ISSUE No. 6

Pharma Web

Newsletter of Tamilnadu Pharmaceutical Sciences Welfare Trust

Apr.-May-Jun. 2010

Tamilnadu Pharmaceutical
Sciences Welfare Trust

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ISSUE : 6 **Apr.-May-Jun. 2010**

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EDITORIAL

Dear Readers,

This is the sixth issue for the quarterly period of April – June '10. This issue is a special issue of IPA Convention – March 2010. I, as President of IPA (TN Branch), alongwith other members of Local Organizing Committee have successfully conducted IPA Convention at Sri Ramachandra University, Porur on 12th -14th March 2010. The theme of the Convention was – **"India Surging Forward as Global Pharma Destination"** Our Trust office was utilized as Secretariat and undertook the task of registration of 2500 delegates. The Convention was inagurated by Dr. Sivathanu Pillai, Chief Controller of R&D, DRDO, Ministry of Defence, New Delhi. The stalwarts of the profession like Dr. Henri Manasse, Executive Vice-President of American Society of Health System Pharmacists, USA, Mr. Ivan Kotze, President, Commonwealth, Pharmacists Association were Guests of Honour. The Convention was well organized with various scientific sessions on subjects like stability studies of Pharmacuticals, Pharmacist's role on HIV/AIDS, Pharmaceutical education, regulatory and Industry aspects etc. This issue is highlighting the program of the Convention and also some of the important lectures etc. The Convention also deliberated various issues encountering with problems on regulatory aspects, employment opportunities for the Pharmacy professionals and other related subjects. The qualification of Drugs Controller as well as Pharmaceutical manufacturing chemists were discussed in this convention. The participants asked the office bearers of this convention to present a representation to appropriate authorities to amend the provision of Drugs and Cosmetics Act and Rules that only Pharmacy graduate professionals are eligible to occupy the post of Director - Drugs Control.

The most disturbing news was the distribution of spurious and date-expired medicines in and around Tamilnadu markets. Its is very unfortunate to know that it had occured in a well developed state like Tamilnadu. In order to satisfy the consumer at large, governement should take stringent action against all the offenders who are carrying out this unethical practice and also criminal activity.It is also necessary for central government to amend the provisons of Drugs and Cosmetics Rules for proper destruction of date expired medicines and its withdrawl from the market regularly on a time-framed manner.

The readers may be knowing that the Trust has already initiated the steps for employment/Training opportunities for the fresh pharmacy graduates by creating a data base. In the last issue of our newsletter we published the information to get the details of such candidates for creating a database. Now we have uploaded in our website the soft copy of the application format for such candidates. In this issue we are publishing an item to get the details of vacancy positions in various Pharma industries as well as Pharmacy colleges for such fresh graduates.

I am thankful to all the members of the Editorial Board and the Advisory Board for helping me to publish this issues in a time bound manner. I hope the readers will be benefited from this bulletin.

With best regards,

Mr. R. Narayanaswamy

IPA Convention 2010 – A Report

(By Mr. Jayaseelan, Secretary)

Indian Pharmaceutical Association conducted Indian Congress of Pharmacy & Pharmaceutical Sciences - 2010 and Indian Pharmaceutical Association Convention - 2010 in Chennai on 13th and 14th March 2010 through Tamilnadu branch of IPA.

Registration: 152 delegates were registered for CPA, 80 for AAPS and 2051 for IPA Convention. Delegates from 14 states participated in the Convention. Majority of them were from Tamilnadu, followed by Andhra Pradesh, Karnataka and Kerala.

The scientific program was co-ordinated by National Scientific Convener Dr. T. K Ravi. The LOC was guided by Dr. B. Suresh, Prof. K. Chinnaswamy, IPA Coordinator, Mr. C. Gopalakrishna Murty and seven Advisory Committee members.

The Chief Patrons of the Convention were Mr. V. R. Venkataachalam, Chancellor – Sri Ramachandra University and Mr. S S Vanangamudi, Managing Director, Apex Laboratories. Patrons of the convention were Mr. A. M. Sulaiman - The Madras Pharmaceuticals, Dr. Isari K Ganesh, Founder – Chancellor, Vel's University, Mr. Bharat Jhaver, Executive VP – Tablets India Ltd and Mr. Udhan Kumar Chordia, CEO Medopharm.

The venue of the program was Sri Ramachandra University, Porur. The Theme of the Convention was "INDIA – SURGING FORWARD AS THE GLOBAL PHARMA DESTINATION".

Details of two pre-conventional workshops held on 12th & 13th March 2010:

1. Satellite workshop on Stability Testing for global submission organized by Regulatory Affairs Division & IPA Tamilnadu branch in association with American Association of Pharmaceutical Scientists (AAPS).

2. Pharmacists preparing to face challenges in HIV/AIDS, TB organized by Commonwealth Pharmacists' Association (CPA) & IPA.

The pre-conventional workshops were inaugurated on 12th March 2010 with Dr. B. Suresh President - IPA & PCI, Mr. Ivan Kotze President, Commonwealth Pharmacists Association as Guest of Honor and our Director of Drugs Control (TN) Mr. M. Bhaskaran, Mr. P.D. Sheth - Vice President, FIP & Mr. Saji Thomas - Par Pharmaceuticals, USA, representative of AAPS as special invitees.

LOC Chairman, Mr. S. V. Veerramani, in his Welcome Address, mentioned that the workshop on the stability protocol will help the Indian Pharmaceutical Industry to surge forward. Presidential Address was given by Dr. B. Suresh where he insisted upon the necessity of proactive role of pharmacists in the management of HIV and AIDS. Dr. P. D. Sheth highlighted the objective of HIV/AIDS conference and Dr. Saji Thomas briefed about the uniqueness of AAPS and the Stability Protocol Workshop. Keynote Address was given by Dr. Ivan Kotze, where he highlighted the importance of pharmacists in the prevention and management of HIV & TB. Mr. Bhaskaran gave the Felicitation address. Guests were honored by Mr. S. D. Joag, Hon. Secretary IPA. Vote of Thanks was given by LOC Secretary Mr. J. Jayaseelan.

After inauguration, the sessions were held in different halls.

The following topics were covered in CPA-IPA HIV/AIDS workshop:

1. Introduction to HIV/AIDS, brief of worldwide scenario, including MCH - Dr Joseph, Amuzu, Health Adviser at the Commonwealth Secretariat, London.

2. HIV/AIDS – Indian Scenario & National Plan for HIV/AIDS – NACP III – where the Pharmacist fits in patient care - Dr. Indu, Tamilnadu State AIDS Control Society.

3. Government policy on availability of Antiretroviral drugs in India – for general and for stopping Mother-to-Child Transmission - Dr. S. P. Thyagarajan, Pro-chancellor - Research, Sri Ramachandra University.

4. Role of Pharmacist in HIV/AIDS & TB – In Hospital & Community Pharmacy – Dr. Adepu Ramesh. Professor, Dept. of Pharmacy Practice, JSS College of Pharmacy.

5. Role of Pharmacists in TB – Public–Private Partnership – Mrs. Manjiri Gharat, Hon. Secretary, IPA – CPD.

6. A Report on IPA-SF AIDS Awareness Campaign - Ms. Jimita Toraskar.

Later, participants were divided into working groups and they were trained to workout strategies for pharmacists to enhance their role in HIV/AIDS through hospital and community pharmacies. There was a good interaction and participation from delegates.

The following topics were covered in AAPS STABILITY TESTING workshop:

1. Pharmaceutical Stability Testing: Scientific basis and Global Regulatory Requirements – Dr. Prabu Nambiar, Vertex Pharmaceuticals, Inc. USA.
2. Optimizing Stability Program in support of Drug Development Process – Dr. Kim Huynh-Ba, Pharmalytik, USA.
3. Strategies for developing a stability indicating method – Dr. Charanjeet Jassal, Pfizer USA.
4. Validation of Stability Indicating Methods – Dr. Saji Thomas, Par Pharmaceuticals, USA.
5. Impact of Pharmaceutical and Biopharmaceutical Stability on the Specifications for Drug Substances and Drug Products – Dr. Ravi Harapanhalli, Parexal Consulting, USA.

Fellowship Awards function was organized by Central IPA at GRT Grand Days Convention Centre. Thiru. V. K. Subburaj, Principal Secretary to Government, Health & Family Welfare Department, Tamilnadu, was the Chief Guest. He released the IPA Convention 2010 Souvenir during the function and also gave the awards for the Award Winners of IPA.

IPA Convention Inauguration:

On 13th Mar 2010, Padmashri Dr. Sivathanu Pillai, Chief Controller, Research & Development, DRDO, Ministry of Defence, New Delhi was the Chief Guest , Dr. B. Suresh President - IPA & PCI presided over the function and Dr. Henri Manasse, Executive Vice President and Chief Executive Officer, American Society of Health-System Pharmacists, USA was the Guest of Honour. Mr. P. D. Sheth - Vice President, FIP, Dr. Soo Ja Naam, President, FAPA & Mr. Ivan Kotze - President, CPA were special invitees.

Mr. S. V. Veerramani gave the Welcome Address. Mr. S. D. Joag, Hon. Secretary, IPA, Mumbai, Mr. P. D. Sheth, Mr. Ivan Kotze & Ms. Soo Ja Naam also addressed. Felicitation was done by Dr. S. P. Thyagarajan, Pro Chancellor, Sri Ramachandra University. Mr Ivan kotze pointed out that Indian Pharma companies are helping American society by providing them quality medicines at economical prices. The president of FAPA mentioned that they were very proud to be associated with IPA and welcomed our participation in the next FAPA conference. Dr. Henri Manasse reinforced the importance of having specialized curriculum for Hospital and Community pharmacists during their education which should be different for the Industrial Pharmacists. The address by Chief Guest, Dr. A. Sivathanu Pillai was a milestone. He presented various factors as to why India has

a potential to become No. 1 and the strategy for making India as No. 1 in Pharma destination of the world. Dr. B. Suresh addressed the gathering on the theme "India Surging Forward as the Global Pharma Destination". Vote of Thanks was given by Mr. J. Jayaseelan, the Secretary of the LOC.

In the Plenary Session after inauguration, Dr. Henri Manasse addressed on the case for Pharmacy education reform in India. Mr. P. D. Sheth addressed the delegates on the role of Pharmacists in realizing Millennium Development goal. Later, scientific sessions for different fields of Pharmacy were held simultaneously in different halls.

On the final day of the CPA conference, the following topics were addressed:

1. View of Global Strategies in HIV & MCH Care – And the Role of the Pharmacists - Dr. Mothi.
2. Management & leadership role of Pharmacists in HIV & MCH care – towards achieving Millennium Development Goals - Dr. Jaideep Tank, FOGSI.
3. Continuing Education of Pharmacists to take leadership in care of HIV/AIDS & MCH (Quality Improvement, Advocacy) - Dr. Mini Jacob, Faculty, The Tamilnadu Dr. M. G. R. Medical University, Chennai.
4. Strategies for developing Pharmacist's Role in HIV & MCH care – hospital and community - Dr. Manju Chuggani.

Concluding session was by Ms. Betty Falcon Bridge, CPA and the concluding remarks were given by Mr. Raj Vaidya, Chairman, CPD, IPA.

The final day of the AAPS Stability Testing For Global Submission workshop covered the following topics.

1. Handling OOS/OOT investigation – Dr. Saji Thomas, Par Pharmaceuticals USA.
2. Challenges in the Stability Testing of Novel Dosage Forms and Combination Products: Impurities, Degradants and Beyond – Dr. Ravi Harapanhalli, Parexal Consulting, USA.
3. Key factors to bring Quality to Stability Records and Reports – Dr. Kim Huynh-Ba, Pharmalytik.
4. Pharmaceutical Stability Testing: Managing CMC Changes and Risk Management – Prabu Nambiar, Vertex Pharmaceuticals, Inc. USA

Panel Discussion on Stability Testing for Global Submission was conducted by Dr. Prabhu Nambiar, Dr. Ravi Harpanhalli, Dr. Kim Huynh - Ba, Mr. R. Thiruvengadam, & Mr. J. Jayaseelan. Concluding remarks were given by the coordinators Dr. Subash Mandal and Mr. J. Jayaseelan.

In the scientific session of the IPA convention three streams of lectures were conducted for the delegates.

STREAM I - Pharma Industry – Emerging Technologies & Regulations:

1. Developing India as global outsourcing base for manufacturing – Mr. S. M. Mudda, Executive Director-Technical & Operations, Micro Labs Ltd., Bangalore.
2. Indian Pharma Industries – R&D needs to meet the future challenges – Dr. M.D. Nair, Pharma Consultant.
3. USP Standard Setting - The public process & participation – Dr. K. V. Surendernath,
4. USP Quality by Design (QbD) - A Modern System Approach to Pharmaceutical Development and Manufacturing - FDA Perspective– Dr. Sumathi, Aurobindo Pharma.
5. Patent Strategies for Indian Pharma Companies – Mr. Gopakumar Nair

STREAM II - Emerging Trends in Pharmacy Practice:

1. Pharmacovigilance – Core value of Pharmacotherapy – Dr. Y. K. Gupta, AIIMS.

2. Optimal role of Pharmacist at Community Pharmacies in Asia – Dr. Soo Ja Naam, President, FAPA.

3. Rational Use of Medicines- Perception & Practice – Dr. Gitanjali, JIPMER,

4. Management of CBRN Disaster: Role Pharmacists can play – Dr. Rakesh Kumar Sharma, DRDO,

5. Professional Practice Regulations – Ms. Archna Mudgal, Secretary, PCI, New Delhi.

6. Quality Community Pharmacy Services - Issues & Concerns – Mrs. Manjiri Gharat

STREAM III - Pharmacy Education: Assuring Quality & Competencies:

1. Two Perspectives on Professional Autonomy – Dr. Henri Manasse, Executive Vice President and Chief Executive Officer, American Society of Health System Pharmacists.

2. Bridging the gap in Education: Collaborative efforts of Stakeholders and Educators – Dr. V. S. V. Vadlamudi Rao, VP, Nektar Therapeutics, Hyderabad.

3. Clinical Research – Ethics and Regulations – Dr. Ravindra B. Gooi, Dean, Bilcare Academy.

4. Continuing Professional Development (CPD) for Better Competence.

5. Quality Assurance of Pharm D Education – Dr. T. K Ravi.

6. A short session about IPA SF and its activities – Mr. T. V. S. S. Karthik, Jt. Secretary, IPASF Mumbai.

Panel Discussion: the Theme was **Indian Pharma Education Assuring Quality & Global Relevance** by Dr. B. Suresh, Dr. K. P. R. Chowdary, Dr M. N. Saraf, Dr. Hojjat Sadeghi – Aliabadi, Mr. G. Shivakumar.

On 14th March, 2010 the session begun with following Plenary Lectures:

1. Developing India as a global CO base – T. S. Jaishankar, Quest Life Sciences.

2. Emerging Opportunities & Future Trends for Exports - Dr. Appaji, Executive Director, Pharmexcil,

3. Developing Good Storage Practices - Shri R. Srinivasan.

Parallel Business meetings of Individual Divisions of IPA were conducted by the Chairman and Secretary of each division. IPA Presidents & Secretaries met and CEC meeting was conducted by Dr. B. Suresh where the new President Dr. Gopalakrishna Murty and other office bearers were introduced.

Simultaneously, Poster session was conducted where 14 Oral presentations and 389 Poster presentations were exhibited. 11 posters got the best poster award and 3 oral presentations got the best oration award.

Open Session was conducted by the President Dr. Suresh where few resolutions were passed.

The incoming President of IPA, Dr. Gopalakrishna Murty took charge. The next IPA Convention was granted to Indore branch of IPA. Present and future presidents of IPA appreciated the LOC of Tamilnadu for organizing such a wonderful convention and mentioned that this convention will be the Gold Standard for forthcoming IPA conventions.

Valedictory Function was presided over by Dr. B. Suresh. Dr. Gopalakrishna Murty, LOC Chairman Mr. S. V. Veerramani, Dr. Chinnaswamy, Co-chairmen, Secretary of the LOC all thanked the participants. All the chief patrons, patrons, sponsors, volunteers, delegates, advisors, Task Committee members, Core Committee members, all supportive staffs and others were thanked and honoured with mementoes. Everyone appreciated the excellent food & hospitality provided,

IPA Award Function 2010

During the IPA Convention 2010, the prestigious awards to the eminent functionaries of the Indian Pharmaceutical Association along with Fellows' Dinner were arranged at GRT Grand, T. Nagar, Chennai on the evening of 12th of March, 2010. The glittering function was attended by the Fellows of IPA, Industry doyens, Regulators, Educators, Healthcare professionals & representatives of national and international affiliating organizations, FIP, FAPA, CPA. Mr. V.K. Subburaj, the Principal Secretary, Healthcare & Family Planning, Tamilnadu was the Chief Guest of this glittering function. Prof. H. R. Manasse, Professional Secretary, FIP and Mr. Ivan Kotze, President, CPA were the Guests of Honor for the function.

The programme began with an invocation & ceremonial lamp lighting by IPA President, Dr. B. Suresh, Chief Guest and other dignitaries. This was followed by felicitation of Mr. Subodh Priolkar, recipient of IPA Eminent Pharmacist Award 2009 & Dr. Rao V.S.V. Vadlamudi, recipient of Prof. M. L. Khorana Memorial Lecture Award 2009. Mr. S. D. Joag delivered the Welcome Address and then presented a live show on global warming. Dr. B. Suresh in his Presidential Address reflected on his dreams for the Association. Mr. V. K. Subburaj, in his talk, highlighted the need to increase the role of pharmacists in the healthcare scenario and make healthcare affordable and accessible to the masses.

Dr. Rao Vadlamudi, Editor, Indian Journal of Pharmaceutical Sciences then announced Prof. M. L. Khorana IJPS Best Research Paper Awards. The awards were given to Dr. Mrs. Madhur Kulkarni, Dr. Munira Momin, Dr. R.D. Yeole, Mr. S. Soni, Dr. Mrs. Sandhya K. Desai, and Mr. A.S. Dasoondi by the Chief Guest.

The Awards function continued with IPA Best Local / State Branch Awards. IPA - Karnataka State Branch and Peenya Local Branch were given the Best State and Local Branch Awards for 2009 respectively. Special Recognition Award was given to Jharkhand and Gujarat State Branch and Vallabh Vidyanagar Local Branch for their exemplary work. The much coveted IPA Fellowships were conferred on Dr. K. P. R. Chowdary, Dr. T.K. Ravi and Dr. H.G. Shivakumar for their contributions to the cause of profession & association activities.

The prestigious IPA - Ramanbhai Patel Foundation Life Time Achievement Award was presented to Dr. P.M. Naik for his pivotal role in the growth of the pharmaceutical profession and the industry and meritorious contribution in the activities of IPA for more than three decades. The Awards function was followed by The Fellows' Dinner.

Inaguaration of IPA Convention 2010 on 13th March 2010

Inaguration of CPA workshop on 12th March 2010

Inaguaration of IPA Convention 2010 on 13th March 2010

IPA Fellowship Dinner on 12th March 2010

For the kind attention of Pharmaceutical manufacturers / Pharma educational institutions

TRAINING / PLACEMENT VACANCIES FOR PHARMACY GRADUATES

TNPSWT is creating a database for placement of graduates / post-graduates in Pharmacy who require job opportunities like academics / industries (Production, QA & QC) / marketing / Research and Regulatory Affairs, etc.

You are requested to forward the details of positions available in your organisation to enable us to communicate to the appropriate candidates. The details may be emailed to us at pharmjobs2010@yahoo.in

ARTICLES

Stability Testing - Scientific Basis and Global Regulatory Requirements

Dr. Prabu Nambiar,
Vice President, Regulatory Affairs, Vertex Pharmaceuticals, Cambridge, USA
At the Satellite Workshop on **Stability Testing for Global Submission**
Organised by IPA Regulatory Affairs Division & IPA, Tamilnadu Branch
in association with American Association for Pharmaceutical Scientists (AAPS)

Stability Testing – Science and Regulations

Overview of The Talk

- Stability – Definition / Background
- Stability – A Critical Quality Attribute
- Stability Studies – Statutory/Legal Requirement
- GMP Implications
- Stability during various phases of drug development
- FDA / ICH Stability Guidance
- Stability Challenges for Climatic Zone III & IV
- Conclusion

Presentation is focused on small molecules

Disclaimer: The scientific views and regulatory interpretations presented in these slides are the speaker's perspectives and do not represent any specific company or regulatory agency position

IPA Convention, Chennai, March 2010 1

Stability Testing – Science and Regulations

Stability of Pharmaceutical Product

- The ability of the pharmaceutical product to withstand stress (exposure to temperature, humidity, & light over time)

- Capacity of a drug substance or drug product in a given packaging system to remain within established specifications to maintain its identity, strength, quality, and purity throughout the retest or expiration period

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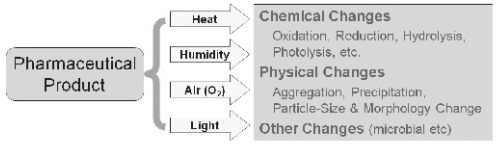
Stability Testing – Science and Regulations

Why do Pharmaceutical Product (DS/API or DP) Properties Change Over Time?

- The drug substance (small molecule/protein) is a chemical entity with many reactive functional groups (-OH, -SH, $-NH_2$, COOH etc)
- Similarly, the excipients used in the formulation are also chemicals with reactive functional groups



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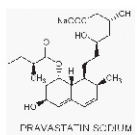
Stability Testing – Science and Regulations

Example



Drug Substance: Chemical Properties	
Functional Groups	**Reactivity**
Alcohol	Oxidation, esterification, etherification
Carboxylic acid	Decarboxylation, esterification
Ester	Hydrolysis, trans esterification
Double bond	Oxidation
Chiral centers	Racemization
Drug Substance: Physical Properties	
Particle size / morphology / solvation	

Drug product: Tablets
Excipients: Lactose, MgO, Mg Stearate, Microcrystalline cellulose, Povidone, Croscarmellose Na
Colorants: Yellow FeO, FD&C (aluminum lake)

Pre-formulation Research

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Stability Testing – Science and Regulations

Chemical Reactivity Checklist

API/ Excipient Functional Groups	Reactivity that can affect stability
- Alcohol	- Oxidation, esterification, etherification,
- Carboxylic acid	- Decarboxylation, esterification
- Ester / Lactones	- Hydrolysis, trans-esterification
- Double bond	- Oxidation
- Amides / Peptides / Lactams	- Hydrolysis
– α–β unsaturated ketones, -esters	- Addition, adduct formation

IPA Convention, Chennai, March 2010
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Stability Testing – Science and Regulations

Chemical Reactivity Checklist

API/Excipient Functional Groups	Reactivity that can affect stability
- Amines	- Addition, N-oxidation, quaternary ammonium salt formation
- Imines / Ethers	- Hydrolysis
- Thiols	- Disulfide formation
- Chiral centers	- Racemization
- Aldehyde	- Reaction with amines (Schiff's base formation)
- Chloride, Bromide etc	- Alkylation
	- Rearrangements, polymerization

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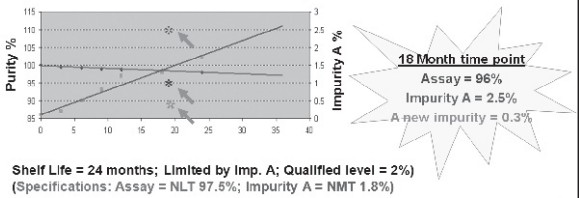
Stability Testing – Science and Regulations

Hypothetical Case for Illustration



Shelf Life = 24 months; Limited by Imp. A; Qualified level = 2%)
(Specifications: Assay = NLT 97.5%; Impurity A = NMT 1.8%)

Has the quality changed?	YES
Is the efficacy same as claimed in the Label? Is the safety profile same? Can it continue to serve the intended purpose?	Don't Know

Stability Testing – Science and Regulations

Scientific Basis of Stability Regulations

- The quality, safety & efficacy of a pharmaceutical product are established based on Chemistry, Manufacturing and Controls (CMC), animal toxicology & human clinical studies.
- The **quality** (identity, strength, purity, impurity, potency) of the product established via the CMC/tox/clinical studies will define the **quality of commercial product** (***specifications***) that **must** be maintained throughout the *product lifecycle*.
- Any changes in product-quality outside the established specifications may cause the product to be unfit for intended use.....because of potential impact of the change on established safety & efficacy!

Stability Testing – Science and Regulations

Potential Impact of Instability on Drug Product

- Reduction of labeled quantity
- Sub-potent drug product
- Toxicity due to degradants
- Loss of container-closure integrity
- Super-potent drug product
- Loss of microbial integrity/sterility
- Modification of Content uniformity
- Modification of Bioavailability
- Loss of cosmetic aspects
- Loss of functional aspects (device)

→
- Unreliable quality
- Potential Safety/Tox and/or Efficacy Issues

⇓

- Potentially Unsafe / ineffective product

Objectives of Health Agency: Protect public health / Prevent harm from unsafe products

Stability Testing – Science and Regulations

Stability Study is a Statutory/Legal Requirement

USA cGMP (21 CFR 211.166)
There shall be a written stability testing program to assess the stability characteristics of drug products

USA GLP (21 CFR 58.31(d)
Assure that test and control articles or mixtures have been appropriately tested for identity, strength, purity, stability, and uniformity, as applicable

ICH Q7A: GMP for API
Requires stability monitoring of APIs: A documented, on-going testing program is needed to monitor the stability of APIs; results should be used to confirm appropriate storage conditions and retest or expiry dates

- **Similar expectations from EMEA, WHO, and other Health Agencies**

Stability Testing – Science and Regulations

Stability Issues for commercial products

- Result in investigations
- GMP Inspection findings / Warnings
- Potential drug recalls

Stability Issues for investigational products

- Might result in "clinical hold" – Delays in development
- Might cause delays in Approval

Stability Testing – Science and Regulations

FDA 483 Warnings – Stability Related http://www.fda.gov/foi/warning.htm

Examples of stability related FDA 483 observations

GMP Citations

- Your **stability program is insufficient** in that samples are not tested at the established frequency, results are not correctly compared against specifications, stability sample container/closures are not equivalent to the containers you use for marketing, and investigations of aberrant results are not fully investigated....
- **Failure to establish a written testing program to assess the stability characteristics** of drug products
- **Failure to place an adequate number of batches of finished drug product on stability studies** to determine an appropriate expiration dating period....
- **A change to the process was not evaluated as to impact on material stability** and other aspects of material quality to ensure consistent, acceptable results.

Stability Testing – Science and Regulations

- **Failure to conduct stability** studies or to have such studies conducted for you to justify the expiration dates that you use on solid oral dosage forms repacked into unit-for-use containers……
- **Failure to implement an adequate testing program designed to assess the stability** characteristics of drug products. For example, the USP HPLC assay method for stability testing Acetaminophen tablet and caplet products was not validated to show it is stability indicating

GLP Citations
Your testing facility management **failed to assure the stability of the test article** under the conditions of the study….

Stability Testing – Science and Regulations

Recalls

PRODUCT Enalaprail Maleate Tablets, USP, 5mg, 100 and 1000 count bottles
CODE Lot # 109832A # 115188A # 117962A # 117962U
RECALLING FIRM: XYZ Pharmaceuticals
REASON Stability Failure.
VOLUME OF PRODUCT IN COMMERCE 26,424 bottles/units.

PRODUCT Doxepin HCl Oral Solution, USP (Concentrate), 10 mg/ml, 120 mL
CODE Lot Number 21451 exp 2/2007.
RECALLING FIRM XYZ Pharmaceuticals
REASON Failed pH specification (6 month stability).
VOLUME OF PRODUCT IN COMMERCE 8,618 bottles.

PRODUCT Calcitriol Injection, 2 mcg/mL, 1mL Single Dose Vial, 25 pack box
CODE Lot 03B139.
RECALLING FIRM PQR Pharmaceuticals, Inc, Irvine, CA.
REASON Impurity failure (18 month stability).
VOLUME OF PRODUCT IN COMMERCE 92,300.

PRODUCT Vivelle-Dot, Transdermal System, (estradiol) 0.1 mg (Samples)
CODE Batch # 76061011, 76991011, 74961021, 74961012, more
RECALLING FIRM: ABC Pharmaceuticals
REASON Stability Failure
VOLUME OF PRODUCT IN COMMERCE 340,726 units

Impact
Lost Revenue $$$
Product Withdrawal
Potential Law Suits
Corporate Image

Stability Testing – Science and Regulations

Pharmaceutical Stability
A Critical Quality Attribute

Stability Could Affect	Leading to	Impacting the
Physical Property	Degradation	Quality
Chemical Property	Racemization	Safety
Functional Property	Contamination	Efficacy
Microbial Property	Agglomeration	Desired Function
Container-closure Integrity	Precipitation	

Stability During Various Stages of Drug Development

Development Phase	Pre-IND Preclinical Research	Phase I	Phase II	Phase III	File NDA	NDA Approval	Phase IV
CMC Activities	•API •Drug Product •Analytical (Med Chem. / Process Chem.)	Process Development •API •Drug Product Analytical Development		Scale-up/Validation •API •Drug Product Analytical Development			Post-approval - CMC commitments - CMC changes
Objectives	-Provide material for Pharm/Tox Studies Preliminary CMC Development (API/Anal. Mcth) API / Solution Stability	•Provide Phase I /II Clinical Supplies Understand & optimize • API Process • Formulation • Drug Product Process •Analytical Methods Developmental Stability -API -Drug Product		Provide Phase III Clinical Supplies Develop commercial • API Process • Drug Product Process - Analytical methods NDA Stability (ICH) - API - Drug Product Set API / DP Specs Re-test date & shelf life			CMC commitments - Postapproval Stability - Annual Stability CMC changes - Improvements in Process, Scale, Site, Vendors etc., for • API • Drug Product - Stability (ICH) New Dosage forms - Development - Stability (ICH)

Stability Testing – Science and Regulations

Purpose of Stability Studies

- To understand one of the basic properties of the API
- Assure Integrity/Quality of material used in various Tox/Clinical studies
- API / DP Development (Identify process & product parameters)
  - API: Synthetic Route, Solvents, Operating Conditions etc
  - DP: Dosage form / Composition / Process / Operating Conditions / Equipment etc
- Define API / DP Specifications (Analytical Test / Method / Limits)
- Define API Packaging / Storage condition / Re-test or expiry date
- Define DP Packaging / Storage condition / Shelf life
- API / DP shipping conditions
- DP In-use Limitations
  - compatibility with diluents, other drugs, delivery devices
- Intermediates (API / DP) Packaging / Storage condition / Shelf life

Stability Testing – Science and Regulations

Attributes Investigated for API

Physical Properties
Color/Appearance
pH/Solubility/Melting Point
Optical Rotation
Density/Viscosity
Particle size
Morphology/Crystal structure

Chemical Properties
Reactivity/degradations
- Purity/Potency
- Impurities
- Solvent content (e.g. H_2O)

Spectroscopic Properties
IR, NMR, UV, MS, X-Ray

Microbial Properties
Sterility, Microbial limits

Stability Testing – Science and Regulations

Attributes Investigated for DP

Physical Properties
Color/Appearance

Chemical Properties
Moisture content
Purity/Potency/Impurities
Leachables/Extractables

Microbial Properties
Sterility, Microbial limits

Functional Properties
Solid Orals (Tablets/Capsules)
Dissolution / Disintegration / brittleness

Liquid Orals (Suspension/Syrups)
Preservative content, Viscosity, pH

Inhalation Products (Nebules/MDI/DPI)
Dose uniformity, Number of actuations
Aerodynamic particle size, Agglomeration, Foreign particles, Leak rate, Shot weight

Parenteral Products
Reconstitution time/Particulates
Container closure integrity

Transdermal Patches/Implants/Suppositories
Adhesion, leakage, Drug release, Softening

Stability Testing – Science and Regulations

Attributes Investigated for Container Closure System

Chemical Properties
- Chemical degradations
- Extraction & Leaching of additives / chemicals into drug product

Physical / Functional Properties
- Moisture/Vapor transmission
- Light permeation
- Adhesion / Sealing
- Corrosion
- Elasticity / Fragility, etc

Stability Testing – Science and Regulations

Standard Practices

- Early phases of clinical research (phase 1)
  - Stability data depends on the dosage form; many times, they are simple/rudimentary
    - powder in capsule/oral solution etc - API stability data plus in-use solution stability should suffice
  - Need to support the stability of the clinical supplies for duration of study
- As clinical research advances (late phase 1, phase 2)
  - There is better definition of dosage form (e.g. tablets or capsules) , strength and container closure (bottle or blisters) for clinical supplies
  - Need stability data to support the use of product for the duration of the clinical study – usually a concurrent activity
  - Uncertainty about the commercial process/dosage form/strength/and container closure system (e.g. bottles or blisters)

Stability Testing – Science and Regulations

Standard Practices

- Final stages as clinical research advances (Phase 3)
  - Commercial **manufacturing process** defined
  - Final commercial **dosage form, strength** and **packaging** in place
  - Regulatory filing strategy in place (which countries etc)
  - Start ICH stability studies (accelerated and long term)
    - For API
    - For drug product
  - Continue to provide stability data to support the use of product in clinical study
  - Consult with regulatory agencies
    - e.g. End-of-Phase 2 meeting with FDA to achieve concurrence on the stability plan

Stability Testing – Science and Regulations

Standard Practices

- Post-approval stability Activities
  - Post-approval commitment for commercial batches
  - Annual Stability batch (one lot / strength / packaging configuration / site)
  - Post-approval changes
    - Stability requirements depends on the nature of change - major/moderate/minor
    - Changes in components and composition/process/site/scale/packaging system
    - Site-specific stability requirement
    - In the US, usually can (and recommended to) discuss with the FDA and get agreement on path forward
  - Line extensions (e.g. iv to oral, pediatric dose etc)
    - Full stability study

Stability Testing – Science and Regulations

Standard Practices

Other studies

- **Forced degradation studies** (heat/humidity/acid/base/oxidizing agent) are performed on the API early on to
  - understand stability profile/mechanism of degradation of the API
  - Develop stability indicating analytical methods (HPLC etc)
- **Photostability study** (on API and drug product)

Performed during early stages

- **Miscellaneous studies**
  - Stability data for intermediates / Bulk product
  - Temperature cycling study
  - Shipping studies
  - In-use studies (e.g. IV antibiotics)
  - Admixture compatibility with other drugs (e.g. IV antibiotics)

Performed during late stages

Stability Testing – Science and Regulations

Regulatory Guidance

FDA Guidance

On June 1, 2006, the FDA (CDER and CBER) withdrew the following stability guidances, among other CMC guidances.

- *Submitting Documentation for the Stability of Human Drugs and Biologics (1987)*
- *Stability Testing of Drug Substances and Drug Products (Draft) (1998)*

Reason for withdrawal: To align guidances with the principles of FDA initiative "Pharmaceutical Current Good Manufacturing Practices (cGMPs) for the 21st Century".

BOTTOM LINE: Follow ICH Stability Guidance

Stability Testing – Science and Regulations

ICH Guidance for Stability Studies

Q1A (R2) - Stability of New Drug Substances/Products
Q1B - Photostability
Q1C - Stability testing for new dosage forms
Q1D - Bracketing and Matrixing
Q1E - Evaluation of Stability data
~~Q1F - Climatic Zone III and IV~~ WITHDRAWN

Stability Testing – Science and Regulations

Key Features of Q1A

- Outlines the core stability data package for new drug substances and products
- Covers stability information needed for marketing application in EU, Japan, and USA
- Some other countries have either adopted this "as is" or with some modification (Canada/Australia/NZ)

Major Points

- Storage Conditions and Amount of Data
- Selection of Batches

Stability Testing – Science and Regulations

Key Features of Q1A – Testing Conditions

General Case (Drug Substance / Drug Product)

Label Storage Condition	Stability Studies	Study Conditions	Data Requirement
Room Temperature	Long term	25 °C ± 2 °C / 60% RH ± 5 % RH or 30 °C ± 2 °C / 65% RH ± 5 % RH	12 months
	Intermediate	30 °C ± 2 °C / 65% RH ± 5 % RH	6 months
	Accelerated	40 °C ± 2 °C / 75% RH ± 5 % RH	6 months
Refrigerated	Long term	5 °C ± 3 °C / Ambient humidity	12 months
	Accelerated	25 °C ± 2 °C / 60% RH ± 5 % RH	6 months
Freezer	Long term	-20 °C ± 5 °C	12 months

Stability Testing – Science and Regulations

Key Features of Q1A – Testing Conditions

For Aqueous-Based Drug Products Packaged in Semi-permeable Containers

Label Storage Condition	Stability Studies	Study Conditions	Data Requirement
Room Temperature	Long term	25 °C ± 2 °C / 40% ± 5 % RH or 30 °C ± 2 °C / 35% ± 5 % RH	12 months
	Intermediate	30 °C ± 2 °C / 65% ± 5 % RH	6 months
	Accelerated	40 °C ± 2 °C / NMT 25% RH	6 months

Stability Testing – Science and Regulations

Key Features of Q1A

Selection of Batches

Material	Number of Batches / Scale	Formulation
API	At least 3 batches / Pilot scale	N/A
Drug Product	At least 3 batches 2 of them should be pilot scale 3rd can be smaller	Same as proposed commercial product

(Pilot Scale = 10% of production scale; or 100,000 units, whichever is larger for solid orals)

Process: API and Drug Product should be manufactured by a process representative of commercial process

Container Closure: Same as proposed commercial packaging

Testing Frequency: 0, 3, 6, 9, 12, 18, 24 months, then yearly

Stability Testing – Science and Regulations

Q1B: Photostability Testing

	Forced Photo-degradation study	Confirmatory studies	
		No. of batches*	Conditions
Drug Substance	Yes	1	1.2 million lux hours; Near-UV energy of ≥200 watt hours/square meter
Drug Product**	No	1	

* Two additional batches should be studied if the results are equivocal.
** Studies carried out sequentially; First fully exposed product, then product in the immediate pack and then in the market pack

Stability Testing – Science and Regulations

Q1C: Stability Testing for New Dosage Forms

New dosage form: A pharmaceutical product, containing the same active substance as included in the existing approved drug product, differing in

- Route of administration (e.g., oral to parenteral)
- New functionality/delivery systems (e.g., immediate release to modified release tablet)
- Dosage forms / same administration route (e.g., capsule to tablet, solution to suspension)

A reduced stability database at submission time (e.g., 6 months accelerated and 6 months long term data from ongoing studies) may be acceptable in certain justified cases.

Stability Testing – Science and Regulations

Q1D: Bracketing and Matrixing Designs

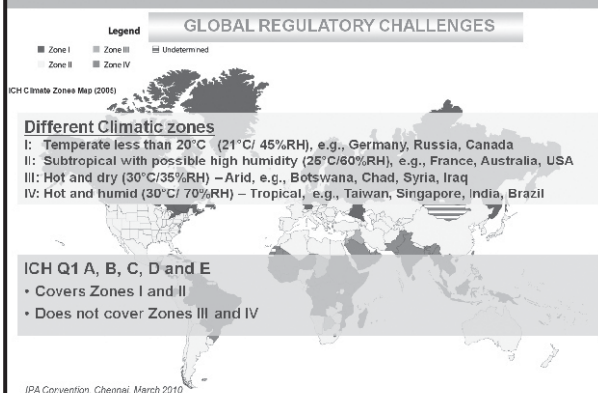
Bracketing:
Design of a stability schedule whereby only samples on the extremes of certain design factors (e.g., strength, container size and/or fill) are tested at all time points as in a full design, assuming that the stability of any intermediate levels is represented by the stability of the extremes tested.

Matrixing:
Design of a stability schedule where testing is performed on a selected subset of samples for one time point and on another subset of samples for a subsequent time point.

Q1E: Evaluation of Stability Data

- How to use stability data generated per ICH Q1A(R) to propose a retest period or shelf life
- When and how extrapolation can be considered when proposing a retest period for a drug substance or a shelf life for a drug product

Stability Testing – Science and Regulations



GLOBAL REGULATORY CHALLENGES

Different Climatic zones
I: Temperate less than 20°C (21°C/ 45%RH), e.g., Germany, Russia, Canada
II: Subtropical with possible high humidity (25°C/60%RH), e.g., France, Australia, USA
III: Hot and dry (30°C/35%RH) – Arid, e.g., Botswana, Chad, Syria, Iraq
IV: Hot and humid (30°C/ 70%RH) – Tropical, e.g., Taiwan, Singapore, India, Brazil

ICH Q1 A, B, C, D and E
- Covers Zones I and II
- Does not cover Zones III and IV

STABILITY CHALLENGES FOR HOT & HUMID COUNTRIES

ICH Q1F – For Zones III and IV (Hot & Dry or Hot & Humid)

Stability Studies	Study Conditions	Data Requirement
Long-term	30 °C ± 2 °C / 65% RH ± 5 % RH	12 months
Accelerated	40 °C ± 2 °C / 75% RH ± 5 % RH	6 months
Stress Conditions: 50°C/ambient humidity to cover extremely hot and dry conditions; 25°C/80% RH to cover extremely high humidity conditions		

WITHDRAWN

WITHDRWAN in June 2006

Reason:
- Several countries/ regions have revised their own stability testing guidelines for larger safety margin (e.g. 30°C/75%RH as long-term storage condition)
- Respective regions and WHO responsible for defining of storage conditions

Impact on ICH Q1A (R2):
- Intermediate testing condition is unchanged: 30°C/65%RH
- 30°C/75% RH is acceptable, should the applicant decide to use them.

STABILITY CHALLENGES FOR HOT & HUMID COUNTRIES

Stability Needs of ASEAN Countries

Association of Southeast Asian Nations
Brunei, Cambodia, Indonesia, Laos, Malaysia, Myanmar, Philippines, Singapore, Thailand, Vietnam

- ASEAN average temperature/humidity = 27 °C and 79% RH
- To provide appropriate safety margin, recommended the following in 2004
  - Long term stability testing at **30 °C / 75 % RH**
  - Accelerated testing at **40 °C / 75 % RH**
- Supported by various S. American countries (Brazil, Cuba, Columbia)

STABILITY CHALLENGES FOR HOT & HUMID COUNTRIES

WHO / Expert Committee & International Developments

- October 2005 – WHO Expert Committee recommended
  - Zone IVa 30 °C / 65 % RH
  - Zone IVb 30 °C / 75 % RH
  - Each Member State to designate what applies to them
- April 2006 – Intl. Conf. of Drug Regulatory Authorities (ICDRA; Regulators from >80 countries)
  - Member States to identify and inform WHO what testing condition applies to them
  - WHO to communicate on an International basis
- October 2006 – WHO Expert Committee
  - Endorsed ICDRA recommendation
  - Accordingly, revise WHO Stability Guidelines

IPA Convention, Chennai, March 2010

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STABILITY CHALLENGES FOR HOT & HUMID COUNTRIES

WHO / Expert Committee & International Developments

Proposed criteria and long-term testing conditions

Climatic zone	Definition	Criteria Mean annual temperature measured in the open air/ mean annual partial water vapour pressure	Long-term testing conditions
I	Temperate climate	≤ 15 °C / ≤ 11 hPa	21 °C / 45% RH
II	Subtropical and Mediterranean climate	> 15 to 22 °C / > 11 to 18 hPa	25 °C / 60% RH
III	Hot and dry climate	> 22 °C / ≤ 15 hPa	30 °C / 35% RH
IVA	Hot and humid climate	> 22 °C / > 15 to 27 hPa	30 °C / 65% RH
IVB	Hot and very humid climate	> 22 °C / > 27 hPa	30 °C / 75% RH

Reference: WHO Technical Report Series, No. 953, 2009, Annex 2

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Stability Testing – Science and Regulations

Conclusions

- Pharmaceutical stability is a critical quality attribute. Any deviation from the established stability profile has potential impact on quality, safety and / or efficacy
- Thorough understanding of the stability of the drug substance and drug product is important for
  - designing the optimal pharmaceutical product, define API / DP process development and establish appropriate specifications and expiry dates
  - Avoid commercial product recalls and clinical holds
- Developing global stability programs are challenging due to climatic variations and differences in local regulatory requirements
- ICH Q1 A-E offers sound scientific principles and covers majority of the regions; but there are exceptions
- Stay tuned to changing regulations
- When in doubt, use science based approach and ask the experts / regulators

IPA Convention, Chennai, March 2010

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Stability Testing – Science and Regulations

References

- Q1A(R2) Stability Testing of New Drug Substances and Products http://www.fda.gov/cder/guidance/5635fnl.pdf
- Q1B Photostability Testing of New Drug Substances and Products http://www.fda.gov/cder/guidance/1318fnl.pdf
- Q1C Stability Testing for New Dosage Forms http://www.fda.gov/cder/guidance/1319fnl.pdf
- Q1D Bracketing and Matrixing Designs for Stability Testing of New Drug Substances and Products http://www.fda.gov/cder/guidance/4985fnl.pdf
- Q1E Evaluation of Stability Data http://www.fda.gov/cder/guidance/5531fnl.pdf
- Q1F *Stability Data Package for Registration Applications in Climatic Zones III and IV, revision 1* Withdrawn 7/6/2006
- WHO Technical Report Series, No. 953, 2009, Annex 2

IPA Convention, Chennai, March 2010

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TRAINING / PLACEMENT FOR PHARMACY PROFESSIONALS

Tamilnadu Pharmaceutical Sciences Welfare Trust is creating a database for the placement of graduates and post-graduates in Pharmacy who require job opportunities in Pharmacy field like academics/ industries (production, QA & QC) / marketing / research and regulatory affairs, etc. Persons who are fresh graduates or experienced in pharmacy field may forward their CV clearly mentioning the area if interest, to this Trust by email to pharmjobs2010@yahoo.in

Emerging Opportunities and Future Trends in Indian Pharmaceutical Exports

Dr. P.V. Appaji
Executive Director, Pharmexcil
During the IPA Convention 2010, Chennai

Global Trade in Pharmaceuticals

- The global pharmaceutical markets are estimated at US$773.1bn (2008) growing at 4.8% percent (at constant $) over the previous year. (IMS Health)
- As per the latest statistics available from United Nations trade database 'Comtrade' the global exports of Bulk Drugs and Pharmaceuticals in the year 2008 stood at US$ 404.2bn growing by 10.37% over the previous year.
- Global exports of formulations stood at US$374.69bn. growing by 10.38% and Bulk drugs exports occupy a share of 7.3% in the total trade valued at US$29.5bn.

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Top Exporting Countries of Bulk Drugs & Pharmaceuticals of the World (figs. in US$ mn.)

Rank	Country (Exports)	2007	2008	% share
1	Germany	55,520.78	67,438.88	16.68
2	Belgium	47,377.79	50,665.56	12.53
3	Switzerland	36,232.92	44,145.34	10.92
4	USA	33,379.84	38,076.67	9.42
5	France	28,291.37	33,189.47	8.21
6	United Kingdom	28,975.58	31,342.25	7.75
7	Ireland	18,749.69	22,546.15	5.58
8	Netherlands	15,361.05	17,231.52	4.26
9	Italy	15,646.15	16,595.01	4.11
10	Sweden	8,719.60	9,167.87	2.27
11	China	6,093.35	8,117.00	2.01
12	Denmark	7,237.12	8,076.41	2.00
13	Austria	6,303.99	7,382.23	1.83
14	Canada	6,188.93	6,191.10	1.53
15	India	4,475.95	5,822.45	1.44

Source: UN trade database 'Comtrade', Pharmexcil Research

pharmexcil 2

Top Importing Countries of Bulk Drugs & Pharmaceuticals of the world (figs. in US$ mn.)

Rank	Country	2007	2008	% share
1	USA	53,954.01	59,868.18	15.38
2	Germany	40,934.01	46,669.00	11.99
3	Belgium	41,602.36	44,332.86	11.39
4	France	22,068.56	24,820.57	6.37
5	United Kingdom	20,418.65	20,658.26	5.31
6	Italy	18,176.71	19,974.99	5.13
7	Switzerland	16,693.44	17,777.67	4.57
8	Netherlands	16,353.47	12,981.00	3.33
9	Japan	9,145.98	10,998.52	2.82
10	Canada	10,315.06	10,770.32	2.77

Source: UN trade database 'Comtrade', Pharmexcil Research

pharmexcil 3

Indian Pharmaceutical Industry – Current Status

- Indian pharmaceutical industry is among the world's largest and most developed. As per UN Comtrade, in the year 2008, the country ranks:
  - 5th largest exporter of Bulk Drugs & Formulations in value terms with a share of 1.44% during 2008.
  - India exported US$5bn. worth of formulations in 2008 growing by 30.56% over the previous year when the country's formulations exports were valued at US$3.82bn. It ranked 14th in value terms and 3rd in volume terms.
  - The country is 9th largest exporter of APIs/Bulk Drugs valued at US$819.1mn. and the country ranked 8th in terms of export volumes. (The HS codes identified by international agencies does not include chemical based HS Codes and therefore, the actual value is under reported).

pharmexcil 4

Is among Major Exported Principal Commodity of India

- The Indian domestic pharmaceutical market size is estimated at US$10bn (Rs.55,454 crores) in the year 2008 growing by health 10%. *(Source: IMS)*
- India's Healthcare Expenditure in the year 2008 is estimated at US$68.6bn *(as per Espicom Reports).*
- Pharmaceuticals expenditure occupies a share 17.78% in healthcare expenditure and 0.8% in country's GDP.
- The per capita Pharmaceutical expenditure in the country is approximately US$10 (compared with US$1,154 of USA).
- It is consistently fifth largest principal commodity exported from India.

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Proven Manufacturing capabilities

The country has:

- Proven chemistry & manufacturing skills.
- Exports intermediates, APIs, FDFs, bio–pharmaceuticals, Clinical Services to various parts of the world.
- Significant design capabilities for manufacturing assets in manufacturing intermediates, APIs, formulations, biotech products and herbals.
- Distinction of providing healthcare at very low cost and still profitable. Proven capability as measured by number of ANDA approvals, DMF filings, USFDA/UK MHRA approved manufacturing facilities/ bio equivalence centers. (India has largest no of US FDA approved plants outside US.)

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Proven R&D capabilities

India's Capabilities can be understood by the number of product approvals received in various countries and compliant facilties:

- India has filed type-II Active DMFs for a total of 464 molecules of the total 1,117 molecules filed with US FDA (as on Sep. 2009)
- These DMFs have been filed from a total of 169 facilities by a total 136 Indian companies.
- In 2008, the exports of formulations from India to top 28 regulated countries surpassed API exports firmly demonstrating the shift in credibility and Quality Compliance of the Country
- The country has over 1,000 WHO cGMP approved pharmaceutical plants.
- The country has 153 EDQM approved pharmaceutical manufacturing facilities.

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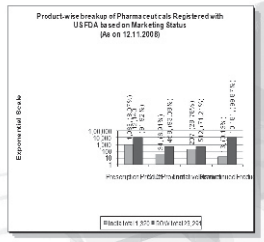

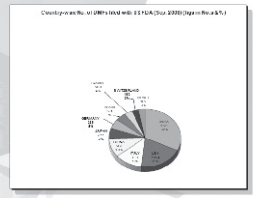

Source: Research based on CDER, U.S. FDA database

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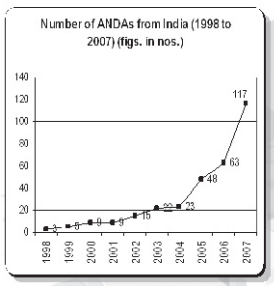
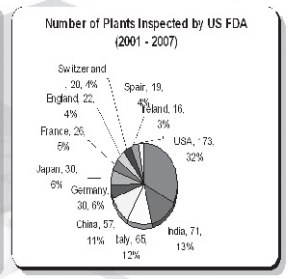
Source: Thomson Scientific, New Port Horizon 'Global





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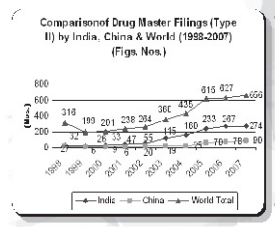
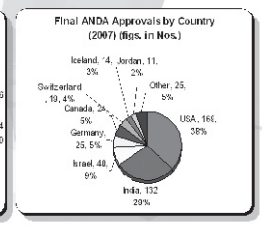
- The largest number of US FDA approved facilities outsi in India.
- 1/3rd of all DMFs & 30% of all approved ANDAs in US are from India, ranking next only to USA.





Source: Thomson Scientific, New Port Horizon 'Global

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U.S. FDA ANDA Approvals (As on 12.11.2008)				
Sl. No.	Total Therapeutic Category (Product-wise)	ROW Total	Total	% share of India
1.	Anti-HIV	59	13	18.05
2.	Anti-Microbial	1,581	274	14.77
3.	Cardiac	2,029	254	11.12
4.	Anti-Diabetic	313	37	10.57
5.	CNS	2,158	247	10.27
6.	Dermatological	79	9	10.22
7.	GI Tract	547	60	9.88
8.	Other Anti-Viral	120	12	9.09
9.	Anti-Allergic	127	10	7.87
10.	Analgesic	1,000	53	5.03
Total ANDAs: 13,206				
Therapeutic Categories : 23				
Source: U.S. FDA, Pharmexcil				

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List of Molecules having more than 15 U. S. DMFs from India			
Sl. No.	Subject	Therapeutic category	No. of DMF
1	Metformin	Anti diabetics	20
2	Amlodipine	Anti hypertensive	19
3	Venlafaxine	Anti depressant	18
4	Omeprazole	Anti Ulcer	16
5	Cefuroxime Axetil	Anti Biotics	15
Source: U.S. FDA, Pharmexcil			

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2. Europe*

- Highest number of Certificate of Suitability (CEPs) is granted to India.
- India has 539 CEPs (21.47%) of the total 2,511 granted by EDQM.
- The country has 153 EDQM approved facilities for 195 molecules out of the total 693 molecules approved by EDQM.

** Source: European Directorate of Quality Medicine EDQM) (As on July, 2009)*

Registration Summary

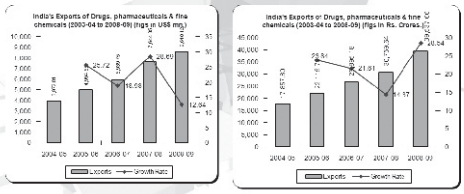
Table 5: Approvals Received by Indian Pharma Companies from Various Regulatory Agencies of the World (*As on Sep. 2009*)

Name of Regulatory Agency	No. of Companies Approved from India
DMFs filed with U.S. FDA (companies)	136
DMFs filed with U.S. FDA (facilities)	169
Number of molecules filed for which DMFs have been filed	464
Formulation Plants approved by U.S. FDA	23
EDQM (European Directorate of Quality Medicine) (Bulk drug facilities)	153
Number of CEPs received	539
Number of Molecules for which CEPs have been filed with EDQM	195
WHO GMP Certified Plants	Over 1,000
DACA (Drug Administration and Control Authority), Ethiopia	50
(TFDA) Tanzania Food and Drugs Authority	75

Source: FDA sites of respective countries, Pharmexcil Research

Exports of Indian Pharmaceutical Industry

- Exports for the year 2008-09 stood at Rs. Rs.39,537.66 crores (US$8.6bn.) which is 28.54% growth over the previous year (Rs.24,942.08).
- CAGR (2004-05 to 2008-09) was 21.33% (21.98% in US$ terms)
- Pharmaceutical exports occupy a share of 5.2% to 4.4% in India's total exports over the last 5 years.



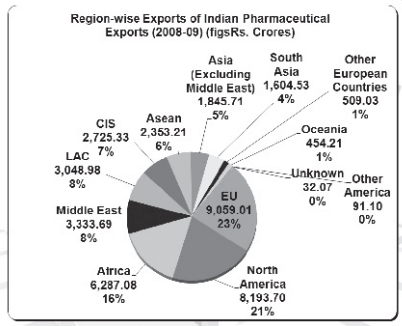
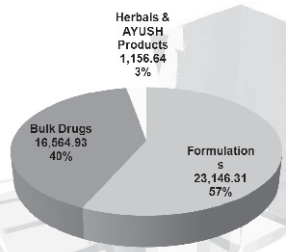


Chart 5: India's Imports of Drugs, Pharmaceuticals & finechemicals (2008-09) (figs. in Rs. crores)



Country-wise Exports of India's Drugs, Pharmaceuticals & fine chemicals (figs. in US$ mn.)

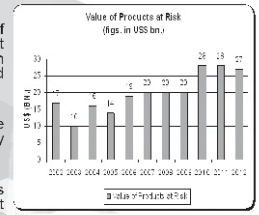
Rank (2008-09)	Importing Country	2007-08	2008-09	% Share	Cumulative % Share	CAGR	YoY Growth (%)	Rank (2007-08)
1	USA	1,451.13	1,546.88	17.97	17.97	26.51	6.60	1
2	Russia	309.10	330.84	3.84	21.81	17.74	7.03	3
3	Germany	359.84	314.00	3.65	25.46	11.04	-12.74	2
4	Austria	27.68	308.61	3.58	29.04	192.26	1014.92	58
5	UK	284.92	268.53	3.12	32.16	19.79	-5.75	4

Country-wise Exports of India's Drugs, Pharmaceuticals & fine chemicals (figs. in US$ mn.)

Rank (2008 -09)	Importing Country	2007-08	2008-09	% Share	Cumulative % Share	CAGR	YoY Growth (%)	Rank (2007-08)
6	South Africa	170.05	245.37	2.85	35.01	50.22	44.29	8
7	Canada	196.11	237.48	2.76	37.77	21.16	21.09	6
8	Brazil	191.75	221.88	2.58	40.34	19.46	15.71	7
9	Nigeria	166.81	218.15	2.53	42.88	20.64	30.78	9
10	Ukraine	123.54	149.66	1.74	44.62	18.89	21.14	13

Opportunities for Indian Pharmaceutical Industry

- Germany is the top exporting country with exports valued at US$67.44bn. followed by Belgium and Switzerland in that order.
- Germany was the largest exporter of formulations with exports valued at US$62.47bn. followed by Belgium (US$48.69bn.) and Switzerland (US$40.09bn.).
- In quantity terms also Germany was the largest exporting country followed by China and India.
- China was the largest bulk drugs exporting country with exports at US$5.25bn. followed by Germany (US$4.97bn.) and USA (US$4.11bn.).



Source: IMS Health Market Prognosis Sep. 2007.

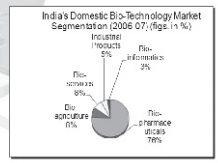
Generics

- World Generic pharmaceutical sales are estimated at US$80bn (2009).
- Block buster drugs worth US$103bn are expected to go off patent between 2009-2012 creating a further opportunity.

Bio-pharmaceuticals

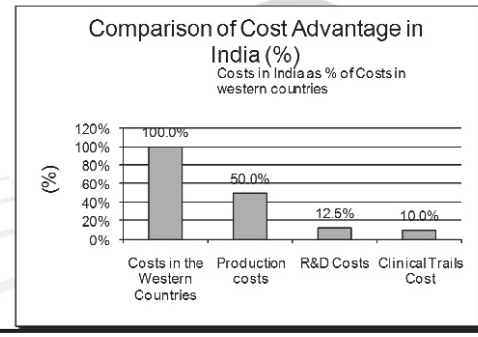
- Biotechnology products accounted for over 10 percent of global pharmaceutical sales.
- 20 Patents and the first generation of blockbuster biopharmaceuticals are beginning to expire.
- With 200 companies, India's biotechnology sector is fast growing and is in the early stages of development with initial emphasis on vaccines and bio services. The industry grew by 37% and Bio pharmaceutical, the largest segment exceeded US$1 billion.

Source: Deutsche Bank



Contract Manufacturing

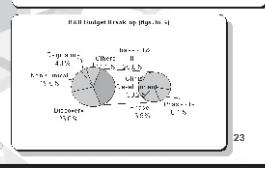
- The contract manufacturing opportunity of prescription drugs is estimated to increase from a value of $26.2 billion to $43.9 bn. in the next 5years.



- India and China could potentially account for 35% to 40% of the outsourced market share for APIs, FDFs and intermediates.

Contract Research

- In the drug research value chain, there are certain key strengths such as:
  - Significant valid population to participate in clinical trials
  - Significant capabilities in medical skills, hospital beds and IT
- There exists an opportunity to capture the market share in global clinical R&D market such as clinical trials, data management, testing, etc.



Company-wise Sales & Exports of Indian Pharmaceutical Companies (figs. in Rs. Crores)

Rank	Company Name	2005-06 Sales	2005-06 Export of goods (net)	2006-07 Sales	2006-07 Export of goods (net)	2007-08 Sales	2007-08 Export of goods (net)	2008-09 Sales	2008-09 Export of goods (net)	% share (2008/09)	Cumulative % Share (2007/08)
	Total	64,866.65	16,988.33	83,458.19	21,976.82	86,118.75	25,730.76	62,782.66	21,921.79		
1	Ranbaxy Laboratories Ltd.	8,284.03	2,224.34	8,999.15	2,589.18	8,656.20	2,517.28	9,992.23	2,681.79	9.78	9.78
2	Dr. Reddy'S Laboratories Ltd.	2,154.18	1,196.86	4,196.69	1,848.33	8,615.40	2,259.90	4,581.90	2,892.50	8.78	18.57
3	Cipla Ltd.	3,103.81	1,513.64	3,657.95	1,780.44	4,295.24	2,101.74	5,297.35	2,742.69	8.17	26.73
4	Lupin Ltd.	1,717.43	761.10	2,051.70	927.94	2,661.62	1,355.53	2,993.85	1,582.12	5.27	32.00
5	Aurobindo Pharma Ltd.	1,475.75	816.33	1,991.03	1,096.83	2,408.28	1,339.50			5.21	37.21
6	Orchid Chemicals & Pharmaceuticals Ltd.	883.18	621.01	934.19	701.08	1,230.19	1,008.96			3.92	41.13
7	Divi'S Laboratories Ltd.	894.21	534.80	740.41	675.25	1,047.55	962.82	1,203.82	1,103.35	3.74	44.87
8	Jubilant Organosys Ltd.	1,578.60	681.45	1,827.69	614.57	2,205.19	856.25	2,556.80	1,078.37	3.33	48.20
9	Sun Pharmaceutical Inds. Ltd.	1,853.02	365.21	1,722.13	480.56	2,427.35	806.45	2,833.65	813.77	3.13	51.33
10	Glenmark Pharmaceuticals Ltd.	620.93	140.81	838.76	303.76	1,408.71	677.41	879.79	206.85	2.63	53.96

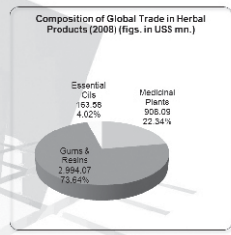
- India has a well developed drug regulatory system. The Central Drug Standards Control Organisation (CDSCO) set up under Ministry of Health & Family Welfare, Government of India is the Apex drug regulatory & licensing agency in the country.
- The organization headed by Drug Controller of India (DCGI) and is responsible for Standards of Drugs, Market authorizations, clinical trails, Import licenses, cGMP, monitoring of quality of drugs & cosmetics manufactured, pre & post licensing inspections, etc. Department of Pharmaceuticals under Ministry of Chemicals & Fertilizers is responsible for Pharmaceuticals policy and regulation including price regulation.
- Further, there are state level Drug Control Authorities to inspect and monitor pharmaceutical manufacturing facilities on regular basis.

- Some important laws related to Pharmaceutical sector in India are:
- The Drugs and Cosmetics Act, 1940
- The Pharmacy Act, 1948
- The Drugs and Magic Remedies (Objectionable Advertisement) Act, 1954
- The Narcotic Drugs and Psychotropic Substances Act, 1985
- The Medicinal and Toilet Preparations (Excise Duties) Act, 1956
- The Drugs (Prices Control) Order 1995 (under the Essential Commodities Act)
- Foreign Trade (Development & Regulation) Act 1992
- Foreign Exchange Management Act & RBI Regulations
- Customs Act 1962, Customs Tariff Act
- Central Excise Act 1994 & Rules,
- The Trade and Merchandise Marks Act, 1958
- The Indian Patent and Design Act, 1970

- The overall objective of a National Regulatory Authority (NRA) is to ensure that medicinal products are of acceptable quality, safety and efficacy, are manufactured and distributed in ways which ensure their quality until they reach the patient/consumer, and their commercial promotion is accurate.
- The Drugs and Cosmetics Act of India has laid down that standards of quality of drugs shall be as given in the second schedule to the Act.
- Any drug including API should conform to the specifications of the prescribed pharmacopoeias or those claimed on the label.
- In addition, patent and proprietary medicines, Surgical designs, Medical Devices, Mechanical Contraceptives are required to comply with the requirements of the national rules.
- Samples are drawn for every export shipment either at the production facility or at the airport by Assistant Drug Controller (ADC) appointed at designated ports for pharmaceutical exports.

Global Herbal Trade

- **The global market for herbal medicines currently is estimated at around $60 billion.**
- **The Global Exports of Medicinal Plants, Gums & Resins & Essential Oils last year is estimated at US$6.07bn. which is a decline of 3.2% for the second consecutive year as per the latest data available from International Trade Centre (ITC).**
- **The exports of all three segments have been declining at Compounded annual rate of 1.71% over the five year period 2004-2008.**
- **Gums & resins constitute the largest traded segment with 64% share at US$2.99bn. followed by Crude herbs and Essential Oils.**



Segmentation of Herbal Markets

The Herbal Products industry comprises a number of inter-related sub-sectors including

1. **Herbal Teas**
2. **Functional Foods/Parnuts**
3. **Nutraceuticals**
4. **Phytochemicals**
5. **Ethical OTC medicines**
6. **Flavours and fragrances**
7. **Aromatherapy**
8. **Culinary herbs and**
9. **Spices**

Another way of classifying is:

1. **Medicinal Herbs**
2. **Medicinal Essential Oils**
3. **Gums & Resins**
4. **Base Oils**
5. **Spices**
6. **Specialty/organic foods**

Top Exporting & Importing Countries

Top Exporting Countries of Gums & Resins (US$ mn.)

Rank	Country	2007	2008	CAGR
1	Germany	498.91	723.64	19.42%
2	USA	425.30	509.13	10.42%
3	China	257.05	495.07	46.26%
4	India	388.05	482.05	11.01%
5	Denmark	254.30	268.89	2.24%
6	France	224.72	239.68	2.55%
7	United Kingdom	118.82	210.45	26.51%
8	Italy	141.39	163.45	4.94%
9	Switzerland	92.59	106.84	7.94%
10	Philippines	70.69	97.65	15.69%

Top Importing Countries of Gums & Resins (US$ mn.)

Rank	Country	2007	2008	CAGR
1	USA	723.72	830.09	10.33%
2	Germany	414.13	469.69	11.62%
3	Japan	355.29	392.01	1.56%
4	France	264.81	324.82	10.49%
5	United Kingdom	188.33	185.92	4.06%
6	Italy	153.21	170.93	2.94%
7	Netherlands	122.08	151.75	7.43%
8	Belgium	116.65	144.93	12.81%
9	Denmark	138.22	142.23	16.07%
10	China	121.00	139.43	11.03%

Top Exporting & Importing Countries

Top Exporting Countries of Medicinal Plants (US$ mn.)

Rank	Country	2007	2008	CAGR
1	China	418.24	450.45	14.39%
2	India	113.12	130.19	22.14%
3	Germany	106.94	122.90	9.28%
4	USA	113.95	85.85	-2.84%
5	Poland	60.12	75.70	20.57%
6	China, Hong Kong SAR	67.22	73.54	-9.21%
7	Canada	90.50	72.41	4.87%
8	Egypt	32.60	58.46	23.78%
9	France	47.96	54.00	-2.57%
10	Singapore	49.60	48.34	4.50%

Top Importing Countries of Medicinal Plants (US$ mn.)

Rank	Country	2007	2008	CAGR
1	USA	247.60	276.11	12.15%
2	China, Hong Kong SAR	179.05	175.03	-0.69%
3	Germany	154.25	169.68	9.64%
4	Japan	117.98	148.52	6.78%
5	France	80.01	93.90	11.91%
6	Singapore	83.15	77.11	15.27%
7	Italy	66.80	75.38	11.18%
8	Canada	50.88	62.56	8.11%
9	Other Asia, nes	69.83	60.23	5.80%
10	United Kingdom	51.17	53.87	3.78%

Top Exporting & Importing Countries

Top Exporting Countries of Essential Oils (US$ mn.)

Rank	Country	2007	2008	CAGR
1	Brazil	70.83	70.91	7.80%
2	USA	48.33	44.97	0.20%
3	United Kingdom	13.64	14.86	-7.00%
4	Germany	11.43	13.75	11.54%
5	Switzerland	7.56	7.82	0.15%
6	Italy	5.77	7.17	-20.72%
7	France	3.87	6.92	2.18%
8	Mexico	4.09	6.85	36.60%
9	Tunisia	6.08	6.20	27.04%
10	Netherlands	3.25	4.82	8.08%

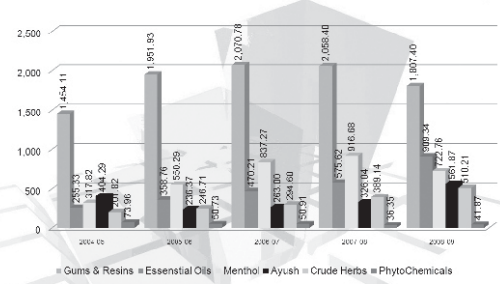
Top Importing Countries of Essential Oils (US$ mn.)

Rank	Country	2007	2008	CAGR
1	USA	44.97	43.53	1.81%
2	Germany	16.91	17.87	7.15%
3	United Kingdom	13.64	15.69	11.75%
4	Japan	20.74	14.01	-7.15%
5	France	10.78	12.75	-1.89%
6	Switzerland	10.08	9.47	-9.08%
7	Ireland	7.49	8.89	-0.51%
8	China	10.14	8.85	4.59%
9	Netherlands	5.77	6.89	0.30%
10	Canada	6.54	6.72	5.70%

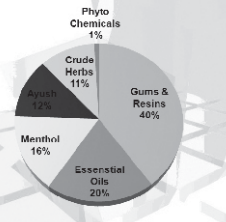
India's Herbal & AYUSH Trade

Commodity Name	2004-05	2005-06	2006-07	2007-08	2008-09	CAGR
Gums & Resins	1,454.11	1,951.93	2,070.78	2,058.40	**1,807.40**	**5.59%**
Essenstial Oils	255.33	358.76	470.21	575.62	**909.34**	**37.37%**
Menthol	317.82	550.29	837.27	916.68	**722.76**	**22.80%**
Ayush	404.29	236.37	263.00	326.04	**561.87**	**8.58%**
Crude Herbs	201.82	246.71	294.60	389.14	**510.21**	**26.09%**
Phyto Chemicals	73.96	50.73	50.91	36.35	**41.87**	**-13.26%**
Total	**2,707.34**	**3,394.79**	**3,986.76**	**4,302.23**	**4,553.45**	**13.88%**
% Growth (Total)		25.39%	17.44%	7.91%	5.84%	
Gums & Resins		34.21%	6.09%	-0.60%	-12.19%	
Essenstial Oils		40.51%	31.07%	22.42%	57.98%	
Menthol		73.15%	52.15%	9.48%	-21.15%	
Ayush		-41.54%	11.27%	23.97%	72.33%	
Crude Herbs		22.24%	19.41%	32.09%	31.11%	
PhytoChemicals		-31.42%	0.35%	-28.59%	15.19%	

India's Exports of Herbals, AYUSH Products (figs. in Rs. Crores)



Composition of India's Exports of Herbals & Auysh Products (2008-09) (figs. in Rs. Crores & %)



India's Top 20 Herbals & AYUSH Products (2008-09) (figs in Rs. Crores)

Rank	Commodity Code	Commodity Name	2006-07	2007-08	2008-09	Category
1	13023230	Guargum treated & pulverised	931.65	810.38	1,046.56	Gums & Resins
2	33012590	Of other mints	172.72	115.52	490.81	Essential Oils
3	29061100	Menthol	561.16	639.70	447.93	Menthol
4	12119032	Psyllium husk (isobgul husk)	254.69	346.66	446.62	Crude Herbs
5	30049011	Medicaments of ayurvedic system	169.18	196.25	315.29	AYUSH Products
6	30039021	Menthol crystal	276.10	276.98	274.83	Menthol
7	13023220	Guar gum refined split	193.28	302.07	249.99	Gums & Resins
8	33012400	Essntl oil of peppermint (mentha piperita)	173.49	337.88	245.08	Essential Oils
9	30039011	Medicants of ayurvedic system	90.36	125.19	236.21	AYUSH Products

India's Top 20 Herbals & AYUSH Products (2008-09) (figs in Rs. Crores)

Rank	Commodity Code	Commodity Name	2006-07	2007-08	2008-09	Category
10	33019013	Pepper oleoresins	79.16	111.82	132.86	Gums & Resins
11	33019022	Capsicum oleoresines	50.33	78.02	117.38	Gums & Resins
12	12119022	Senna leaves and pads	26.70	30.71	49.07	Crude Herbs
13	33019014	Turmeric oleoresins	41.51	36.62	40.45	Gums & Resins
14	9081020	Nutmeg not in shell	26.73	16.13	37.55	Gums & Resins
15	33012990	Essential oils of geranium	7.96	7.40	29.95	Essential Oils
16	13023900	Othr mucilags & thickenrs whtr/not modifd, derivd from vegtbl prdcts	22.27	22.39	29.49	Gums & Resins
17	33012935	Pepper oil	10.76	19.70	24.17	Essential Oils
18	13021100	Saps & extracts of opium	19.00	15.44	22.54	Phyto Chemicals
19	13012000	Gum arabic	1.25	0.91	22.23	Gums & Resins
20	33019017	Nut meg oleoresins	9.53	13.66	19.53	Gums & Resins

Emerging Issues

- Understanding, Indentifying and Meeting the demand of the importing country
- In many countries there are established Local Health Traditions and huge domestic markets
- Many countries have developed monographs and well laid procedures for registration of herbal products
- Outreach and acceptability of AYUSH systems is critically dependent on a sustained availability of quality plant base raw material.
- The Indian industry to comply with a higher level of GMP's (if possible) as laid out in the two following international sources.
  - A (non-binding) WHO publication called "Quality Control Methods for Medicinal Plant Materials" published in 1998, which has been revised in 2005.
  - WHO technical Report Series 943, which are recommendations of the WHO Expert Committee on Specifications for pharmaceutical preparations.

Pharmexcil – In Service of Nation

- Pharmexcil is an autonomous export promotion council (EPC) promoted by Ministry of Commerce & industry, Government of India
- With the objective of focusing on healthcare and pharmaceutical products in the global arena on 12 May, 2004 and
- With the support of all Major Pharma Associations IDMA, BDMA, OPPI, IPA, ETC. and Govt., of A.P.

- Pharmexcil is the designated authority for drugs & pharmaceutical sector dealing in the following products/ services from India:

- ♠ Bulk drugs (APIs)
- ♠ Drug formulations
- ♠ Biological products
- ♠ Medicinal plants
- ♠ Diagnostics
- ♠ Contract research
- ♠ Clinical research
- ♠ Collaborative research
- ♠ Technologies/consultancy
- ♠ Drug intermediates
- ♠ Biotechnology
- ♠ Herbal products
- ♠ Homeopathy
- ♠ Nutraceuticals & Phytochemicals
- ♠ Contract manufacturing
- ♠ Surgical dressings
- ♠ Pharma industry related services

- In the duty of export promotion, Pharmexcil provides the following services to Indian pharmaceutical companies:
  - Dissemination of trade enquiries
  - Organizing trade delegations from India to overseas markets as also reverse delegations
  - Organizing buyers-sellers meets
  - Organizing participation in international trade fairs
  - Providing policy inputs to the government of India on India's bilateral trade in pharmaceuticals
  - Dissemination of India's pharmaceutical trade statistics
  - Preparing technical publications, exporters' directory, etc.

- **Resolving grievances of pharmaceutical importers and exporters**
- **Organizing national & international seminars on areas related to pharmaceutical industry.**

Break-up of Pharmexcil Members	
Category	No. of Companies
Large Scale Manufacturer	297
Small Scale Manufacturer	1,270
Merchant Exporters	1,302
Source: Pharmexcil	

Break-up of Pharmexcil Members		
Sl. No.	Category	Number of Companies
1	Active Pharmaceutical Ingredients (API) & intermediates	1,515
2	Pharmaceutical Formulations	1,714
3	Biotech & Biological Produts	50
4	Herbal/Neutraceuticals	530
5	Veterinary Products	53
6	Medical Diagnostics	48
7	Contract Manufactures, R&D,, Trials etc	48
Source: Pharmexcil		

International Conferences

- **India – Africa, GCC & ASEAN Pharma Meet – December 2005 at Hyderabad** - 40 visitors, both FDA officials & buyers from 15 African countries visited. Over 350 Indian delegates participated.
- **India – CIS International Pharma Conference – March 2006 at Mumbai** – 100 visitors from 12 CIS countries attended and over 500 Indian delegates participated
- **India – LAC International Pharma Business Meet – June 2007 and Hyderabad** – 50 delegates from 20 LAC countries attended the Meet. About 400 Indian delegates took part in the event.
- **International Arogya** – For the benefit of AYUSH sector, Council arranged an International conference & one-to-one Meetings at Delhi in October 2007. About 30 overseas visitors and 150 Indian delegates participated in the event.
- **India – ASEAN Pharma Business Meet – February 2008 at Hyderabad** – 55 delegates from 5 ASEAN countries and 175 Indian delegates participated in the event.

Trade Delegations

- Council organizes Trade delegations to various countries, as part of its export promotional activities. Some of the major trade delegations organized during last four years are:
- South Africa in 2004
- Russia, Uzbekistan and Kazakhstan in January 2005
- Malaysia, Vietnam and Indonesia in March 2005
- Tunisia in April 2005 & October 2008
- Uzbekistan, Kazakhstan and Belarus in October 2005
- Trinidad & Tobago, Dominican Republic in March 2006
- Tajikistan in December 2006 & July 2007
- Sudan & Libya in August 2007
- Germany, Hungary & Poland in Oct 2007
- Congo, Uganda & Tanzania in March 2008
- Brazil, Argentina, Chile and Peru in August 2008
- Nigeria, Ghana & Ivory cost in February 2009
- Uzbekistan, Turkmenistan, Kyrgyzstan in January 2009
- Malaysia, Indonesia & Thailand in March 2009

International Trade Fairs

For the benefit of SMEs, Council organizes 'India Pavilion' in major exhibitions every year. Some of the important exhibitions are:

- CPhI Worldwide held every year in one of the European countries - About 50 companies participate in the pavilion. This event is for APIs & Intermediates sector
- CPhI South America – This event is for Pharmaceutical formulations & APIs – About 25 companies participate every year in India Pavilion organized by Council
- Arab Health – This event is for Medical devices & Surgical sector held every year at Dubai, UAE – About 20 companies participate in our pavilion every year
- Apteka, Moscow, Russia – A major event of pharmaceutical formulations and AYUSH products – 10-15 companies participate every year
- CPhI India - This is a major international event held in India. About 70 companies participate in Pharmexcil Pavilion every year.
- Southeast Asia Healthcare Show, Malaysia
- Pharma Expo, Bangladesh
- India-CIS Show – Uzbekistan
- Supply Side East, USA,
- MediPharma, Vietnam
- Vitafoods, Switzerland

Activities for 2009-10

Delegations/BSM to Abroad :

- South Africa, Nigeria, Kenya, Libya - June/July 09
- Vietnam, Cambodia, Philippines and Taiwan - Sep 09
- Russia, Ukraine, Armenia, Belarus, Moldova - October 09/February 10
- Brazil, Bolivia, Paraguay, Uruguay, Venezuela - August 09
- Kuwait, Syria, Jordan, Egypt, Turkey - November 09
- Hungary, Slovenia, Poland, Slovakia - January 10
- Exhibitions Abroad
- 1. BIO 2009, Atlanta, USA UAE May 18-21
- 2. Vitafood, Geneva, Switzerland 5-7 May 2009
- 3. CPhI China June 09
- 4. Pharmed & Healthcare 09, Vietnam 16-19 Sep 09
- 5. Apteka, Moscow or Apteka, Ukraine Oct 09 or Feb10
- 6. CPhI, South America, Brazil 26-28 Aug 09
- 7. CPhI Worldwide 09 13-15 Oct 09
- 8. CPhI, India, 1-3 Dec 09
- 9. Arab Health, 26-29 Jan 10
- International Conferences
- India – CIS Countries – January / February 2010

Quality Assurance of Pharm D. Education

Dr. T. K. Ravi
Principal, College of Pharmacy, Sri Ramakrishna Institute of Paramedical Sciences, Coimbatore
During the IPA Convention 2010, Chennai

QUALITY ASSURANCE

Quality assurance in Pharm.D education is an integral management tool concerned with prevention of problems in quality education through planned and systematic activities which ensures that the professionals produced by an institution are dependable and to be taken with confidence

QUALITY ASSURANCE (contd.)

- These internal management tool includes establishment of a documented quality system that sets out the organization structure, responsibilities, procedure, processes and resources to implement quality management and assessment of adequacy of quality education system.
- Audit of its operations and review of system itself.

PHARMA EDUCATION IN INDIA

- D. Pharmacy
- B. Pharmacy
- M. Pharmacy
- Ph. D in Pharmacy
- Pharm. D
- Pharm. D. (Post Baccalaureate)

WHY PHARM.D EDUCATION?

- Pharmacists have moved out of their dispensaries into wards and clinics. Their value is becoming more appreciated by other members of the health care team.
- There are number of reasons for changing to patient oriented practice, as more complex drugs come onto the market, there is a greater need for monitoring appropriate use of medicines by a suitable, qualified, competent person.
- There is also a greater threat of litigation for inappropriate use of medicine. The magnitude of medication-related problems, highlight the need for interventions to improve patient safety and cost effectiveness.
- India has become a global point for conduct of clinical trials, which could be facilitated through practice oriented education.

PROFESSIONAL EXPECTATIONS

- Vital member of the health care team.
- Valuable member of Society.
- Should posses top quality scientific and professional skills.
- Capable of making decision and taking responsibility.
- Be a good communicator.
- Be a good educator.
- Be a good manager.
- Be a good leader.
- With unquestionable sense of ethics.

GLOBAL SCENARIO

- In 1990, the American Association of Colleges of Pharmacy (AACP) mandated that a doctor of pharmacy degree would be the new first-professional degree.
- Currently all accredited schools and colleges of pharmacy in the US offer the Pharm.D. degree.
- Many also offer post-Pharm.D. graduate programs in specialized areas of the profession.
- Pharmacists are well known healthcare professionals with high respect in the society for their Pharmaceutical Care services.

STEPS TAKEN BY PCI

- In exercise of the powers conferred by section 10 of the Pharmacy Act, 1948 (8 of 1948), the PCI with the approval of the Central Govt made regulations.
- Pharm D regulations 2008 framed under section 10 of Pharmacy Act, 1948.
- Presently around 40 Institutions are given approval to run Pharm.D course.

INDIAN SCENARIO

Pharm. D & Pharm. D. (Post Baccalaureate)

- The Indian Pharm.D program being offered in a number of pharmacy schools to 30 students in each intake, has internship or residency training during the sixth year involving posting in speciality units.
- This internship is defined as a phase of training wherein a student is exposed to actual pharmacy practice or clinical pharmacy services and acquires skill under supervision so that he or she may become capable of functioning independently.
- The curriculum appears to retain a high pharmaceutical science input, which is crucial for the increasingly important Indian pharmaceutical industry, as well as clinical subjects.
- However, there is still a shortage of suitably qualified preceptors.
- A number of Indian schools of pharmacy have been running Masters programs in Pharmacy Practice(Clinical Pharmacy) for the one last decade.

CHALLENGES FOR PHARM. D EDUCATION IN OUR COUNTRY

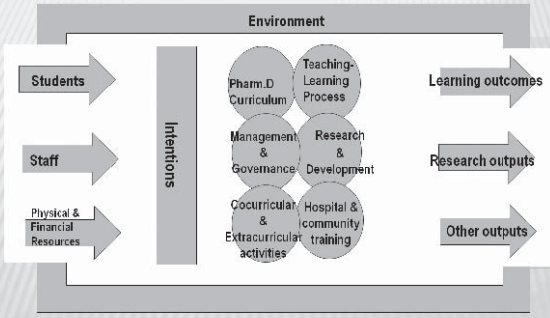
- How many subjects should be in the curriculum?
- How much professional experience should be in the curriculum?
- How many faculties are required?
- What types of practice experience included?
- How are they evaluated?

"The program must balance scientific knowledge with practical training."

RVICES OF PHARM.D PROFESSIONALS

- Patient medication history interview
- Adverse Drug Reaction monitoring
- Medication Error monitoring
- Interpretations of Lab Data
- Dosage adjustment for special population
- Drugs & Poison Information
- Patient medication counseling
- Clinical research
- Therapeutic Drug Monitoring

QUALITY ASSURANCE PROCESS IN INSTITUTIONS



THE PILLARS OF QUALITY

The Pillars of Quality

CONTROL OF QUALITY PHARM.D EDUCATION

- Policy makers
- Professional bodies
- Regulatory bodies
- Educational Institutions
- Other stakeholders

COURSE CONTENTS

- Basic Sciences
- Pharmaceutical Sciences
- Biomedical Sciences
- Social and Administrative Sciences
- Integration Activities
- Pre-professional practice

PHARM.D SUBJECTS

1	Human Anatomy and Physiology
2	Pharmaceutics
3	Medicinal Biochemistry
4	Pharmaceutical Organic Chemistry
5	Pharmaceutical Inorganic Chemistry
6	Remedial Mathematics/ Biology
7	Pathophysiology
8	Pharmaceutical Microbiology
9	Pharmacognosy & Phytopharmaceuticals
10	Pharmacology-I
11	Community Pharmacy
12	Pharmacotherapeutics-I
13	Pharmacology-II
14	Pharmaccutical Analysis

14	Pharmacotherapeutics-II
15	Pharmaceutical Jurisprudence
16	Medicinal Chemistry
17	Pharmaceutical Formulations
18	Pharmacotherapeutics-III
19	Hospital Pharmacy
20	Clinical Pharmacy
21	Biostatistics & Research Methodology
22	Biopharmaceutics & Pharmacokinetics
23	Clinical Toxicology
24	Clinical Research
25	Pharmacoepidemiology and Pharmacoeconomics
26	Clinical Pharmacokinetics & Pharmacotherapeutic Drug Monitoring

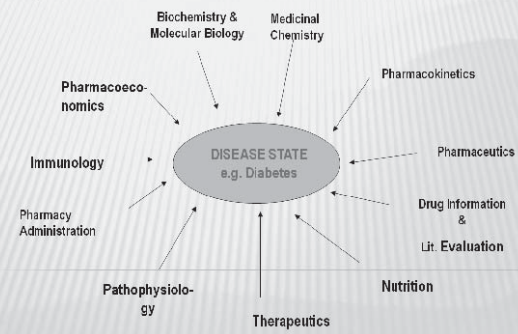
PRE - PROFESSIONAL PRACTICE

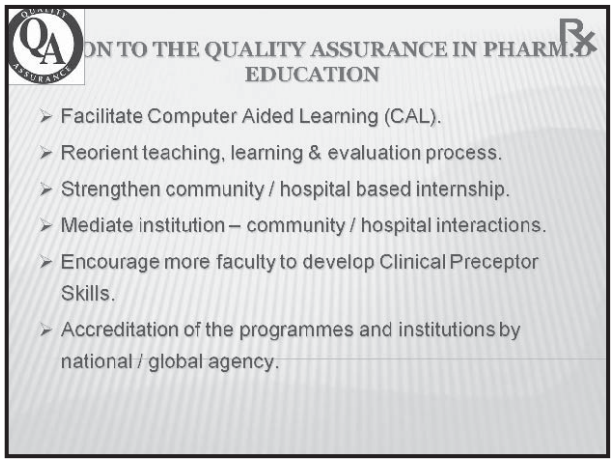
- Simulation of cases
- Training to develop critical thinking
- Projects
- Hospital & Community Training

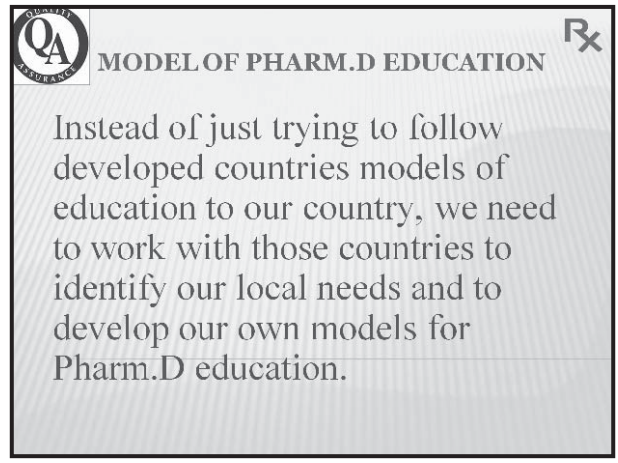
TEACHING – LEARNING PROCESS AND OUTCOMES

- Problem Based Learning (PBL)
- Introducing Computer Aided Learning (CAL) in relevant programmes
- Should improve reasoning
- Stimulate self directed search for solution
- Orient the students for life-long learning.
- Assessment methodologies must be coherent with the learning process.

INTEGRATED LEARNING PROCESS







Advertisement for Admission for one year Certificate Courses through Distance learning: Session 2010-2011 for the subject of:

1. Hospital Management (HM)
2. Health and family Welfare Management (H&FWM)

Eligibility Criteria for the Admission:

M.Pharm with 2 years experience
B.Pharm with 3 years experience
D.Pharm with 5 years experience

Experience of working: in Govt./Private/corporate hospitals/Institutes/organization/in the field of Public health.

Course Fees: Rs. 10,000/- on one time.

Prospectus may be obtained on or before 7th June 2010 from "Distance learning cell (DLC), Room No. 417, Academic block
National Institute of Health and Family Welfare (NIHFW)
Baba Gangnath Marg, Munrika, New Delhi – 110067
Phone Direct: 011-26183416
Phone EPABX: 011-26165959, 26166441, 26188485, 26107773 Ext. 336, 239, 240 Fax: 011-26183416
E.mail: director@nihfw.org, dean@nihfw.org. dlc@nihfw.org,
Website: www.nihfw.org

For all the details including the last date of submission of application and fees for getting application may be seen in the Website mentioned above.

M. Pharm Scholarships 2009-2010 awarded by TNPSWT

Profile of 2nd Rank Projects
(Continuation from Issue 5)

PHARMACEUTICS

Project Title: Inlay tablet of Atorvastatin calcium with sustained release Metoprolol tartarate for Hypertension
Name: Mr. Brito Raj S.
Periyar College of Pharmaceutical Sciences for Girls, Trichy
Guide's Name: Mrs. K. Reeta Vijaya Rani

PHARMACEUTICAL CHEMISTRY

Project Title: Synthesis of Amino triazolo thiadiazine derivatives and evaluation of anticancer activity
Name: Mr. Padmaraj C. P.
Sri Ramakrishna Institute of Paramedical Sciences, Coimbatore
Guide's Name: Prof. R. Vijayaraj

PHARMACEUTICAL ANALYSIS

Project Title: Validated UV, RP-HPLC methods for simultaneous estimation of Atorvastatin calcium, Glimepride and Metformin Hydrochloride in combined solid dosage form and in plasma by liquid Chromatographic – Mass Spectroscopy method.
Name: Mr. Somasundaram M.
Adhiparasakthi College of Pharmacy, Melmaruvathur
Guide's Name: Mr. A.S.K. Sankar

PHARMACOLOGY

Project Title: Pharmacological and biochemical evaluation of Tinospora cordifolia for its Antiparkinson's activity in 6-Hydroxy Dopamine lesioned rat model
Name: Mr. Partha Deb Roy
J. S. S. College of Pharmacy, Udhagamandalam
Guide's Name: Mr. A. Shanish Antony

PHARMACOGNOSY

Project Title: Formulation, development and evaluation of an eco friendly biopolymer from plant resources as a substitute for gelatin and synthetic polymers
Name: Ms. Raveesha Peeriga M.S.
J. S. S. College of Pharmacy, Udhagamandalam.
Guide's Name: Mrs. Nilani Packianathan

PHARMACY PRACTICE

Project Title: A study and analysis of adverse drug reactions (ADRs) in a multispecialty hospital and development of ADRs software for health care professionals
Name: Mr. Vinoth Kumar B.M.
Periyar College of Pharmaceutical Sciences for Girls, Trichy
Guide's Name: Mr. K. Sakthivel

PHARMACEUTICAL BIOTECHNOLOGY

Project Title: Extraction, evaluation and medicinal applications of value added amino sugar from Button mushroom wastes (Agaricus bisporus) and Absidia blakesleeana NCIM 889
Name: Ms. Priya N.
Sri Ramakrishna Institute of Paramedical Sciences, Coimbatore
Guide's Name: Mrs. R. M. Akila

NEWS

Bright future envisaged for Pharma industry

CHRONICLE OF EVENTS: Sivathanu Pillai (third from right), Chief Controller, Research and Development, DRDO, releasing a souvenir, which is received by S.V. Veerramani, chairman of the Indian Congress of Pharmacy and Pharmaceutical Sciences 2010. (From left) S.P. Thyagarajan, Pro-Chancellor of Sri Ramachandra University; Henri Manasse, Executive Vice-President and Chief Executive Officer of American Society of Health System Pharmacists; B. Suresh, President of IPA and PCI; and S. Thanikachalam, Director, Cardiac Centre, SRU are in the picture.

The Indian pharmaceutical industry is the only sector that receives huge fund allocations for research and development, Sivathanu Pillai, Chief Controller, Research and Development, DRDO, Ministry of Defense, said.

Making a presentation on the future prospects of the Pharma industry at the Indian Congress of Pharmacy and Pharmaceutical Sciences 2010, Dr. Pillai said India had advantages of an existing vibrant industry, large skill base, unmatched cost competitiveness and availability of capital.

The Congress was organised by the Indian Pharmaceutical Association (IPA).

The knowledge potential India had could not be ignored either, as the nation had huge trained manpower resources.

In terms of absolute growth, India would be among the top five pharmaceutical markets globally by 2015. He released the Congress chronicle on the occasion.

Dr. Henri Manasse, Executive Vice-President and CEO, American Society of Health System Pharmacists, said even as the industry spoke of growth, it would have to keep the patient at the centre of all considerations. India and many other nations need caregivers who would be well-educated and trained.

Dr. Venugopal Somani, Deputy Drug Controller General of India, said India was now an exporter of drugs, as low-cost, quality pharmaceuticals were in great demand across the world.

However this was just a beginning. Now that the nation has allowed the global Pharma industry to conduct clinical trials in India, it would increase the scale of operations manifold. B. Suresh, President, IPA, said India was emerging as a hub for clinical research and questioned if the industry had sufficiently geared itself up to meet the challenges in the future.

Source: *Press Report: The Hindu, 14th March 2010.*

Drug control procedures to be streamlined

The Intelligence Wing of the Directorate of Drug Control in Tamilnadu has been asked to investigate how expired drugs made their way to medical shops.

Drug Control officials have been asked to coordinate with police authorities in their investigation into the inter-state racket in procuring expired drugs.

Mr. V. K. Subburaj, Principal Secretary, Health and Family Welfare Department told The Hindu here on Saturday that the procedures with regard to destroying expired drugs would also be streamlined.

"The department will come out with a mechanism to prevent recycling of expired drugs. Raids will be carried out across the State and the Health Department will coordinate with the police," he said.

Stating that the surveillance of drugs, particularly in the retail side, would be strengthened, the Health Secretary said that more steps were being taken at the level of Directorate of Drugs Control.

The State government would recruit 25 more drug inspectors through the Tamiladu Public Service Commission in about three or four months, Mr. Subburaj said.

According to him, the investigation requires focus on how to prevent spurious drugs from entering medical shops and a concerted strategy was essential for syrups, capsules, strips and solutions. "We think that the problem of expiry date is only with costly medicines. We will see it in all aspects during our raids," he said.

Mr. Subburaj felt that strict regulations in Drugs Control were required in the context of increasing number of retail medical shops/pharmacies in the State.

"There are about 42,000 medical shops in Tamilnadu. It is a good sign that people have easy access to medicines but it is also a challenge when it comes to implementing the regulations," he opined.

According to the Health Secretary, one important step that has been taken was to have a person appointed as regular Director of Drugs Control.

"For nearly 10 years in the State, the Director of Drugs Control was on an in-charge basis. A few months ago the Director was appointed," he said.

Source: *The Hindu, 21st March 2010.*

Foolproof disposal of expired drugs soon

The Health Department will soon introduce a foolproof system for disposing off time-barred drugs, M. Bhaskaran, Director, Directorate of Drugs Control said.

The move follows the seizure of expired drugs that were sent to retail outlets with fake manufacture/expiry dates.

While seven persons were arrested and two surrendered in a city court on Tuesday, special teams were rushed to a neighbouring state to apprehend three prime suspects in the case.

"We have evolved a procedure that will ensure foolproof disposal of time-barred drugs. Because of timely intervention, we have been able to prevent large stocks of expired drugs from reaching the people. Drug Inspectors have been asked to look for three particular medicines that are being circulated with fake dates of manufacture or expiry. Pro-active steps are being taken to expose the entire nexus," Mr. Bhaskaran told The Hindu.

The Chennai police seized expired drugs worth about Rs.1 crore from a godown here.

The medicines, mostly vitamin supplements in the form of tablets or tonic for pregnant women, were seized from the storage point of Sanjay Kumar, one of the prime suspects wanted in the case pertaining to sale of expired drugs.

"We are following some specific inputs and more seizures will follow soon. This is a very elaborate case and a special team of more than 60 police personnel are involved in the investigation and the arrest of accused persons. The seized medicines are being sent for forensic analysis," Commissioner of Police T. Rajendran said.

Asked if the recent death of a three-year-old girl in Pulianthope allegedly due to consumption of expired drugs was linked to this case, Mr. Rajendran said a Forensic Science Laboratory report was expected in that regard. Information on how and where the suspects managed to procure the expired drugs and who assisted them in circulating them to retail outlets would be known only after the arrest of the main suspects.

According to police sources, police and health officials launched an intensive operation to detect time-barred or spurious drugs across the State. Director-General of Police Letika Saran said instructions have been given to zonal Inspectors General of Police and Commissionersof Police to take appropriate action on complaints preferred by Drug Inspectors.

"This will be a joint operation in coordination with health officials. They (the health department) have listed certain companies indulging in the sale of expired drugs. We are assisting them in taking action against the persons involved," Ms. Letika Saran added.

Source: *The Hindu, 25th March 2010.*

Manufacturing and sale of expired or spurious drugs denied

Representatives of the Pharmaceutical Manufacturers Association of Tamilnadu and Retail Medical Shop Owners Association in the city deny manufacturing or stocking and selling expired or spurious drugs.

Shop-owners say they are required to return the medicines three months before the date of expiry to the stockists, who, in turn, send them to the manufacturers for destruction.

Fast moving drugs

"Each of us buys only a few strips of tablets and less than 100 bottles/vials of fast-moving drugs such as cough syrup as we do not have the money to stock large amounts of such medicines," explained R. Manjini, President of Retail Medical Shop Owners Association.

The organisation has about 1,200 members.

"It is impossible for anyone to collect expired drugs from across the 4,000 medical shops in the city at the same time without our knowledge as we buy according to our requirements only," he said.

"We do not have to worry about disposal or sale of expired drugs as the manufacturer will reimburse the entire amount for the expired drugs," said N. Balaraja, Association secretary.

These representatives say it is mandatory for pharmaceutical companies to certify that the drugs are destroyed under the supervision of a competent authority.

Liquids are diluted in water and sent through effluent treatment plants (ETP) before disposal. Tablets are crushed and dissolved in ETP, industry sources say.

B. Sethuraman, president of the Pharmaceutical Manufacturers Association of Tamil Nadu, confirmed this. "Distributors must return the expired drugs to the manufacturer using a credit note.

There is a lot of paperwork involved. The shop owners are refunded the entire amount for the expired drugs. We destroy the expired drugs in our factory using proper safe disposal methods," he said.

Qualified pharmacist

The State Drug Control Authority requires every pharmacy to have a qualified pharmacist either as a partner or worker. Pharmacies/medical shops are expected to display their licence in the shop.

Shop-owners must also fulfil other conditions (such as storing drugs in the required temperature) for them to be able to renew their licence.

Source: *The Hindu 26th March, 2010*

Spurious drugs: stern action ordered

Chief Minister Mr. M. Karunanidhi reviewed the situation arising out of the seizure of expired drugs and instructed senior officials of the Health and Police departments to take severe action against those involved in the production of spurious drugs or distribution of expired drugs.

Mr. V.K. Subburaj, Principal Secretary (Health), said under the legal amendment effected about six months ago, the guilty could be levied the penalty of a maximum of Rs. 10 lakh and life imprisonment.

The Chief Minister wanted the State Drug Control Authority to be provided with more powers and to carry out frequent sensitisation campaigns on drugs.

Mr. Karunanidhi also wanted the Police and Health departments to conduct joint raids on establishments belonging to producers of spurious drugs and sellers of expired drugs.

Meanwhile, Principal Sessions Judge P. Devadoss dismissed the anticipatory bail petitions of five persons in the case relating to the recycling of expired drugs.

The case pertains to sale of expired drugs collected from a garbage dumping yard at Kodungaiyur to medical stores after printing fake expiry dates on them.

Anticipatory bail plea rejected

Meenakshi Sundaram, Director of a health care company, Meena Health Care, and four others had applied for anticipatory bail.

When the petitions came up before the Principal Sessions Judge, the prosecution strongly objected to their release.

Source: *The Hindu, March 23, 2010.*

TB: first new drug in 50 years

Researchers at Sydney's Centenary Institute announces they have made an exciting discovery that could lead to the first new drug for Tuberculosis (TB) in almost fifty years. The discovery comes on the World TB Day.

Dr Nick West, Associate Faculty of the Mycobacterial group at Centenary, is looking at the genetics of TB in the hope they will reveal a way to reduce the impact of one of the deadliest diseases in the world.

Dr. West, explains, "When someone is infected with TB they either become sick immediately or the disease stays inactive, latent."

"Unfortunately, the antibiotics we use to fight TB aren't effective against latent TB and can only be used when the disease becomes active. This is a major problem as 1 out of 10 people who have latent TB will develop the active disease, becoming sick and contagious."

Dr West and his team have made a vital discovery in the development of a new drug that could cure TB in the latent stage. If the project succeeds, it will be the first new treatment for TB since 1962.

TB kills almost 2 million people each year. One third of the world's population, or two billion people are infected with TB.

Dr West explains, "We have investigated a protein that is essential for TB to survive and we have had some success in developing a drug that will inhibit this protein. Our goal over the coming months is to find out the full extent of this drug's potential."

"If we can figure out a way to treat TB when it's in a latent stage, then we could save millions of lives throughout the world."

Source: *The Hindu 25th March 2010.*

Ranbaxy recalls two batches of its antibiotics from US market

Ranbaxy Laboratories is voluntarily recalling two consignments of one of its antibiotics from the US market, a move that may not impact its revenues but will affect its ongoing problems with the drug regulator, say analysts.

The drug maker is recalling the antibiotic Amoxillin & Clavulanate Potassium from the US market because its oral suspension turns brown during reconstitution, instead of white.

"The recall is being carried out at the retail level and conducted with the full knowledge of the US FDA," a company spokesman said. A total of about 35,000 bottles are in the US retail market and the drug expires in May this year. Ranbaxy's share price at the Bombay Stock Exchange (BSE) closed at Rs. 460.05, down 0.70%. Ranbaxy is majority owned by Japan's Daichii Sankyo.

There were complaints with some of drugs in two batches but Ranbaxy said its tests showed the drugs to be within specification. The company decided to recall all the lots in question for precautionary reasons, he said.

Hemant Bakhru an analyst with brokerage firm CLSA said such recalls will negatively impact Ranbaxy's ongoing process to settle its problem in the US. "Financially there should not be much impact," he said. The US FDA has already banned the company's 30 drugs made at its two Indian plants for violating US manufacturing norms.

Source: *The Economic Times, 15th April 2010.*

தமிழ்நாடு தேர்வாணையம் மூலம்

75 மருந்து ஆய்வாளர்கள் விரைவில் நியமனம்

அமைச்சர் பன்னீர்செல்வம் அறிவிப்பு

மருந்து கட்டுபாட்டுத் துறைக்கு புதிதாக 75 மருந்து ஆய்வாளர்கள், தேர்வாணையத்தின் மூலம் நியமிக்கப்படுவார்கள் என்று அமைச்சர் எம்.ஆர்.கே.பன்னீர்செல்வம் அறிவித்தார்.

மக்கள் நல்வாழ்வு மற்றும் குடும்ப நலத்துறை மானியக் கோரிக்கை மீது நேற்று பேரவையில் நடந்த விவாதத்துக்கு அமைச்சர் எம்.ஆர்.கே.பன்னீர்செல்வம் அளித்த பதில்:

மருந்து கட்டுபாட்டுத் துறை, சமீபத்தில் "ரிநெர்வ்" என்ற போலி மருந்தையும், பெனட்ரில் காஃப் பார்முலா கலப்பட இருமல் மருந்தையும் திடீர் ஆய்வு செய்தது. அப்போது, காலாவதியான மருந்துகள் மீண்டும் விற்பனைக்கு அனுப்பப்படுவது கண்டுபிடிக்கப்பட்டது.

இதுபோன்ற செயல்களில் ஈடுபட்டுள்ளவர்களை மருந்து கட்டுப்பாட்டு துறையும்,போலீசாரும் இணைந்து நடவடிக்கை எடுத்து கைது செய்து வருகின்றனர். போலி மற்றும் காலாவதியான மருந்துகளையும் கண்டுபிடித்து பறிமுதல் செய்யப்படுகிறது.

1985ம் ஆண்டு 16,000 மருந்து கடைகள், 400 மருந்து உற்பத்தி நிறுவனங்கள் இருந்தன. தற்போது 43,218 மருந்து கடைகளும் 851 மருந்து மற்றும் அழகு சாதனப் பொருட்கள் உற்பத்தி நிறுவனங்களும், 260 ரத்த வங்கிகளும் உள்ளன. எனவே, மருந்து கட்டுபாட்டுத் துறை மேலும் வலுப்படுத்தப்படும்.

இதற்காக 50 மருந்து ஆய்வாளர் பணியிடங்கள் உருவாக்கப்படும். தற்போது உள்ள காலியிடங்களையும் சேர்த்து 75 மருந்து ஆய்வாளர்கள், தமிழ்நாடு தேர்வாணையத்தின் மூலம் விரைவில் நியமனம் செய்யப்படுவார்கள்

இவ்வாறு அமைச்சர் எம்.ஆர்.கே.பன்னீர்செல்வம் தெரிவித்தார்.

ASSOCIATION NEWS

NEW ASSOCIATE- EDITOR FOR PHARMA WEB

Mr. Prafulla Chandra, who has taken over as Associate Editor of "Pharma Web" from April 2010 is a Pharmacist with an M. Pharm degree from B.I.T.S. Pilani. He has about 38 years of Industrial Experience and about two and a half years of Teaching Experience. He was a Past President Indian Pharmaceutical Association, Tamil Nadu Branch (1994-1996), Local Organizing Secretary for 48th Indian Pharmaceutical Congress held at Chennai in Dec 1996, Hon. Secretary of Tamil Nadu Pharmaceutical Sciences Welfare Trust from 1998 to 2001, Life Member Indian Pharmaceutical Association and Permanent Trustee of Tamil Nadu Pharmaceutical Sciences Welfare Trust. Recently he has returned back to Chennai after an absence of 9 years and has taken up Pharma Consultancy.

The Indian Pharmaceutical Association, Mumbai (Central)

Office Bearers for the term April 2010-March 2012

President- Dr. C.Gopalakrishna Murthy
Past President – Dr. B.Suresh
Hon. Gen. Secretary – Mr. S.D.Joag
Hon. Treasurer – Mr. Mohan Kekatpure
Editor – Pharma Times – Dr. Alka Mukne
Editor – I.J.P.S. – Dr. Rao V.S.V. Vadlamudi
Chairman Industrial Pharmacy – Mr. Kaushik Desai
Chairman Regulatory Affairs – Mr. Ram Banarse
Chairman Community Pharmacy – Mr. Raj Vaidya
Chairman Hospital Pharmacy – Dr. R.N.Gupta
Chairman Education – Prof. T.V.Narayana
Executive Secretary – Mr. T.B.Nair

EVENTS

KMCH College of Pharmacy, Coimbatore

The fourth alumni meet of KMCH College of Pharmacy was held on 26 Jan 2010 in the KMCH premises. More than 100 alumni from India and abroad participated in this meeting. In the welcome address, Prof. Dr. A.Rajasekaran updated the current activities of the college.

Dr. Nalla G. Palaniswami, Chairman and Managing Director and Dr. Thavamani D Palaniswami, Secretary, Kovai Medical Center Research and Educational Trust, Coimbatore praised the Alumini for their important role in their career and also advised them to support the students from this college for their industrial training.

The meeting adjourned after vote of thanks proposed by Dr.K.S.G. Arulkumaran, Staff Co-ordinator of KMCH College of Pharmacy Alumni Association.

Faculty of Pharmacy, Sri Ramachandra University, Chennai

1. The Department of Pharmacognosy and Department of Pharmacology organised "Herbotech 2010" a National Conference on Recent Advances in Herbal Drug Processing, Development and Research, on 21/1/10, at Sri Ramachandra University.

2. The Department of Pharmaceutics organised a Seminar entitled “Pharmacy Education and Research in United States" on 17/2/2010 at Sri Ramachandra University. The Speaker was Dr .Daniel Robinson, Dean, School of Pharmacy, Western University of Health Sciences, California, USA.

3. The Indian Pharmaceutical Association Convention 2010 was held on March 12th, 13th and 14th at Sri Ramachandra University.

4. Mr. S. Gopinath, Assistant Professor, Department of Pharmaceutics received best paper award for paper entitled" A factorial study on the evaluation of formulation variables on the dissolution rate of Etoricoxib tablets" in the poster session, presented at the IPA convention-2010", held on 14th March 2010 at Sri Ramachandra University, Chennai. The paper was authored by Mr. S. Gopinath, Dr. K.P.R. Chowdary, Dr. C. Uma Maheswara Reddy and Dr. J.S.N. Murthy.

5. The Annual General Body Meeting of Alumni Association of Sri Ramachandra College of Pharmacy was held on 26/3/2010 between 10.30 a.m. to 12.00 noon at Faculty of Pharmacy and 60 alumni members participated.

Vel's College of Pharmacy, Chennai

School of Pharmaceutical Sciences, Vels University, Chennai-117, conducted seminar on WTO and Patent Processing and its Applications by Prof Dr. K. Anbudurai, Patent Attorney – Chennai, emphasizing on the need and awareness of patent filling for innovative research work in Pharma field and impact of new patent law on global market.

2) A gathering of Vels alumni (1992-2009) batch was organized on 27th Feb. 2010. More than 100 alumni gathered for the meet. It was a wonderful occasion to meet and share the experience with the alumni. The meeting was inaugurated with the lighting of lamp. Prof. Dr. V. Ravichandiran, Director of School of Pharmaceutical Sciences, welcomed the alumni and explained the purpose of alumni association. Mr.Charles Jesudasan, the senior most alumni, chaired the session. An opportunity was given to every alumnus to share their experiences on Vel's and their career.

SRM College of Pharmacy, Chennai

A national seminar on 'Emerging Trends on Molecular Modeling & Drug Design' was organized by the Department of Pharmaceutical Chemistry and Department of Pharmacology at Dr. T.P. Ganesan Mini Hall –II on 23rd January 2010.

Dr. Mukesh Doble, Professor, Department of Biotechnology, IIT-Madras delivered the most conceptual ideas on “Target Based Drug Design”. The incredible subject to account and acquire the knowledge in “Structure based Pharmacophore Design in Computer Aided Drug Discovery” was comprehended and mentored by Mr. Raghu, Director, Schrondinger, Hyderabad.

Mr.Ramanathan, Professor & Head, Department of Pharmacology, PSG College of Pharmacy, Coimbatore, offered a session on “Approaches in Drug Design” and the points to ponder on the “Applications of Molecular Modeling” was briefly enlisted by Dr. V. Subramanian, Scientist, CLRI, Chennai.

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