongoing nationwide voluntary recall by Nostrum Laboratories Inc for Nitrofurantoin Oral Suspension, USP, 25 mg/5 mL is a class II recall, according to the latest enforcement report on USFDA site.

The 2,839 bottles were manufactured and distributed by Sun Pharmaceutical Industries Inc, it added. Citing reasons for the recall, the United States Food and Drug Administration (USFDA) said was due to “failed dissolution specifications.”

Nitrofurantoin oral suspension, USP is specifically indicated for the treatment of urinary tract infections.

As per the USFDA, a class II recall is initiated in a “situation in which use of, or exposure to, a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote”.

Source: *The Financial Express*, 22nd June 2016



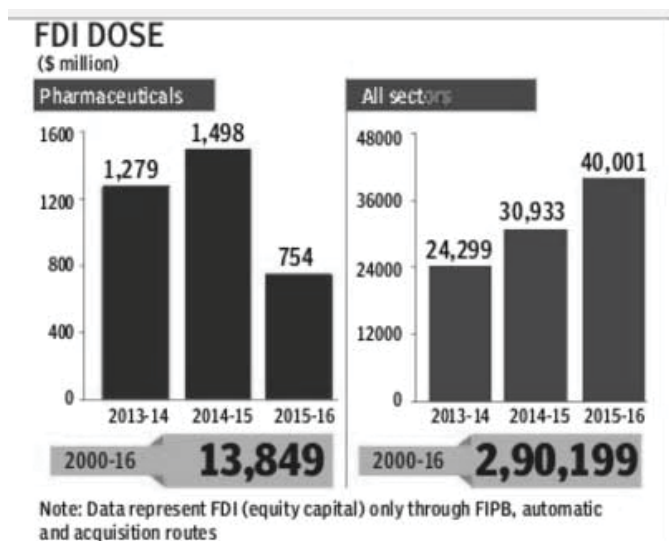
Govt's Pharma FDI Sop May Hit Affordable Healthcare

The government's decision to allow foreign direct investment (FDI) up to 74% through automatic route in existing pharmaceutical companies is likely to hit affordable healthcare in the country, especially in the vaccine (in which the government also runs programs) and injectables segments, according to senior domestic industry executives.

The government's decision to allow foreign direct investment (FDI) up to 74% through automatic route in existing pharmaceutical companies is likely to hit affordable healthcare in the country, especially in the vaccine (in which the government also runs programs) and injectables segments, according to senior domestic industry executives.

Vaccines and injectables are challenging verticals with very few good manufacturing facilities in India and even fewer firms invest in research and development in these verticals. Hence, the acquisition of existing companies could potentially undermine the government's efforts to keep costs of such essential public healthcare items at reasonable levels for the masses, they said.

“The main issues before the government today are how it will ensure that healthcare costs, especially in the vaccine and injectables segments, remain affordable and the interest of the sun-rise domestic pharmaceutical industry isn't compromised,” said Dilip G Shah, the secretary general of Indian Pharmaceutical Alliance (IPA) and the CEO of Vision Consulting Group



Although such companies were also acquired by foreign firms earlier, such takeovers were subject to the approval of the Foreign Investment Promotion Board (so the government could put some checks and balances, if required and there have been instances in the past of the health ministry raising objections to such proposals).

In 2009, France's Sanofi had bought a 80% stake in Shantha Biotech, a pioneer in developing, manufacturing and marketing indigenous Hepatitis B Vaccine at a fraction of the price at which it was being imported then, for around `3,000 crore. Later, the French company raised its stake even further.

Also, without any checks and balances, easier mergers and acquisitions by big pharma firms may not necessarily result in the transfer of advanced foreign technology or an increase in manufacturing prowess, according to analysts.

This is because foreign firms can now take over domestic companies to grab market shares or brands, aimed at just strengthening marketing muscles and supply chain, which can then be used to import finished formulations from units elsewhere and sell it in India, they say. This may also impact the country's current account deficit.

For instance, the acquisitions of the formulations business of Piramal Healthcare by US company Abbott Inc for \$3.7 billion in 2010 and some popular brands of Universal Caps by France's Sanofi didn't bring fresh investment in manufacturing or result in any transfer of technology or know-how, said an industry executive.

The latest FDI policy will also discourage whatever little investments that were flowing into new projects where 100% FDI was already allowed through the automatic route. The latest announcement will just provide a fresh leg-up to foreign companies, who were forced to change their business models due to a stagnation in the mature markets, rapidly growing demand from emerging markets and stiff competition from low-priced quality products from India, the industry executives say.

They say the government's latest FDI move is intriguing. "On the one hand, the government says it won't give in to demands of the Big Pharma and stick to provisions of Section 3(d) and compulsory licensing of the Patents Act to make life-saving drugs available at a reasonable cost.

But on the other hand, it is facilitating the acquisition of brown field projects, which will serve to enhance the power of foreign companies in pricing of drugs in the domestic market and can potentially raise healthcare costs," said another domestic industry executive.

Section 3(d) prevents ever-greening of drug patents. Apart from novelty and inventive step, the section provides for improvement in therapeutic efficacy for the grant of patents when it comes to incremental inventions.

Compulsory licensing allows domestic players to produce cheaper versions of patented drugs in cases of national emergency or to meet "extreme urgency" or for public non-commercial use. India has invoked this provision only once — in 2012, Hyderabad-based Natco Pharma was allowed to make and sell generic version of German drug maker Bayer AG's patented cancer drug Nexavar.

The US and the EU have been putting pressure on India to make appropriate changes to these provisions to boost innovation, research and development (R&D) and foreign investment.

The pharmaceutical sector has been the sixth largest beneficiary of FDI over the years, accounting for roughly 5%(\$13.85 billion) of the total FDI inflows into the country since March 2000.

Some of the brown field acquisitions by foreign firms in recent years include the takeover of Ranbaxy Labs by Daiichi Sankyo (Japan), formulation business of Piramal Healthcare by Abbott Inc (US), Matrix Labs by Mylan (US), Shantha Biotech by Sanofi (France), J K Drugs and Pharmaceuticals by Teva (Israel), injectable business of Orchid Chemicals by Hospira (US) and some popular brands of Universal Caps by Sanofi.

Source: *The Financial Express*, 23rd June 2016



Cells From Gums May Cure Spinal Wounds

Inside every gum tissue are numerous living stem cells, called gingiva cells, that scientists hope will offer cure to spinal injuries.

After successfully converting the stem cells into nerve cells in the laboratory, a team of dentists at the Chennai-based Sri Ramachandra University is working with rats as a part of an animal trial to further ascertain the possibilities of these cells.

Two weeks ago, Dr R Suresh, professor of peridontology, and his team induced gingiva cells into lab rats with spinal injuries. "We are waiting to see if these gingiva cells will convert into nerve cells just like they did on a petridish in our lab," said Dr Suresh.

In February, the medical journal *Experimental Molecular Medicine* published a scientific paper on how Dr Suresh's team was able to isolate stem cells from human gum tissues, culture them into nerve cells after adding stimulating protein. Stem cells produce cells that mature into specific types, such as heart and bone cells, or neurons and glia that compose the nervous systems.

If the animal trial is successful then the next step will be to see if these cells can be used to heal wounds. "It will take a few weeks for us to tell that if these cells are doing that," he said. If everything goes well, the university will move to human trials. "It may take several years but it holds a hope for a cure," he said. In 2014, scientists in the US turned stem cells inside the tooth into nerve cells, but they found the tooth was damaged in the process or that they had to use cells from a donor.

Doctors in Chennai say they will now be able to do the same thing without leaving scars or causing damage to the tooth. These stem cells from gums potentially offer scientists a new starting point from which they can grow human tissues for therapeutic or research purposes without using embryos, said Dr Suresh.

Source: *The Times of India*, 25th June 2016



Drug Resistance : A Dent in the Anti malaria armour

The emergence of resistance to the artemisinin drug, a potent anti-malarial medicine, now threatens to affect the big gains achieved in recent years in reducing the global burden of malaria — an estimated 1.2 billion fewer malaria cases and 6.2 million fewer malaria deaths globally between 2001 and 2015. This resistance, to artemisinin, becomes all the more dangerous as it has been the “backbone of combination therapy” for more than 10 years and will continue to be used to treat malaria caused by *Plasmodium falciparum* — a protozoan parasite and one of the species of *Plasmodium* that causes malaria in humans; it is transmitted by the female *Anopheles* mosquito. The use of artemisinin came into the picture at a critical time when resistance to commonly used chloroquine was making malaria treatment highly inefficient.

It was only in December 2013 that researchers could conclusively prove that resistance to this powerful drug was due to mutations seen in the malaria parasite. Mutations in specific regions of the parasite's kelch gene on chromosome 13 (K-13) was found to confer resistance to artemisinin.

On the flip side, with K-13 mutations serving as a marker for artemisinin resistance, the spread of artemisinin resistance across the world could be mapped. A study published on June 23, 2016 in *The New England Journal of Medicine* has done precisely this and the results are quite positive. The K-13 mutations are still restricted to Southeast Asia and China with “no immediate threat to artemisinin efficacy in most countries where malaria is endemic”. “The prevalence of K-13 mutations in Southeast Asia and China is high: from 30-60 per cent to close to 100 per cent,” says Dr. Didier Menard, the first author of the paper from the Institut Pasteur in Cambodia, Phnom Penh, Cambodia.

A link with human movement

While no sample was collected from India, those from Bangladesh did not show K-13 mutations. “I think that resistance is (still) confined to Southeast Asia because we are at the beginning of the story. Emergence of artemisinin-resistant parasite is quite recent. Secondly, the containment strategy deployed has possibly been effective in limiting the spread. But the risk [of the resistant parasites spreading to other countries] is high due to intensive human population movement,” says Dr. Menard.

It is particularly important that the highly malaria-endemic region of Africa is free of artemisinin-resistant malaria. Otherwise it would lead to a global health crisis. Nearly 88 per cent of the malaria cases and deaths in 2015 had occurred in the World Health Organisation (WHO) African region, the 2015 World Malaria Report says.

Even in Asia, a majority of the K-13 mutations are distributed within two regions — Cambodia, Vietnam and Laos as one region and western Thailand, Myanmar and China as the other.

Combination therapies

The WHO insists that artemisinin must not be used as oral mono therapy as it promotes the development of drug resistance. Instead, it recommends artemisinin-based combination therapies (ACT) as first-line treatment for acute uncomplicated *Plasmodium falciparum* malaria. The combination therapies are effective as the mechanism of action of the two active ingredients is different.

While resistance to artemisinin generally leads to a delay in clearing the parasites from the body and not treatment failure, high treatment failures have been seen in Cambodia, Lao PDR and Vietnam despite the use of combination drugs. This arises due to resistance emerging in drugs that are used in combination with artemisinin.

A recent study in the journal Clinical Infectious Diseases says that along the Thai-Myanmar border, artemisinin resistance is leading to failure of the mefloquine (a partner drug used in combination therapy) drug and, in turn, the failure of the drug combination (mefloquine-artesunate) that was introduced in 1994. In fact, the study says that K-13 mutations in artemisinin and multiple copies of a particular multidrug resistant gene (Pfmdr-1) in mefloquine have a multiplicative than additive effect on risk of treatment failure. As a result, while patients are not being cured, the malaria parasite continues to spread further.

As early as 1992, the cure rate of even a high dose of mefloquine drug when used alone (monotherapy) had dropped to 50 per cent but was rescued by the use of artemisinin as a combination therapy (mefloquine-artesunate). "But when K-13 mutation emerged, [the] artemisinin component couldn't compensate for the already feeble mefloquine component and the whole combination failed," says Dr. AungPyaePhyo, the first author of the Clinical Infectious Diseases paper from Shoklo Malaria Research Unit, Thailand.

The only recourse left for Thailand was to change the combination drugs used. "We switched our first-line anti malarial to another combination therapy (Dihydroartemisinin-Piperaquine), which relies mostly on piperaquine component. We don't have piperaquine resistance in this area yet," Dr. Phyo says.

But changing to a different combination drug is only a short-term solution. Western Cambodia, for instance, has started seeing high piperaquine resistance.

"We don't have many options except eliminating the resistant malaria before the resistance progresses to a higher degree," Dr. Phyo says.

Source: *The Hindu*, 26th June 2016



Prices of 42 Essential Drugs Slashed by 15%

Prices of 42 essential medicines used in treatment of various ailments including tuberculosis, cancer, cardiac diseases, asthma, epilepsy and depression have been capped by the government, reducing their cost by up to 15 per cent.

Drug price regulator, National Pharmaceutical Pricing Authority (NPPA), in a notification on its website, said it "has fixed/revised ceiling prices of 45 scheduled formulations of Schedule-I under Drugs (Price Control) Amendment Order, 2016."

"Out of the 45, the prices of 42 medicines have been reduced by up to 15 per cent," a official source said.

NPPA said manufacturers not complying with the ceiling price would be liable to deposit the overcharged amount along with interest thereon under the provisions of the Drugs (Price Control) Order, 2013.

The authority has also fixed the retail price of 12 formulations under DPCO, 2013.

In another notification, the NPPA said it has also "fixed/revised ceiling prices of 32 scheduled formulations packs of IV Fluids".

Source: *The Hindu*, 28th June 2016



India's Pharma Industry 'Expected to grow to \$55 Billion' by 2020

India's rapidly growing pharmaceutical market is expected to grow to \$55 billion by 2020 and emerge as the sixth largest globally by size, said Indian ambassador to the US Mr. Arun Singh.

Formally inaugurating the 34th annual convention of the American Association of Physicians of Indian Origin (AAPI) here Friday, he outlined the rapid growth of the health sector in India, particularly in pharmaceuticals.

He said that the Indian sector had a competitive edge over others because its productions costs were significantly lower than that of the US and almost half that of Europe.

"Branded generics dominate the pharmaceuticals market, constituting nearly 70 to 80 per cent of the market," Singh said. "India is the largest provider of generic drugs globally with the Indian generics accounting for 20 per cent of global exports in terms of volume."

Praising the work of Indian doctors in the US who are estimated to number about 80,000, the envoy said: "You have excelled in your fields of medicine, and thus make significant contributions through hard work, commitment and dedication to your profession and the people you are committed to serve."

Speaking at a business session at the convention, New York Republican congressman Lee Zeldin, said Indian doctors are known around the world for their compassion, passion for patient care, research, and leadership. "Indian-Americans constitute about one per cent of the country's population, but you account for nine per cent of the American doctors and physicians, serving one out of seven patients being treated across the nation," Zeldin said

He called Prime Minister Narendra Modi's address to the US Congress last month inspiring and asserted that Modi's leadership was steering the world's largest democracy to new heights.

At the inauguration, Prasad Srinivasan, a Republican Connecticut state legislator, gave the 1,500 fellow doctors at the convention tips on aspiring to public offices, saying they should work with dedication on public causes and stay focused on their mission and profession.

"We have the choice to be at the table or on the table," said Prasad, who is serving his third term as a State Representative. "Given our heritage, we the Indian Americans belong at the table. Get actively involved in the affairs of the local community and that's the path to larger role in the nation."

AAPI President Seema Jain said the profession must prepare for the challenges faced by profession on the cusp of monumental changes and her organisation was helping ready them for it.

"The Future is now," she said. "Its time to step up to a new era of innovation through a new age of digital health care that transcends biological and chemical medicine into the future. As physicians we must be equipped to tackle the next generation's unique set of challenges and opportunities in health care."

Source: *The Times of India*, 2nd July 2016



Chemists Seek Regulation of Online Sale Threaten Strike

Over 8 lakh chemists across the country have called for an indefinite strike by the end of this month as the government has failed to respond to their concerns, including the demand to regulate online sale of medicines.

This comes almost a year after Pharma retailers observed a daylong strike on October 14. The strike was called off following an assurance from health minister J P Nadda to evaluate the matter at the earliest. Soon after, a sub-committee was set up to look into the matter but nothing has moved since then.

Official sources say the government is planning to introduce provisions under the new drug law to regulate online sale of medicines.

"We had raised our concerns before the health ministry several times but received no response," said Suresh Gupta, general secretary All India Organisation of Chemists and Druggists (AIOCD), which represents over 8 lakh chemists. The decision to call an indefinite strike was taken at AIOCD's annual general meeting in Hyderabad last week.

Despite a tentative ban on online sale of medicines, chemists claim online platforms continue to grow unabated in the absence of proper monitoring and uncertainty over the issue.

Though chemists maintain they are opposing online sales because it may not be in public interest, the fact is e-pharmacies also pose a major threat to on ground retailers who thrive on local sales of over Rs 1 lakh crore annually. Besides the issue of regulation on online drug retail, the chemists have also raised concerns about frequent price changes by the National Pharmaceutical Pricing Authority and a lack of intimation from the companies about revised prices. "Because of this, chemists often continue to sell medicines at the old prices leading to violation of law," says Gupta.

AIOCD has written to the government seeking that it be made mandatory for companies to produce a price list to retailers with the updated MRPs. Seeking a stringent check on sale of medicines by manufacturers, the retailers have asked the government to take action against companies selling banned drugs illegally.

Source: The Times of India 5th July 2016

Aurobindo in fray for \$ 1.5 bn Teva Portfolio

Indian drug maker Aurobindo Pharma Ltd. is among companies considering bids for Teva Pharmaceutical Industries Ltd.'s portfolio of drugs in the U.K., Ireland and Iceland, people familiar with the matter said.

Aurobindo would finance the deal with a loan of more than \$1 billion, according to one of the people, who asked not to be identified because the deliberations are private. No final decision has been made, and the company could still decide against a bid, the people said. The sale could fetch about \$1.5 billion, people familiar with the matter have said previously.

Teva is selling assets as it works to get regulatory approval for its approximately \$40.5 billion acquisition of Allergan Plc's generics business. A buyer for its U.K., Ireland and Iceland assets could emerge in the next few weeks, the people said. Other bidders remain interested in acquiring the portfolio of drugs, they said.

Source: The Times of India, 6th July 2016





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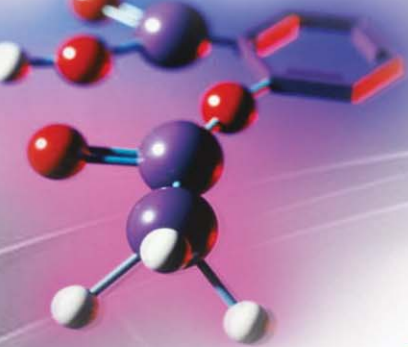
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