ISSUE No. 61

SILVER JUBILEE YEAR 2016

TAMILNADU PHARMACEUTICALS SCIENCES WELFARE TRUST

25 Years

Pharma Web

Newsletter of Tamilnadu Pharmaceutical Sciences Welfare Trust

Jan. - Feb. - Mar. 2024

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Destiny for Innovation

MOVING GLOBALLY

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R & D and Manufacturing of Formulations

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Tamilnadu Pharmaceutical Sciences Welfare Trust

Pharma Web

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TAMILNADU PHARMACEUTICAL SCIENCES WELFARE TRUST
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EDITORIAL

Dear Readers,

We are delighted to present to you the 61st edition of the Pharma Web Newsletter covering **Jan – Mar 2024.**

In this issue, you'll find program highlights along with insightful articles contributed by esteemed figures in the pharmaceutical industry.

One such article is on **"Analytical Method Validation" by Mr. Arularasu Thirunavukkarasu,** Quality Head at Crescent Pharmaceuticals Group, Chennai. We believe his expertise will greatly benefit our readers.

Additionally, we've included various Gazette Notifications concerning the amendment of the Drugs & Cosmetics Act & Rules, as well as important circulars issued by the DCGI pertaining to Drugs & Pharmaceuticals. We've also curated significant news items from national newspapers that are relevant to our profession, providing you with a comprehensive overview of recent developments in the pharmacy sector.

We extend our heartfelt gratitude to M/s. Delvin Formulations, M/s. Medopharm, and M/s. Tablets (India) Ltd., for their steadfast support through advertisements, which helps us sustain the costs associated with publishing this newsletter.

A special mention goes to M/s. Fourrts (India) Laboratories Pvt. Ltd., for their support in Pharma Web advertisement and for their recognition through the meritorious award granted to B. Pharm Students of The Tamilnadu Dr. MGR Medical University, Guindy, Chennai. Their contribution to fostering talent in our field is commendable.

We hope that this Newsletter proves valuable to our Pharma professionals. Your feedback and suggestions for improvement are always welcomed and appreciated.

With Best Regards,

R. NARAYANASWAMY
Chief Editor

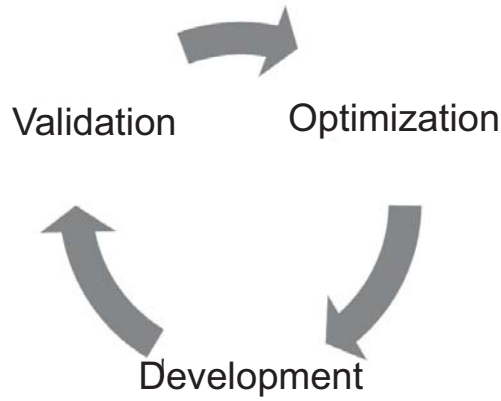
ARTICLES

Analytical Method Validation

by
Mr. Arularasu Thirunavukkarasu,
Quality Head at Crescent Pharmaceuticals Group, Chennai

Lecture Delivered during 10th PKTI Training in Chennai on 7th March 2024

Method Life Cycle



Definitions

The objective of validation of an analytical procedure is to demonstrate that it is Suitable for its intended purpose.
(ICH Q2 (R1) Guideline)

Method validation is the process of demonstrating of confirming that a method is Suitable for its intended purpose. Method validation is a distinct phase from method

Development/Optimization and should be performed subsequent to method developments.
(FDA Guidance for Method Validation)

Definitions

Methods validation means establishing, through documented evidence, a high degree of assurance

That an analytical method will consistently yield results that accurately reflect the quality characteristics of the products tested.
(21 CFR part 210.3 (b) (250))

Validation of an analytical procedure is the process by which it is established, by laboratory studies, that the performance characteristics of the procedure meet the requirement for the intended Analytical application.
(United states pharmacopoeia <1225>)

Why Validation?

- For identification of source of potential errors.
- Determination if Method is Acceptable for Intended Use.
- Establish that test data obtained was consistent, reliable & accurate.
- Validation of analytical methods is also required by most regulations.
- Establish proof that method can be used for decision making,

Analytical Method Validation

Pharmaceutical Industries governed by rules & regulations. Method validation is Mandatory as per regulatory agencies

Analytical methods should be used within GMP and GLP environments

Method Development	Method Validation	Method Transfer

Method Development

Why do we have Method Development?

To have selective, sensitive, reproducible and robust HPLC methods, Method Development is essential & critical at all stages of Drug Development

Methods that are Developed and written into IND and NDA filings will be typically used for >20 years

Exceedingly difficult to change a method or column after an IND filing and virtually impossible after an NDA filing

Hence validated, stability indicating, reproducible and rugged analytical method development is essential in the pharmaceutical industry

Criteria for Better Method Development

- The goal of a new chromatographic method is to obtain adequate separation in reasonable time.
- Good peak shape
- High efficiency
- Reproducibility : Column to column & Batch to Batch
- Excellent lifetime
- Fast separations
- High sensitivity
- Selective/Specific

Separation Mode

Normal phase chromatography

Reversed phase chromatograph

Ion chromatography

Size exclusion chromatography

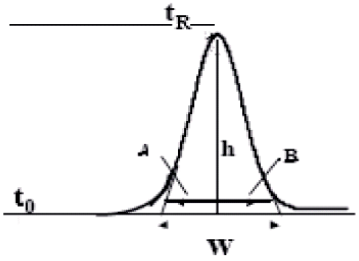
Preparative HPLC Etc..

Separation Basics

- Retention (k)
- Selectivity (α)
- Efficiency (N)
- Resolution (Rs)
- Peak shape (As

Retention Factor or capacity factor

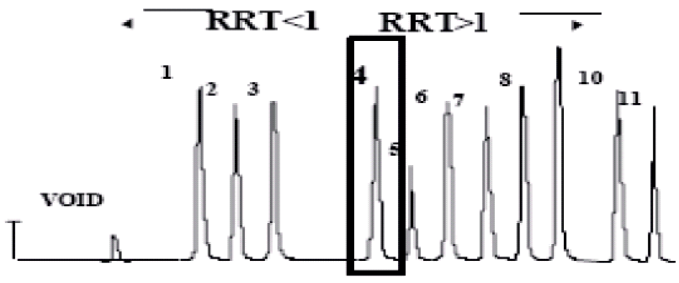
$$k' = \frac{t_R - t_0}{t_0}$$



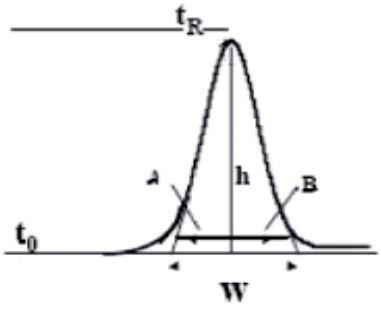
- The capacity factor is a measure of how long each component is retained on the column.
- k is used in preference to retention time.
- Generally the value ok K' is > 2.
- In practice the k value for the first peak of interest should be >1 to assure that it is separated from solvent.
- Hear Tr is retention time of peak of interest & To is unretained peaks retention time.

Relative Retention / Separation

- This describes the relative position of two adjacent peaks. Ideally it is calculated using the capacity factor.
- Because the peak separation depends on the components interaction with the stationary phase.

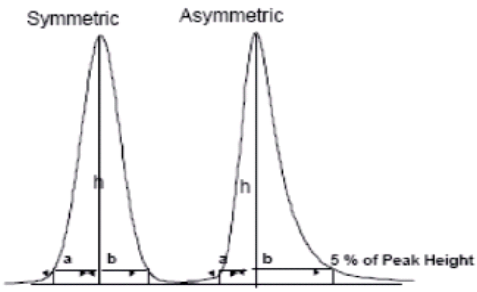


Number of theoretical plate

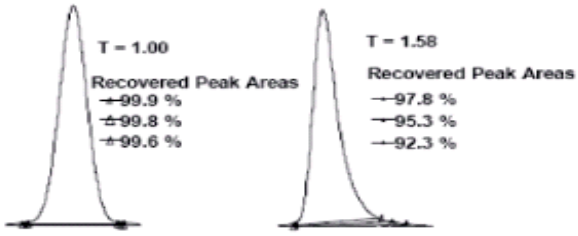


- This is a measure of sharpness of the peaks and therefore the efficiency of the column that is, how many peaks can be located per unit run time of the chromatogram.
- This can be calculated in various ways.
- ex: USP uses the peak width at base and BP at half the height.
- The theoretical plate number depends on elution time but in general should be > 2000

Tailing factor T



- This is a measure for asymmetry of peak.
- Peak asymmetry is measured at 5% of full peak height.



Peak Resolution R

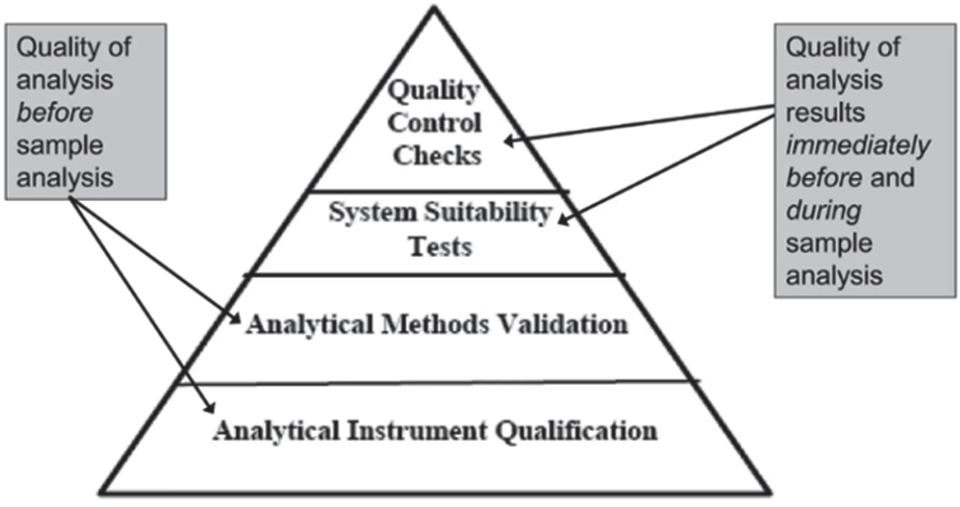
- This is not only a measure of separation between two peaks, but also the efficiency of the column.
- It is expressed as ratio of the distance between the two peak maxima to mean value of peak width.

What is to be Known Before Starting

- Number of compounds present
- Chemical structure (functionality) of compounds
- pKa values of compounds
- UV spectra of compounds
- Concentration range of compounds in sample of interest
- Sample solubility
- More…

Criteria for Adequate Separation

- Capacity factor 0.5<K‘<20. If K' is too small, the 1st peak will distorted by the solvent front.
- If K' is too large, the run takes too long and the peak usually suffers from broadening.
- For quantitation, min. Rs = 1.5. For better ruggedness Rs= 2 is better.
- All peaks should be symmetric, with an asymmetry factor in the range of 0.9-1.5.



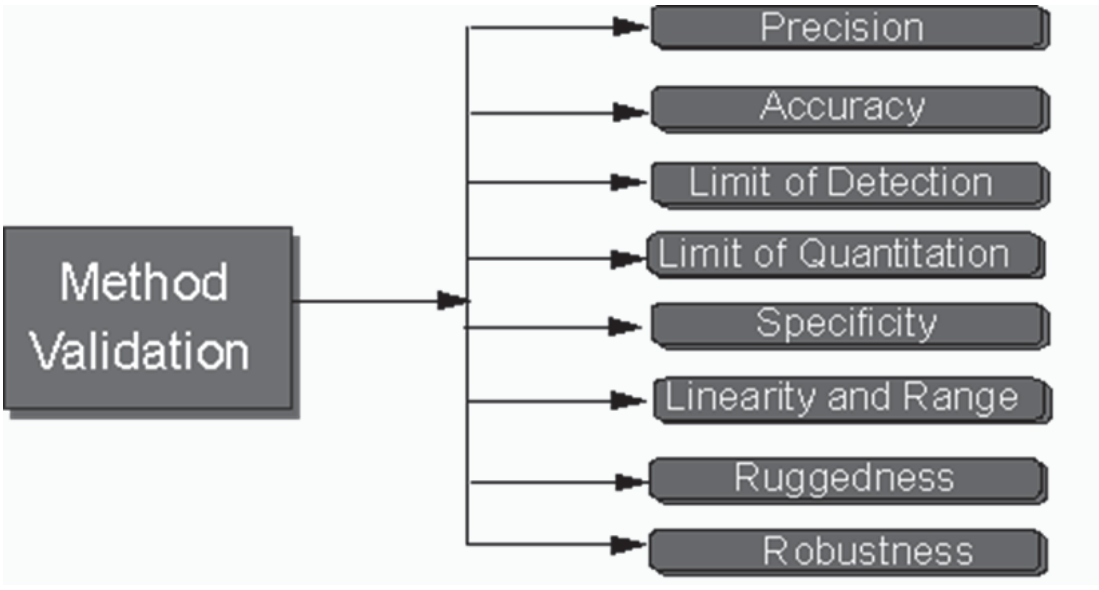
Validation of analytical procedures requires

- Qualified and calibrated instruments
- Documented methods
- Reliable reference standards
- Qualified analysts
- Sample integrity

Validation of analytical procedures requires

- Analytical method should be specific and stability indicating
- It is recommended to report the amount of related substances in % w/w using Response Factors.
- Validation include functions such as data integrity, security and traceability

Method Validation Parameters



Analytical Method Validation

Analytical performance characteristics	Category I	Category II		Category III	Category IV	Category V
		Quantitative	Limit tests			
Accuracy	✓	✓	*	*	×	✓
Precision	✓	✓	×	✓	×	✓
Specificity	✓	✓	✓	✓	✓	✓
Limit of detection	×	×	✓	*	×	*
Limit of quantitation	×	✓	×	*	×	✓
Linearity	✓	✓	×	*	×	✓
Ruggedness	✓	✓	✓	*	✓	×
Robustness	✓	✓	*	*	×	×
Stability of solution	✓	✓	*	*	×	×
System suitability	Required in the case of chromatographic methods.					
✓: To be performed	×: Not required			*: May be required, depending on the nature of the specific test.		

Analytical Method Validation

- Category I: Analytical methods for quantitation of major components of active ingredients in finished pharmaceutical products.
- Category II: Analytical methods for determination of impurities in finished products. These methods include quantitative assays and limit tests.
- Category III: Analytical methods for determination of performance characteristics
- (e.g., dissolution, drug release)
- Category IV: Identification tests.
- Category V: Analytical methods for determination of active ingredients in cleaning validation sample.

Analytical Method Validation

- **Analytical method validation requirements**
- Protocol
- Reference / impurity Standard and Sample
- Procedure
- Chemical / Reagent
- HPLC / GC Column

Analytical Method Validation

Specificity:

Ability to access the analyte in the presence of other components which may be present.

There should not be any interference from the related substance/ impurities with the analyte peak.

Specificity

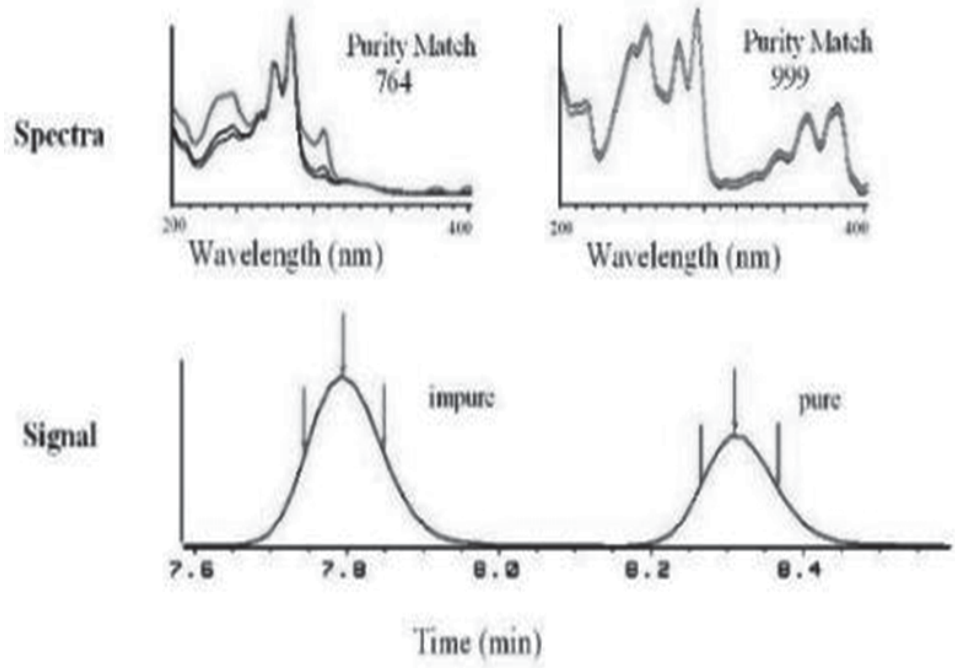
I – UV methods:

a. Identification of the active ingredient peak by UV spectra.

b. Checking interference due to placebo.

II - High performance liquid chromatographic methods:

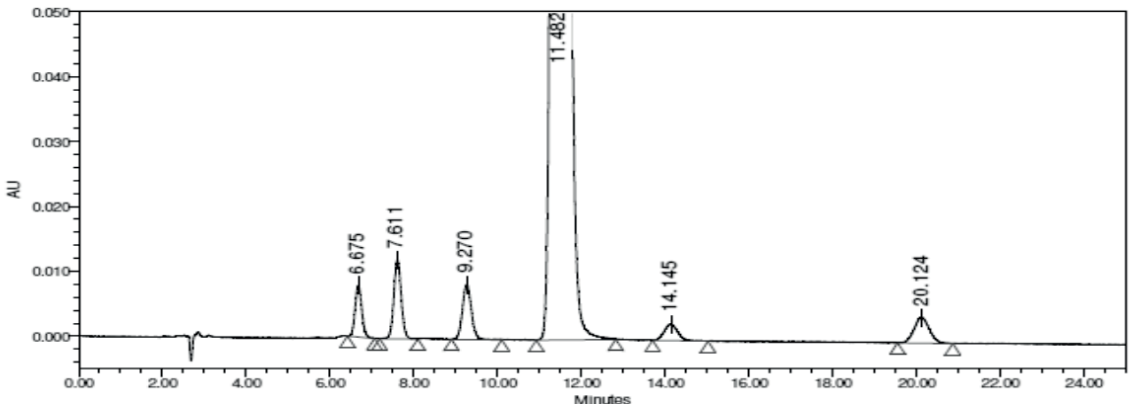
1. Identification of the active ingredient peak and impurity / degrading peaks by retention time.
2. Identification of the peaks due to placebo and diluent.
3. Demonstrate peak purity for the active ingredient peak using diode array detector. Check the peak purity of the active ingredient. Prepare test sample as per the test method. Scan and ensure that the peaks due to active ingredient are spectrally homogenous, if necessary used suitably spiked samples.

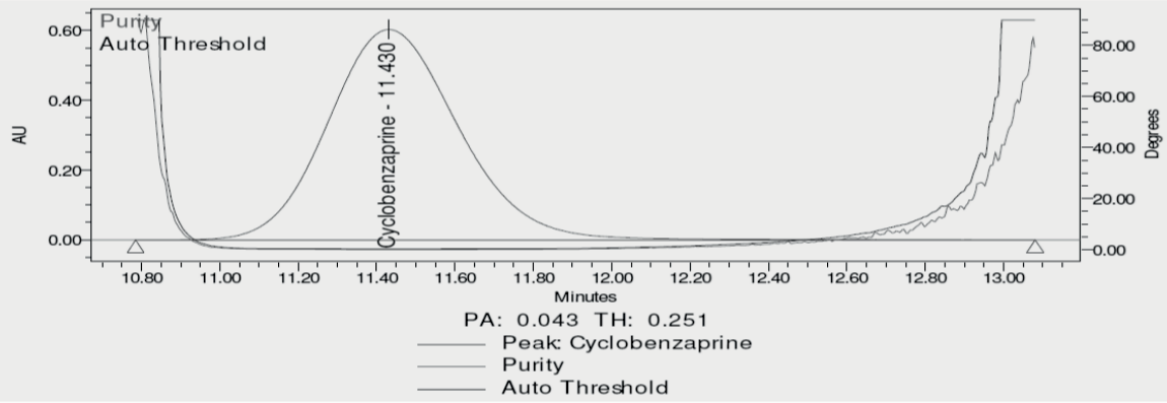


Specificity

4. Stability indicating method/ Forced degradation/ study Stress study:

- The aim of the forced degradation study is to assure that the proposed method is capable to detect and well separate all the known and unknown impurities from the main peak & from each other.
- To establish stability indicating nature of the method, Perform stress study on API and formulation under relevant stress conditions.
    - Hydrolysis (acid and alkali)
    - Oxidation (with peroxide)
    - Humidity stress
    - Thermal stress
    - Photo stress (Overall illumination of not less than 1.2 million LUX hours and an integrated near ultraviolet energy of not less than 200 watt hours/square meter or direct exposure to sunlight for suitable period)
- Carry out the test by trial and error method with an objective to obtain 10%-30% degradation at least in one stress condition. In addition, to ensure that the peaks are single components, use PDA to obtain peak purity information for the analyte peaks





Precision

Repeatability:

- **"The precision of an analytical procedure as the closeness of agreement between a series of measurements obtained from multiple sampling of the same homogeneous sample under the prescribed conditions"**
- Sample prepared in six replicates on the same day and analysed as per the method. The precision is reported in terms of %RSD

Precision

- For test of assay / dissolution, use samples as such.
- Prepare six test samples of the same batch for assay and perform dissolution on six units for precision test. Calculate the results as per the test method.
- For test of related substances / impurities, use samples as such or spiked with impurities (If found below LOQ). Analyze all the six, {test preparation and calculate the results as per the test method.
- Calculate the Mean, Standard deviation and Relative standard deviation of the test results in each case.

Precision

Chromatographic methods STD:

- Relative standard deviation for area of replicate injections. Theoretical plates, tailing factor, resolution to be achieved as per System suitability in the test method

UV methods STD:

- Relative standard deviation for absorbance of replicate observations should not be more than 2.0%.

Assay sample:

- The relative standard deviation for six results should not be more than 2.0%.
- For Preservatives/Antioxidants:
- The relative standard deviation for six results should not be more than 5.0%.

Precision

- **Dissolution:**
- The relative standard deviation for six results should not be more than 10.0 %.

Related substances:

Impurity level (%w/w)	%RSD
>0.10% to 0.50%	NMT 15.0%
>0.50% to 1.00%	NMT 10.0%
More than 1.00%	NMT 5.0%

Precision

- **Intermediate Precision**

  Repeat the precision test using same sample but under different conditions i.e. different day, different analyst, different instrument, different column (Same dimension and particle size with different make/different serial no.) Whichever is feasible.

Analytical Method Validation / Verification

Intermediate precision (Reproducibility)

Assay;

- The relative standard deviation for SIX results should not be more than 2.0%.
- The difference in average results obtained between two analysis should be not more than 2.0%.

Dissolution:

- The relative standard deviation for six results should not be more than 10.0 %.
- The difference in average results obtained between two analyses should not be more than 10% at rune points with less than 85% dissolved and should not be more than 5% for time points above 85%.

Analytical Method Validation / Verification

Related substances

Impurity level (%w/w)	Difference from precision	RSD
>0.10% to 0.50%	NMT 0.05	NMT 15.0% NMT
>0.50% to 1.00%	NMT 0.10	10.0%
More than 1.00%	NMT 15%	NMT 5.0%

Linearity Range

- "Linearity of an analytical procedure is its ability to obtain test results (within the given range) that are directly proportional to the concentration (amount) of the analyte in the sample"

- "Interval between the upper and the lower concentration of analyte for which the method is demonstrated to have suitable level of precision, accuracy & linearity"

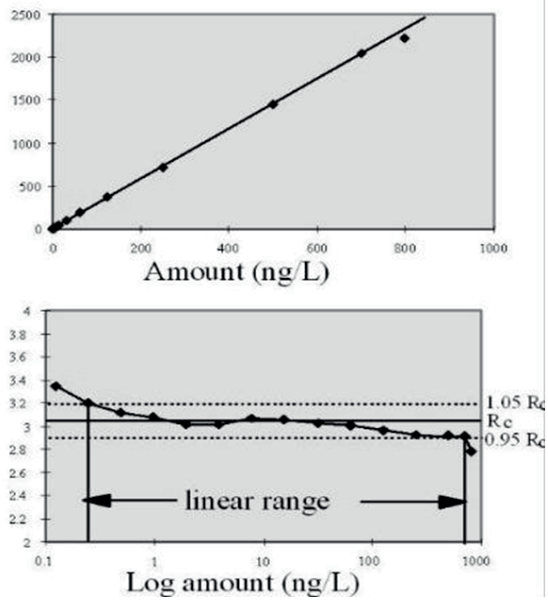
Linearity Range

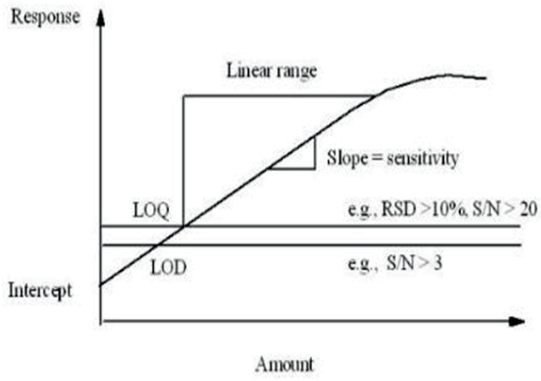
- Minimum 5 different concentrations (by volume/weight) of standard in the range specified as follows:

- Assay of Drug substance / Formulation
- Determination of an impurity
- For dissolution testing

- 80% -120% of the test concentration
- LOQ to 120% of the specification
- +/ - 20% over specified range@

Linearity Range





Linearity Range

- @ For dissolution profile extended linearity can be performed and lower range can be selected based on dissolution profile data. Range would be 0% to 120% of the test concentration for the dissolution profiling, delayed and sustain release products.

- Plot a linearity curve of concentration verses absorbance/area. Calculate the correlation coefficient, Slope of regression, Y-intercept, Square of correlation coefficient, Response factor and Y-intercept bias.

Accuracy

"Accuracy of an analytical procedure is the closeness of agreement between the conventional true value or an accepted reference value and the experimental value"

"Measure of how close the experimental value is to the true value"

Accuracy

Assay:

Prepare recovery samples in triplicate at 80%. 100% and 120% range of the nominal working concentration of the test sample.

Dissolution:

Prepare recovery samples in triplicate at 50%, 100% and 120% range of the nominal working concentration of the test sample.

Note: In case of multiple strengths, consider accuracy concentration as follows:

-50% for Lowest range of the lowest strength,
100% of the middle strength and
120% for upper range of the highest strength.

Accuracy

Related substances:

- Prepare recovery samples at LOQ level of active ingredients. 50%. 100% and 120% range of nominal concentration.

Limit:

Assay:

- The recovery of active ingredient should be between 98.0% and 102.0%.
- Relative standard deviation for recovery at each level should not be more than 2.0%

Accuracy

For Dissolution test:

- For Immediate release tablets:
- The recovery of active ingredient should be between 95.0% and 105.0%.
- Relative standard deviation for recovery at each level should not be more than 5.0%.

For Modified release:

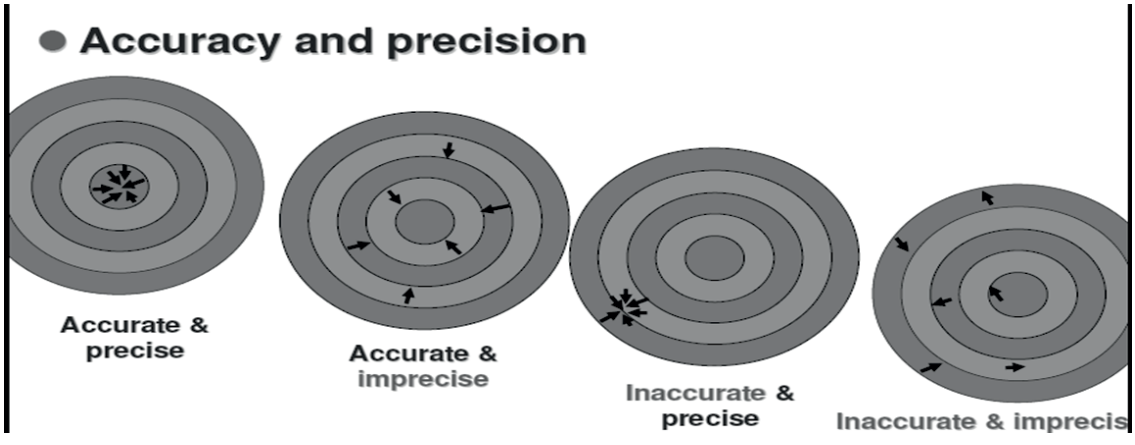
Recovery level ("w/w)	Recovery (%)	RSD (%)
LOQ to less than 50.0%	75.0%to 115.0%	NMT15.0%
50.0 % to 120.0%	85.0% to 110.0%	NMT 5.0%

Accuracy

Table–4: Recovery calculation Table for Cyclobenzaprine Hydrochloride

Recovery Level	Sample wt.(mg)	Area	Amount Observed (mg)	Amount added (mg)	% Recovery
80%	613.08	10968885	32.41	32.44	**99.9**
	612.89	11005472	32.52	32.60	**99.8**
	612.89	10994757	32.49	32.07	**101.3**
100%	611.93	13657766	40.36	40.37	**100.0**
	613.31	13702698	40.49	40.70	**99.5**
	612.62	13678732	40.42	40.56	**99.7**
120%	612.95	16216104	47.92	47.98	**99.9**
	611.44	16325163	48.24	48.00	**100.5**
	612.70	16250962	48.02	48.17	**99.7**

Accuracy and Precision



Detection / Quantitation Limit:

LOD : Lowest amount of analyte that can be detected but not necessary to be quantified.

LOQ : Lowest amount of analyte that can be quantified with suitable level of Precision & Accuracy.

LOD and LOQ

1. Signal to noise ratio

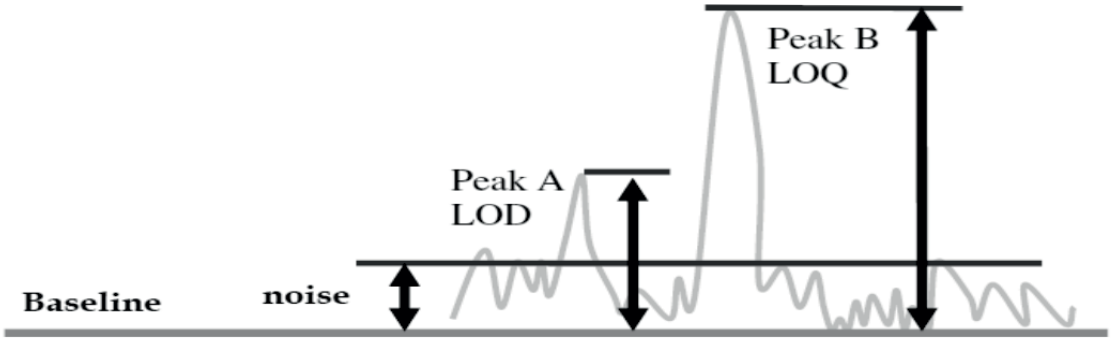
2. Visual evaluation

3. Standard deviation of the Response and Slop

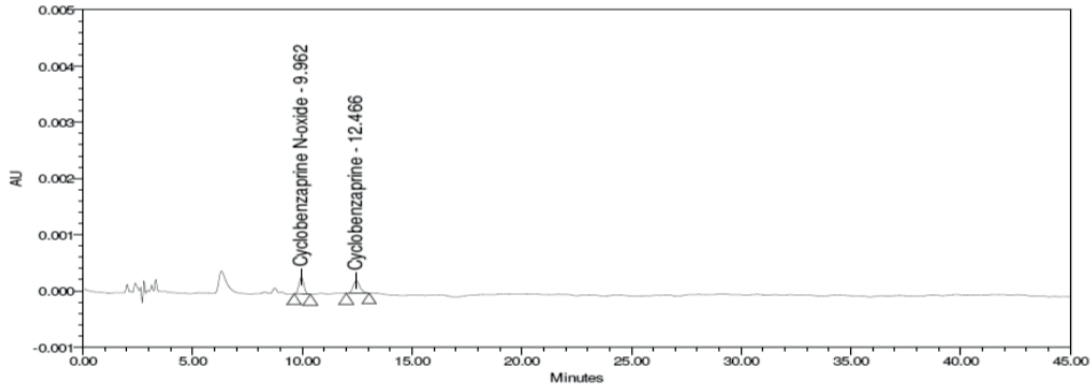
4.Signal to noise ratio $$S/N = \frac{2H}{h}$$

Detection / Quantitation Limit

- Limit of Quantitation (LOQ)
- Limit of Detection (LOD)
- Signal to Noise Ratio (SNR)



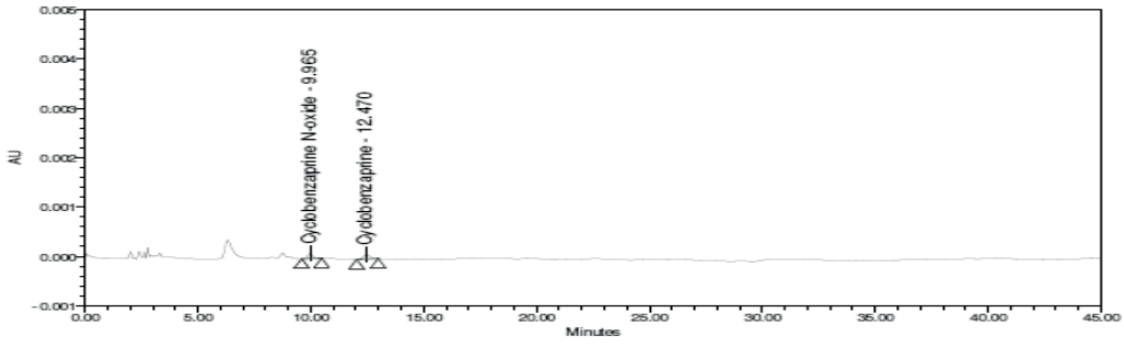
Detection / Quantitation Limit



Peak Results

	Name	Retention Time (min)	Area (µV*sec)	s/n
1	Cyclobenzaprine N-oxide	9.96	4651	16.8
2	Cyclobenzaprine	12.47	4739	12.4

Detection / Quantitation Limit



Peak Results

	Name	Retention Time (min)	Area (µV*sec)	s/n
1	Cyclobenzaprine N-oxide	9.96	1641	4.3
2	Cyclobenzaprine	12.47	1969	3.7

Robustness

"Ability of the method to remain unaffected by small but deliberate variations in the method parameters"

Recommended variations in the method parameters:

- Change in flow rate by ± 10 %
- Change in wavelength of detection by ± 5nm
- Change in pH of buffer / mobile phase by ± 0.2 units.
- Change in organic content in mobile phase by ± 2% absolute.
- Change in column oven temperature by ± 5°C

System Suitability

- System suitability testing is an integral part of many analytical procedures.
- To verify proper functioning of the operating system

Parameters	Recommendation
Resolution	$R \geq 1.5$, between the peak of interest and the closest potential interferent (degradant, Impurity, excipient, etc.)
Tailing	$T \leq 2$
Theoretical plates (N)	In general $N > 2000$
Repeatability % CV	$\leq 2.0\%$ ($n \geq 5$)

"No sample analysis is acceptable unless the suitability of the system has been demonstrated." (USP Chapter 621)

Analytical method verification

- Official monograph methods are not required to validate accuracy and reliability, but merely required to verify their suitability under actual conditions of use.
- Performance characteristics for the pharmacopoeial methods verifications.

3.3 Specific tests/criteria - New Drug Substances

Analytical performance characteristics	Assay	Related substances / Residual solvents	Limit test	Dissolution	Identification	Estimation of Specific content	Cleaning validation
Accuracy	✓#	✓	✓	✓	×	✓	✓
Precision	✓	✓	×	✓	✓	✓	✓
Specificity	✓	✓	✓	✓	*	✓	✓
Limit of detection	×	×	✓	×	×	×	✓
Limit of quantitation	×	✓	×	×	×	×	✓
Linearity	✓$	×	×	✓	×	✓	✓
Filter recovery	×	×	×	✓	×	×	×
System suitability	Required in the case of chromatographic methods.						
✓: To be performed	×: Not required	#: Not applicable for drug substance		$: Not applicable for titration method			

Reference

- USP <1225> - Validation of compendial procedures
- USP <1226> - Verification of compendial procedures
- ICH - Q2(R1) VALIDATION OF ANALYTICAL PROCEDURES: TEXTAND METHODOLOGY Q2(R1)

Join Pharmacists to Ensure Patient Safety

by

Mr. Sathiya Raj. R
College of Pharmacy, SRIPMS, Coimbatore

Note: This article was awarded 2nd prize in the Essay Competition conducted by our Trust

Introduction:

The main objective of a healthcare system is to ensure patient safety apart from efficacy. We, the Pharmacist have a significant role in patient safety and we are trying our best to keep upon. What are the reasons to join with pharmacists? Why should people support them? – let us discuss below.

Bridge of Healthcare System:

The main participant of the healthcare system is the Patient and the Physician, who treats them. In India, we can see an unexplainable communication gap between them, physicians may be busy to get feedback and the patient may also be nervous to ask doubts related to their medications. Pharmacists are the only person who act as a bridge between them, they check the medication errors before dispensing, they provide clarification about the medications to the patient and they also conduct regular checkup whether the patient is safe and effective with those medications.

Voice of Rights:

Pharmacist are the healthcare professionals who communicate effectively to evaluate many factors that affect a patient's ability to take a medicine. Most of the people in India are not aware even about the basic medication remedies, pharmacists are responsible to educate patients about their medication. Some of the healthcare providers misuse their role for profit and they get diverted from their ethical role. This should not be promoted as it is completely involving about an individual's health.

Adverse Drug Monitoring:

In the process of drug discovery, the most important and critical phase is the POST MARKETING SURVEILLANCE- which means the continuous monitoring of the drug products and devices after their approved usage in the market.

Clinical trials are not conducted to every individual who are going to consume those medications, so the continuous monitoring of drug is necessary to prevent the upcoming adverse reaction/ events. The knowledge about the importance of ADR (Adverse Drug Reaction) should be well educated to all the healthcare providers and those responsibilities fall on behalf of the Pharmacists. People should be aware to report ADR as soon as possible. The successful medicine without ADR lies on the pharmacist they are the only people who are well worth in the formulations.

People's Trust:

Indians are familiar with pharmacists than doctors, eventually we go to a community pharmacist before consulting a doctor, the main cause of this practice is they are duly situated in our society and become an inseparable member of our society, it is easy to discuss with a person who is familiar and who'll explain in a simple way than the person who uses complex terms which cannot be understood by common people.

People in India have an unbreakable trust on pharmacists, they have faith more than the doctors, they can understand the medical terms which is highly professional and can translate into a simpler way which can be understood by rural people.

For example, Headache and Cephalalgia both represent the pain in the head. A common man can't understand the complex term and the physicians only prescribe in the medical terms, so the communication gap between physicians and patients are filled by the Pharmacists.

Health and Wellness services:

Pharmacist's review about the total patient medication regimen and access whether they have an acceptable risk benefit ratio. They even check whether the administered medications produce the effect for which it is intended.

"Wellness in Pharmacy: An individual approach to the centre of physical health and mental well-being, with an intentional focus on prevention, treatment, and applied learning from one's history to present, to optimize the future state of care and quality of life through actions taken."

Patient Safety-Key Issues:

The occurrence of adverse events due to unsafe care is one of the 10 leading causes of Death and Disability in the world. In high-income countries, it is estimated that one in every 10 patients is harmed while receiving hospital care.

The harm can be caused by a range of adverse events, with nearly 50% of them being preventable.

Each year, 134 million adverse events occur in hospitals in low and middle-income countries (LMICs), due to Unsafe care, resulting in 2.6 million deaths.

In the Organisation for Economic Co-operation and Development (OECD)countries, 15% of total hospital activity and expenditure is a direct result of adverse events.

Why should you join us:

Pharmacists play a key role in helping patients feel better and get well as quickly as possible. Patients do best when pharmacists are part of their healthcare teams because pharmacists are the medication specialists. Pharmacists improve medication adherence.

Pharmacists are accessible in all healthcare settings: inpatient, ambulatory and community settings. Pharmacists are available to see patients at convenient times every day of the week, during morning, evening and weekend hours, and without an appointment.

Pharmacists work with other health care professionals to maximize health outcomes. Numerous studies have proven that the presence of a pharmacist on hospital rounds as a full member of the patient care team has been shown to prevent medication errors and reduce costs. Pharmacists provide optimal management of medication for chronic diseases such as diabetes, asthma, hypertension, etc.

Conclusion:

Pharmacy is one of the most rapidly progressing sciences that can have a significant impact on people's lives. The increased emphasis on pharmacists' values will also have a substantial effect on the development of the pharmaceutical business. This is because pharmacists are responsible for what medications to recommend in what dosages and combinations with each other. With the advent of many new drugs, the pharmacist profession is becoming more and more popular and in demand.

INFORMATION

M. Pharm & Pharm. D Scholarships 2023-24 Awardes by TNPSW Trust

Profile of 2nd Rank

PHARMACEUTICS

Name: Mr. R. Vigneswaran

Project Title: Formulation, Optimization and Evaluation of Allopurinol loaded Nanosponge for the Treatment of Gout.

College: Adhiparasakthi College of Pharmacy, Melmaruvathur

Guide's Name: Mrs. A. Selvi.

PHARMACEUTICAL CHEMISTRY

Name: Mr. Krutheesh NS

Project Title: Design, Synthesis of 9-Aminoacridine derivatives and Evaluation of Anti-Breast Cancer Activity.

College: JSS College of Pharmacy, Ooty.

Guide's Name: Dr. R. Kalirajan

PHARMACEUTICAL ANALYSIS

Name: Mr. Hem Sharath. V

Project Title: Determination and Estimation of Antibiotic Residue in Poultry Products by LC/MS-MS

College: C. L. Baid Metha College of Pharmacy, Chennai

Guide's Name: Dr. C. N. Nalini

PHARMACOLOGY

Name: Ms. Kodali Sirisha

Project Title: A Novel Herbal Spray Enhanced with Silver Nanoparticles for the Treatment of Psoriasis

College: Swamy Vivekanandha College of Pharmacy, Namakkal

Guide's Name: Dr. P. Manimekalai

PHARMACOGNOSY

Name: Ms. Keerthana. T

Project Title: Exploring the therapeutic potential of Dioscorea alata: Phytochemical profiling by HR-LCMS, molecular docking and evaluation for lung cancer activity with synthesized herbal silver nanoparticles.

College: College of Pharmacy, Madurai Medical College, Madurai

Guide's Name: Dr. T. Venkata Rathina Kumar

PHARMACY PRACTICE

Name: Ms. Chella Kusuma Chowdri

Project Title: Effect of Embryo FixTM supplementation for improving fertility in women: a randomized, open-label trial.

College: SRM College of Pharmacy, Chennai

Guide's Name: Dr. T. M. Vijayakumar

PHARM D

Name: Mr. Jothiswaran. R, Ms. Keerthana. S, Mr. Muthu Prasath. M K

Project Title: A Retrospective and Prospective study on Drug Utilisation Evaluation of Tenecteplase in a Private Tertiary Care Teaching Hospital at Coimbatore

College: College of Pharmacy, Sri Ramakrishna Institute of Paramedical Sciences, Coimbatore

Guide's Name: Dr. Rajalingam. B

EVENTS

Pharma Knowledge and Training Institute (Finishing School)

10th Training

on

Industrial Orientation Training for Production and Quality Management Personnel

The 10th Training program for the fresh Pharmacy graduates by Pharma Knowledge and Training Institute (Finishing School) under the aegis of Tamilnadu Pharmaceutical Sciences Welfare Trust was held at Trust premises in Spencer Plaza, Anna Salai, Chennai from **4th March to 21st March 2024**. The total 37 trainees from GRT Institute of Pharmaceutical Education & Research, Tiruttani, College of Pharmacy, Madurai Medical College, Madurai, Sri Venketeshwaraa College of Pharmacy, Puducherry, The Erode College of Pharmacy, Erode, School of Pharmacy, Sathyabama Institute of Science and Technology, Chennai, School of Pharmacy, VISTAS, Chennai, G.P. Pharmacy College, Jolarpet, Periyar College of Pharmaceutical Sciences, Tiruchirappalli, Sri Vijay Vidyalaya College of Pharmacy, Dharmapuri, & C.L. Baid Metha College of Pharmacy, Chennai, students were trained in this training program.

The students were given training both theoretically and practical on the subject of **"Industrial Orientation Training on Production and Quality Management Personnel".** The following subjects were taught as theory and practical during this training programme.

Theoretical Training Programme

- Overview of the Pharmaceutical Industry and job opportunities for the Pharmacy graduates.

- Rules and Regulations of Import and Export, New Drug Approvals.

- Regulatory Requirements of Production and QC under Drugs & Cosmetics Act and Rules, Role of Govt. Drug Testing Laboratories.

- Good Manufacturing Practices under Schedule “M” of Drugs & Cosmetics Act in respect of Production, Quality Control, Maintenance of record of Drugs & Pharmaceuticals”.

- Plant Design & Site Master File

- cGMP's for manufacturing including entry & exit procedures.

- ICH guidelines for production & Quality Control of Pharmaceuticals.
- IQ, OQ, PQ and DQ of equipment of Production & QC, Validation, Qualification and calibration.
- Market complaints, CAPA, OOS and OOT etc., What is containment? Essential steps to control contamination, handling of deviation, Risk Assessment.
- Change control, Deviation control and the importance
- Documentation and records in Production and QC.
- Standard Operating Procedures.
- Sampling of Raw Materials, Packing materials, In- process Materials and Finished products.
- Preparation and Standardization of Herbal Formulations
- Microbiology - An Introduction, Microbiology for non-sterile preparations.
- Analytical method validation.

- Ethics on Pharmaceutical Marketing.
- Ointments, Creams, Emulsions, Gargle solutions, Sanitizers, etc Different types of equipment used for their manufacture, Ingredients used and in-process tests to be carried during their production. Packing of the above products.
- Quality by Design (QbD)
- Different types of Oral Liquid Dosage Forms such as Liquids, Syrups, Suspensions & Emulsions etc. Facilities required and their methods of manufacture, in process tests to be carried out during their manufacture.
- Selection of Packing Materials like Bottle packing, Strip Packing, Blister Packing etc and selection of different materials according to stability of products Viz: tablets & Capsules, Powders etc.
- Testing of Pharmaceutical Analytical Instruments (TLC, HPLC, HPTLC, Spectrophotometer, GC, ect.)
- Stability Testing, Accelerated and Real Time Studies, Packaging Material Stability, Their Testing, Their Importance with Respect to the Product Stability.
- Dissolution & its Importance, Methods used in Dissolution Testing.
- Calibration of QC equipments, Reference Standards and Working Standards, Reference / retention samples storage.
- Air Systems, Water Systems, their sampling and testing.
- Basic Calculations in Quality Control, Dilutions and Statistical Analysis, Qualitative Analysis, Quantitative Analysis & Elemental Analysis.
- Batch Manufacturing Records, Batch Packing Records and importance of online recording. Basics of production planning & Inventory Control.

- Tablets (Processes involved in the production of Tablets such as size reduction, sieving, granulation, compression, coating etc., Various components of a Tablet with examples of different materials used &, In process tests to be carried during production of Tablets)
- Types of tablets such as Plain Tablets, Press Coated Tablets, Tablet in Tablet, Film Coated Tablets, Enteric Coated tablets, Delayed Release tablets etc, their advantages , How to control and rectify (in case of failure) weight variation, Disintegration time, Hardness, Friability, Dissolution etc during production , Different types of Coating of Tablets, Materials used for coating & coating process
- Preventive maintenance, Predictive maintenance & Break down maintenance.
- Soft Skill
- The above subjects were taught by well experienced senior level pharma industry manufacturing and quality assurance technical personnel through power point presentation.
- One day program was conducted on Chromatography analysis like HPLC, GC, LCMS Spectrophotometer, etc., at M/s. SPINCO Biotech, Perungudi, Chennai with practical training.

Practical Training

M/s. Fourrts (India) Laboratories Pvt. Ltd., Plant 1 & Plant 2, Chennai, M/s. Apex Laboratories Pvt. Ltd.,Alathur, Chennai, M/s. Medopharm, Guduvanchery, Chennai, M/s. Tablets (India) Ltd., T H Road, Chennai, M/s. SaiMirraInnopharm Pvt. Ltd., Ambattur, Chennai M/s. The Madras Pharmaceuticals, OMR, Chennai, and M/s. Crescent Pharmaceuticals, Irungattukottai, offered their facilities for practical training to the trainees for 5 days.

Evaluation

All the trainees were evaluated after each of the lecture programme as well as on the final date of completion of the programme on the basis of the evaluation 3 top scored trainees were awarded with cash prize, during the valedictory function.

ValedictoryFunction

The Valedictory function was held on 21st March 2024. The Chief Guest of the function was Dr. S. V. Veerramnai, Chairman of our Trust and M/s. Fourrts (India) Labs Pvt Ltd., and Dr. Sahnmugasundram, Director, School of Pharmacy, Vels University,

was the guest of Honour. Mr. R. Sabapathy, Mr. N. Sreenivasen, Dr. R. Ilavarasan, were the guests of the valedictory. Mr. R. Narayanaswamy, Director, PKTI Welcomed the gathering and explained about the 10th training program. Certificates were distributed all the trainees.

All the trainees expressed their views that such program enhance their knowledge and more useful for their carrier in Pharma profession.

IPA Awards – TN State Branch

The Indian Pharmaceutical Association, Tamil Nadu State Branch, presents the Best Pharmacist Award annually to distinguished individuals in the Pharmacy Profession. Since its inception in 2022, this award has been extended to various divisions within the field of Pharmacy. The awards ceremony takes place during the valedictory function of the National Pharmacy Week Celebration. Due to delays in scholarships and other awards, a separate award ceremony was organized.

The award ceremony was held on March 2, 2024, at Muthamizh Peravai, T.N. Rajarathinam Kalai Arangam, located at 92, Durgabai Deshmukh Road, Raja Annamalaipuram, Chennai – 600028.

Mrs. R. Lalitha Lakshmi, IPS, Inspector General of Vigilance and Anti-corruption, Chennai, was the Chief Guest. Dr. S. V. Veerramani, Chairman of Pharmexcil, and Dr. M. Karunanidhi, Chairman of Vivekanandha Education Institutions, Tiruchengode, graced the occasion as Guests of Honour.

Mr. J. Jayaseelan, National Vice President of IPA, extended a warm welcome to the attendees. Mr. S. V. Veerramnai delivered a speech on "India – Pharmacy of the World," while Dr. Karunanidhi shared insights from his journey and achievements with the young pharmacists.

Mrs. R. Lalitha Lakshmi encouraged young professionals to focus on hard work and dedication to achieve their goals, advising them against excessive use of social media.

The Recognition Awards were bestowed upon outstanding individuals in various fields: Mr. G. Anandaselvam, Director of Marketing at Icarus Health Care Pvt Ltd., Chennai, received the award for Industrial Pharmacy. Dr. C. Samuel Devaprasad, Former ADC

of CDSCO, was recognized for Regulatory Affairs. Dr. N. Deattu, Assistant Professor at the College of Pharmacy, Madras Medical College, Chennai, was honored for Pharmacy Education. Dr. S. Annadurai, Professor of Pharmacy at the Department of Pharmacy Services, Christian Medical College, received the award for Hospital Pharmacy. Mr. Sivasankaran. V, from M/s. Ravi Pharmacy, Chennai, was acknowledged for Community Pharmacy. Additionally, Mrs. Pratima Mathur was awarded the IPA Special Recognition Award for her contributions as Trustee of TNPSW Trust.

The Best Pharmacist award was presented to Prof. Dr. M. Karunanidhi, Chairman of Vivekanandha Education Institutions, Tiruchengode, in recognition of his outstanding service to the profession. This award was sponsored by M/s. Lalachand Bimraj, Chennai.

The Tamil Nadu Pharmaceutical Sciences Welfare Trust also awarded various awards to Pharmacy graduates and students during the ceremony. Eighteen M. Pharm and three Pharm D students received Scholarship awards. An Essay Competition was organized for final year B.Pharm students on the topic "Join Pharmacist to Ensure Patient Safety," with cash prizes awarded to the top three ranking students. This competition was sponsored by M/s. Pharm Products Pvt. Ltd., Thanjavur. University Merit awards were presented to the top three ranking B.Pharm graduates from The TN Dr. MGR Medical University, along with cash prizes, sponsored by M/s. Fourrts India Labs Pvt Ltd, Chennai.

More than 300 Pharma professionals participated in this event, including senior regulators, industrialists, college faculties, and students from various colleges in and around Chennai.

Mr. T. Sathish, Secretary of IPA TNSB, concluded the event with the vote of thanks.


In association with
Indian Pharmaceutical Association
(Tamil Nadu Branch)
In association with
tanipa


Indian Pharmaceutical Association
(Tamil Nadu Branch)


Indian Pharmaceutical Association
(Tamil Nadu Branch)


Indian Pharmaceutical Association
(Tamil Nadu Branch)

NOTIFICATION

MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health and Family Welfare)

NOTIFICATION

New Delhi, the 18th March, 2024

G.S.R. 216(E).—Whereas a draft of certain rules further to amend the Drugs Rules, 1945, was published, as required by section 12 read with section 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940), vide notification of the Ministry of Health and Family Welfare, Department of Health and Family Welfare, number G.S.R. 687 (E), dated the 25th September, 2023, published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (I), inviting objections and suggestions from the persons likely to be affected thereby before the expiry of a period of forty-five days from the date on which the copies of the Official Gazette containing the said notification were made available to the public;

And whereas, copies of the said Gazette notification were made available to the public on 26th September, 2023;

And whereas, objections and suggestions received from the public on the said rules have been considered by the Central Government;

Now, therefore, in exercise of the powers conferred by section 12 read with section 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940), the Central Government, after consultation with the Drugs Technical Advisory Board, hereby makes the following rules further to amend the Drugs Rules, 1945, namely;-

1.Short title and commencement

(1) These rules may be called the Drugs (Second Amendment) Rules, 2024.

(2) They shall come into force on the date of their final publication in the Official Gazette.

2.In the Drugs Rules, 1945, (hereinafter referred to as the principal rules), in rule 105, in sub-rule (2), in clause

(i), after the words, and figure, “multiples of 5”, the word and figure “or 7” shall be inserted.

3.In the principal rules, in Schedule P1, under the heading “PACK SIZES OF DRUGS”, the drugs “Glyceryl Trinitrate” and “Isosorbide Dinitrate” mentioned in column 1 and entries relating thereto in columns 2 and 3 shall be omitted.

[F.No. X.11035/108/2023-DRS]
RAJIV WADHAWAN, Advisor (Cost).

Foot Note: The Drugs Rules, 1945 were published in the Gazette of India vide notification number F.28-10/45-H(1), dated the 21st December, 1945 and last amended vide notification number G.S.R. 95(E), dated the 5th February, 2024.

MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health and Family Welfare)

NOTIFICATION

New Delhi, the 28th March, 2024

S.O. 1577(E).—In exercise of the powers conferred by sub-section (2) of section 1 of the Jan Vishwas (Amendment of Provisions) Act, 2023(18 of 2023), the Central Government hereby appoints that the amendments mentioned to the Drugs and Cosmetics Act, 1940 (23 of 1940) mentioned in column (5) of the Schedule to the said Act, against serial number 6 mentioned in column (1) of the said Schedule, shall come into force from the 31st December, 2024.

[F. No. X.11035/127/2023-DR]
RAJIV WADHAWAN, Advisor (Cost)

F.No.12-01/2024-DC (SEC)
Directorate General of Health Services
Central Drugs Standard Control Organization
(Expert Committee Coordination Division)

FDA Bhawan, New Delhi
Dated: 31-01-2024

NOTICE

It has now been decided that the meetings of Investigational New Drugs (IND) for evaluation on IND proposals will be conducted by SEC division as per the procedures followed.

In this regard, applicants are requested that the copy of presentation must be submitted through e-vartalap (Sugam Portal) only to concerned division well in advance, after receipt of the invitation letter from CDSCO.

This is for compliance with immediate effect.

Ankit Sharma
Deputy Drugs Controller (India)

To,
All Stakehoders & CDSCO website

F. No. MED-13011(15)/3/2024-eoffice
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
(Medical Devices Division)

Food & Drugs Administration Bhawan,
Kotla road, New Delhi-110002
Dated: 12 FEB 2024

NOTICE

Subject: Online application for Neutral Code for manufacturing of Medical Devices for export purpose - reg.

In order to streamline the regulatory submission procedure, for issuance of Neutral Code to the applicant for manufacturing of Medical Devices for export purpose is now functional through Online System of Medical Devices portal (https://cdscomdonline.gov.in). The applicants seeking for Neutral Code shall now apply through online portal as per the checklist provided on the portal.

It is pertinent to mention that the Neutral Code to the manufacturer will be issued by the Central Licensing Authority under Medical Devices Rules,2017.

In view of the above, it is requested that all stakeholders shall submit application related to Neutral Code through Online System of Medical Devices portal only (https://cdscomdonline.gov.in).

(Dr. Rajeev Singh Raghuvanshi)
Drugs Controller General (India)

To,

1. All stakeholders through CDSCO Website
2. State/UT Licensing Authorities (for information and necessary action)
3. CDAC Team

Ministry of Health and Family Welfare
Directorate General of Health Services
Central Drugs Standard Control Organisation

FDA Bhawan, Kotla Road, New Delhi
Dated the 26th February, 2024

PUBLIC NOTICE

Please refer to Public Notice No. Admin-A012(12)/46/2024-eoffice dated 14.02.2024 vide which it was informed that Drug Controller General of India (DCGI) will be meeting with stakeholders on Every Tuesday and Thursday (except Gazetted holidays) in CDSCO (HQ) from 5:00 PM to 6:00 PM.

2. In this regard, all the stakeholders are hereby informed that upcoming meeting to be held on Tuesday (27.02.2024) stands cancelled due to exigency of work and other official commitments of DCGI.

3. Stakeholders from outside Delhi are requested to contact Nodal Officer, PRO Cell for fixing the meeting on other appropriate dates.

Signed by Dileep Kumar Rajput
Date: 26-02-2024 20:38:00
(Dileep Kumar Rajput)
Director (Admin)

To,

All stakeholders

Copy to:

i. All JDC(I)s, DDC(I)s in CDSCO(HQ)
ii. Staff of DCGI
iii. Notice Board
iv. CDSCO Website
v. PRO Cell
vi. Guard File

File No.:MED/2/2024-eoffice
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
(Medical Device Division)
FDA Bhawan, Kotla Road,
New Delhi - 110002,
Dated: 03 APR 2024

To,
All stakeholders through CDSCO website.

Subject: Strengthening of private Medical Devices Testing Laboratory in the country - Reg.

You may be aware that CDSCO is the National Regulatory Authority under Ministry of Health and Family Welfare responsible for ensuring the quality, safety and performance of medical devices under Medical Device Rules, 2017.

In consequent to implementation of S.O. 648(E) dated 11.02.2020 and G.S.R. No. 102 (E) dated 11.02.2020, all the medical devices have come under Drugs and Cosmetics Act, 1940 and Medical Device Rules, 2017.

Presently, certain private testing labs have been registered under MDR, 2017 for testing & examination of certain medical devices in the country on behalf of the manufacturer. In order to strengthen the private testing facility for medical devices in the country, this office is in the process of identifying the existing private labs having the facility to test the medical devices, so that these labs may be registered under MDR, 2017. It is observed that your organization is having testing facility for carrying out various tests of medical devices. The medical devices require various tests including Physical, chemical, microbiology, mechanical & electrical etc.,

In view of above, it is requested that you may kindly identify your facility for testing of the above tests for medical devices and submit the application in Form MD-39 along with the requisite information with fees as per MDR, 2017 for registration of testing laboratory behalf of the manufacturer.

This is for your information and necessary action in the matter.

(Dr. Rajeev Singh Raghuvanshi)
Drugs Controller General of India.

File No. 4-01/2024-DC (Misc. 08)
Govt. of India
Directorate General of Health Services
Central Drugs Standard Control Organization
(FDC Division)

FDA Bhawan, Kotla Road
New Delhi-110002
Dated: 16 APR 2024

NOTICE

Subject: Manufacturing and marketing of unapproved drug Meropenem 1gm + EDTA for Injection-regarding.

It has been brought to notice of this Directorate that some manufacturers are involved in manufacturing/marketing of **Meropenem 1gm + EDTA for Injection** which is not yet approved by this office for manufacturing/marketing in the country and falls under the category of "New Drug".

No new drug shall be manufactured for sale unless it is approved by the Licensing Authority as defined in Rule 3 of New Drugs and Clinical Trial Rules, 2019. Further, as per Rule 80 of New Drugs & Clinical Trials Rules 2019, a person who intends to manufacture new drug in the form of API or Pharmaceutical formulation, as the case may be for sale or distribution, shall make an application for grant of permission to the Central Licensing Authority in Form CT-21 alongwith a fee as specified in Sixth Schedule.

This information is for all the concerned stakeholders.

(Dr. Rajeev Singh Raghuvanshi)
Drugs Controller General (India)

To:-

All State/UT Drugs Controllers/All Zonal/Sub Zonal offices of CDSCO.

Copy to:-

1. PPS to Secretary/AS(F&D)/JS(R), Ministry of Health and Family Welfare, Nirman Bhawan, New Delhi.
2. Indian Drug &Pharmaceuticals Associations
3. All Indian Origin Chemists & Distributors Ltd.(AIOCD), 6th Floor, Corporate Park, V.N. Purav Mar, Chembur, Mumbai – 400071]
4. Website of CDSCO.

NEWS

Early Metformin Therapy Curbs Gestational Diabetes in Trials in Chennai

A twice daily dose of 250mg of anti-diabetic drug metformin as early as eighth or ninth week of may prevent gestational diabetes in women with mildly elevated sugar levels, says senior diabetologist Dr V Seshiah based on the interim results of an ongoing and yet-to-be-published study at two government hospitals in the city. Preventing diabetes in pregnant women reduces risks of maternal mortality, congenital anomalies and still births, he said

Gestational diabetes mellitus occurs when a hormone made by the placenta prevents the body from using insulin effectively.

Symptoms disappear following delivery but the condition increases risk during pregnancy and labour. “It affects up to 25% of pregnant women in India. We are able to stop women from getting diabetes with a simple medication,” he said. “By the eleventh week, the pancreas in the fetus will start producing insulin to help mother bring down sugar levels. We must bring down sugar levels before the fetus intervenes. So it's best to treat at the 8th week though international studies show it is good to intervene in the 10th week,” he said.

Doctors from the Government Kasturba Gandhi Hospital for Women and Children and Government Hospital for Women and Children selected 152 pregnant women for the study – 82 of whom had sugar levels below 110mg/DL two hours after their meal and 70 of whom had sugar levels above 110mg/dL. Doctors administered 250mg of metformin twice a day to women with elevated sugar levels throughout their pregnancy. They were screened during the 15th, 24th and 32nd week. “Barring one woman who did not adhere to the regimen, none of the others developed gestational diabetes,” said senior gynecologist Dr Anjalakshi Chandrasekar from SRM Medical College, who is a part of the study.

The medicine controls blood sugar levels and helps prevent kidney damage, blindness, nerve problems, loss of limbs, and sexual dysfunction. Eleven women had delivered and they and their children were healthy. “Preventing diabetes in pregnancy will mean fewer complications in mother and child,” said associate professor A Geethalakshmi, Government Hospital Women and Children in Egmore.

Source: *The Times of India,* 13th January 2024

Healthcare, Pharma to Drive Job Growth in H2 FY24

Elaborating on this trend, Team Lease said in its hiring outlook report that in accordance with the India@100 vision, the Indian pharmaceutical sector was aiming to achieve a milestone of $130 billion by 2030. Capacity expansion, talent development, and the cultivation of indispensable skill sets would be critical to drive this ambitious expansion and some 86% of healthcare and pharma firms showed serious intent for additional hiring, it said.

The fast moving consumer durable sector was also positioned for revitalisation in the coming months, following a sequence of obstacles that included sluggish consumer sentiment and delayed inventory liquidation. This reversal is anticipated to be fuelled by a housing sector recovery and a significant single-digit price increase. Some 84% of employers in the fast moving consumer durable (FMCD) industry intend for workforce expansion, the firm has found.

Also, the FMCG sector was witnessing a sustained increase in demand from urban areas, whereas rural demand has remained constrained due to the economic strain on rural areas' incomes. Although with mixed sentiments, some 80% of employers in the FMCG industry intend to expand their workforce, according to TeamLease. "Our findings underscore strategic shifts and emerging opportunities, signifying a positive trajectory for employment stakeholders and city-specific job market dynamics, notably in cities like Mumbai, Hyderabad, and Chennai," said Balasubramanian A, Vice President of TeamLease Services.

In healthcare and pharma, Chennai leads in incremental workforce expansion at 12.8%, followed by Kolkata at 11.6% and Coimbatore at 11.5%. However, Hyderabad emerged as the frontrunner in incremental workforce expansion at 13.2%, followed by Delhi at 10.5%, and Bengaluru, Pune, and Ahmedabad at 9.2% for the FMCD industry. In the FMCG space, Mumbai is leading in incremental workforce expansion at 13.2%, closely followed by Nagpur at 11.3%, and Bengaluru, Pune, and Indore at 9.4%, according to the employment outlook.

Source: *The Hindu,* 13th January 2024

10 Chemists in 4 States Booked for Sale of Narcotics to City Residents

At least 10 chemists from four states have been booked in the past few weeks under the Narcotic Drugs and Psychotropic Substances Act for the bulk sale of narcotics through at least two websites to Chennai residents without prescriptions.

While TN police have issued notices to the websites' proprietors, the state health department has urged the respective states to act under the Drugs and Cosmetics Act.

Medical stores also disperse narcotics

such as hypnotic drug nitrazepam and opioid pain medication tramadol without permission. Between September 2023 and Jan 12, 2024, the directorate of drugs control booked at least 15 cases, suspended drug licenses of 13 traders, and filed two court cases in North Chennai alone.

Simultaneously, Chennai police conducted surprise checks to detect cases of transport and sale of drugs and narcotics. They found that bulk bookings can be made anonymously in the online market. "Customers book in bulk with a wholesaler on specific sites at exorbitant cost. The consignment is simply shipped to the city," said additional commissioner of police (law and order), Chennai North AsraGarg. "We are now probing the illegal online channel including websites associated with pharma companies, wholesalers and retailers."

A drugs directorate, police and health department team decided that cases will be booked under the NDPS Act too and a list of commonly abused drugs was made. "NDPS Act is more stringent as punishment in some cases can be even for life," said a senior directorate of drug control official.

Over the past few weeks, at least 10 wholesale chemists' counterparts in Bihar, MP, UP, and Maharashtra have been booked and TN joint director of drug control M N Sridhar has informed the respective state drug controllers about the cases, urging action under the Drugs and Cosmetics Act under which punishment includes suspension or cancellation of drug licences.

TN health secretary Gagandeep Singh Bedi, in a letter, has urged the health department to initiate action. "The online market for habit-forming seems formidable. With help from police, we want to make access to these drugs difficult."

Source: *The Times of India,* 18th January 2024

Respiratory Drug Foracort No. 1 in Sales

The deadly cocktail of growing pollution and smog seems to be choking us immensely. Foracort, used for asthma and respiratory issues, has assumed the top slot in December in domestic pharma market, which has been largely led by either antibiotics or anti-diabetics. This was the second consecutive month of the drug topping the charts, according to the latest data culled from market research firm IQVIA.

Foracort registered Rs 85 crore of sales, with a growth of 22% in December, in an otherwise lacklustre market.

The first time in recent months it jumped to the number 1 rank was in November 2023, netting sales of Rs 81 crore, recording one of the highest growths during the month. Typically, either antibiotic Augmentin or anti-diabetic Mixtard have maintained the pole position in the organised pharma retail market.

The latest trend is in line with the rising pollution and harsh cold in the North and resurgence of Covid-19 across the country, experts told TOI. Exposure to air pollution can aggravate asthma and respiratory infections, and can even lead to serious issues like chronic obstructive pulmonary disease. Foracort's growth was the second-highest, with Liv-52 growing the most at 36% among top 10 brands in December.

Growth drivers included cardiac and gastro therapies, rising 8% and 6% respectively, in a market, which grew only 5% to Rs 18,067 crore in December. Overall, pharma retail market was valued at Rs 2,13,139 crore, growing 10% for MAT (moving annual total) December, or 12-month period ended December

Anti-diabetic, derma and gynae sales underperformed the market, hurting overall growth, an analyst from Motilal Oswal said. As against this, urology, ophthal, cardiac, pain therapies led the y-o-y growth on MAT basis, growing 14.2%, 11.3%, 10.4% and 10.2% respectively. Antibiotic Augmentin and anti-diabetic Mixtard with sales at Rs 67 crore and Rs 68 crore each, respectively, registered a decline of 14% and 11% year-on-year in December among top 10 brands.

Both domestic and MNC pharma companies posted sluggish mid-single digit growth, around 4-5% each y-o-y. As of December, domestic companies hold a majority share of 83% in the pharma market, while the rest is held by MNCs.

Source: *The Times of India,* 18th January 2024

Govt Asks Doctors, Pharmacists to Mention Reasons for Prescribing Antibiotics

The Union Health Ministry has called on doctors in medical colleges and medical associations to make it mandatory to mention the indication and reason for prescribing antibiotics. Director General of Health Services Dr AtulGoel has also urged pharmacists to strictly follow the Drugs and Cosmetics Rules and refrain from selling antibiotics without a prescription from a qualified doctor.

In a letter dated January 1, Dr AtulGoel emphasized that the misuse and overuse of antimicrobials contribute to the development of drug-resistant pathogens. He highlighted the importance of prudent antibiotic use in order to delay the emergence of resistance, as there are limited new antibiotics in the research and development pipeline.

The letter, addressed to all doctors of

medical colleges and medical associations, emphasized that antimicrobial resistance (AMR) is a major global public health threat. In 2019 alone, bacterial AMR was responsible for approximately 1.27 million deaths worldwide, with an additional 4.95 million deaths associated with drug-resistant infections.

AMR not only jeopardizes the effectiveness of infection prevention and treatment, but also leads to prolonged illness, increased risk of death, and longer periods of infectivity. The high cost of second-line drugs further hinders the treatment of these diseases for many individuals.

While reminding pharmacists to adhere to the Drugs and Cosmetics Rules and sell antibiotics only with valid prescriptions, the letter stressed the importance of doctors including the indication or reason for prescribing antimicrobials on the prescriptions. The Health Ministry urgently appealed to all doctors to make it mandatory to provide the indication/reason/justification when prescribing antimicrobials, in order to promote the judicious use of these drugs and reduce the emergence of AMR.

In a separate letter to all pharmacist associations in India, Dr AtulGoel highlighted that antibiotics are included in Schedule H of the Drugs and Cosmetics Rules 1945, which requires them to be sold only with a prescription from a Registered Medical Practitioner (RMP). High-end antibiotics are included in the list of Schedule HI drugs. The Health Ministry urgently appealed to all pharmacists to strictly implement Schedule H and H1 of the Drugs and Cosmetics Rules, and to refrain from over-the-counter sale of antibiotics.

Source: *The Economic Times,* 19th January 2024

SC Upholds Centre's Notification Terming Surgical Instruments as Drugs

The Supreme Court upheld the Union government's four-year-old notification bringing all surgical instruments within the regulatory framework of Drugs and Cosmetics Act, 1940 and rejected an appeal filed by Surgical manufacturers and Traders Association (SMTA).

A bench of Chief Justice D Y Chandrachud, and Justices J B Pardiwala and Manoj Misra the counsel or SMTA for close to 15 minutes at the admission stage and dismissed the appeal against a Delhi High Court judgment by observing that the policy decision to bring all surgical instruments within the ambit of Drugs and Cosmetic Act was to protect the welfare and safety of patients.

The counsel argued that from 1989 till 2020 none of the surgical instruments were subjected to the regulation of the 1940 Act as the Drug and Technical Advisory Board (DTAB) dealt with only approval of medicines to be sold to patients. However, a 2018 notification, which came into force from January 1, 2020, brought nebulizer, BP monitoring machine, digital thermometer, and glucometer under the Act.

The counsel said DTAB does not have experts to deal with the technology and quality of surgical and medical equipment like CT Scan machines and similar other medical machines. CJI Chandrachud asked, “Is the notification bringing all surgical and medical equipment within the ambit of Drugs and Cosmetics Act, 1940 not in the interest of patients?”

The counsel said the surgical and medical equipment manufacturers and traders are not averse to these instruments being regulated, but for that there has to be a different regime and a body comprising those having expertise in this field.

The bench said what is to be regulated and what not is purely in the policy domain of government, “Overall it is in public interest. The Delhi High Court judgment has reached the correct finding. It is rightly done to protect the patients from getting fleeced. This was also done for the welfare and safety of the patients.”

The Delhi HC, while dismissing SMTA's writ petitions, had said, “The larger public interest, which concerns patient safety, requires that all medical devices be brought within the regulatory regime. This step, as demonstrated by the ministry of health and family welfare, is aligned with the regulatory regime in various jurisdictions across the world.”

Source: *The Times of India,* 26th January 2024

JIPMER Conducts Trial Demo to Deliver Emergency Medicine Using Drones

Jawaharlal Institute of Postgraduate Medical Education and Research (JIPMER) successfully conducted a trial demonstration of the delivery of emergency medicines to a community health centre (CHC) at Mannadipet in the outskirts of the town using a drone. The Union government selected the CHC at Mannadipet for the trial, which was conducted on Jan 22, according to a press release issued by the institute.

The trial was done in the run up to the formal launch of the drone services for medical purposes in all the institutes of national importance across the country, including JIPMER, by the Union government.

Two female self-help group staff members from JIPMER completed a 10-day remote pilot training course conducted by the Drone Destination at Gurugram Base. The National Health System Resource Centre (NHSRC) organised the training course, which is approved by the Directorate General of Civil Aviation.

The drone services to deliver medicines to CHCs located in remote areas is a pilot project launched by the Union health and family welfare ministry in coordination with the NHSRC in all institutes of national importance including JIPMER to improve healthcare services to people, particularly those living in difficult geographical terrains.

It may be recalled that JIPMER launched nano drone services within its premises to spruce up its healthcare facilities extended to patients in December 2018. Doctors and specialists in the institute can monitor patients in the intensive care units by flying the drone. Moreover, the drone will come in handy for the doctors and specialists in cases of multiple casualties reaching the institute for emergency care.

Source: *The Times of India,* 26th January 2024

Medical Devices: A Case for Make-in-TN

Medical devices can become Tamil Nadu's next growth story in manufacturing. The sector's market size in India is projected to hit $50 billion by 2030, though at present 75-80% of medical devices are imported from the US, China and Germany. It's this huge potential for growth that is drawing the attention of companies in Tamil Nadu with expertise in mechanical engineering, electronics, and information technology.

There is a natural synergy between auto and electronic component sectors and the smart medical equipment industry

And with Tamil Nadu being the country's largest exporter in electronics, among the top three players in the IT sector, and an automotive hub, an ecosystem already exists.

State industries Secretary Arun Roy says multinational companies in medical devices manufacturing are showing interest in establishing facilities in Tamil Nadu. “Even last week, we held a meeting with a Switzerland-based manufacturer,” he says.

“Tamil Nadu should focus on attracting investments in R&D to manufacture medical wearable's and electronic devices,” says G S K Velu, Chairman and MD, Trivitron Healthcare. “Different components for medical devices -- whether in electronics, mechanical or IT (software and hardware) -- are already being manufactured in Tamil Nadu to make the final product in other states,” he adds. Trivitron makes ultrasound machines, mammography equipment and intensive care equipment at its facility near Chennai.

Prasad Maganti, CEO of medical devices company vTitan, says electronic sensors are a critical part of any medical device. “If you take any hospital equipment today, it includes mechanical pumps, plastics, a PCB board and many other electronic components. With a robust automotive and electronics sector in TN, most of these parts are available but medical device makers still import a lot of the electronic components, especially sensor modules,” he says. As the state's electronics ecosystem matures and domestic value-add picks up, it will become easier for medical device manufacturers, he adds.

Among the automotive companies that have announced a foray into this segment is Samvardhana Motherson Group. The

company is leveraging its automotive capabilities to expand into diagnostic equipment, patient aid equipment, IT solutions and services. Certification audits are underway at a greenfield plant in Chennai.

The group also recently acquired AD Industry and Irillic Private Limited. AD Industry brings capabilities in reinforced carbon composites, which are essential for radiology products such as patient tables, X-ray detector housing and orthopaedic equipment. Irillic was acquired for its capabilities in R&D and engineering, having secured two patents in India and the US. Irillic has developed imaging systems (fluorescence imaging and 4K laparoscopy) that provide real-time visualisations for medical procedures.

"Auto electronics has matured well in TN and so the manufacturers understand building high reliability equipment, positioning the state as a front runner in the mass manufacture of medical electronics. Bengaluru and Hyderabad are more focussed on R&D and treatment techniques," says Krishna Moorthy K, CEO & president, India Electronics & Semiconductor Association (IESA).

Growing at a CAGR of 15% over the past three years, the medical devices sector comprises five major segments -- consumables and disposables, diagnostic imaging, dental products, orthopaedics and prosthetics, and patient aids. Experts draw a parallel between defence production and medical devices manufacturing. While India's defence production and exports have picked up swiftly in the past five years thanks to the push from the government, large manufacturers have turned their attention to the medical devices segment of late.

C Venkat Subramanyam, founder, Veda Corporate Advisors, says, "The environment is becoming more conducive for the medical devices manufacturing segment. Of late, more private equity or venture capital is available. In the past couple of months, we had three very unusual inquiries for medical devices businesses. It includes one of the largest auto component manufacturers and a leading IT hardware manufacturer."

On its part, the State Industries Promotion Corporation of Tamil Nadu (Sipcot) is setting up a medical devices park at Oragadam. SIPCOT MD K Senthil Raj says 14 companies have been allotted space so far. "The 350-acre park will house more than 80 companies producing a range of medical devices. We are also establishing common facilities such as a gamma irradiation centre and testing centre. We are attempting to woo international companies to the park, as well," he says.

Source: *The Times of India,* 30th January 2024

Top Institute Studying if Herbs Like Ashwagandha Fight Cancer

Turmeric, ashwagandha and more than 500 other medicinal plants are potential recruits for the war on cancer at Mumbai-based Tata Memorial Centre (TMC). While many scientists will arch their eyebrows at this news, TMC is setting up a farm and a 100-bed hospital-cum-research facility in Khopoli near Mumbai to grow plants and test their efficacy in cancer treatment.

TMC had been experimenting with traditional practices like yoga to build immunity and speed up post-operative recovery for some time, but the idea of growing medicinal plants and putting them through rigorous clinical and human trials germinated in Feb 2018, following Dr Vikram Gota's experiments with ashwagandha.

Dr Gota, who is professor and head of clinical pharmacology at TMC's Advanced Centre for Treatment, Research & Education in Cancer (ACTREC) in Navi Mumbai, was testing the efficacy and safety of withaferin-A, an active compound derived from ashwagandha. His research revealed potential reduction of mortality among bone marrow transplant patients by 50%. That's how TMC decided to evaluate hundreds of other medicinal plants for cancer treatment, leading to the establishment of the Rs 300-crore Integrative Center for Treatment, Research, and Education in Cancer (ICTREC) in Khopoli.

Dr Gota and his team have made significant progress since, presenting multiple scientific papers that show turmeric and ashwagandha could be potent anti-cancer agents. While turmeric's anti-inflammatory properties have been known in India for ages, new research shows it also possesses anti-proliferative (tending to inhibit cell growth) and immunomodulatory (helping modify the response of the immune system) qualities.

20 acres, 500 species

While Department of Atomic Energy, TMC's governing authority, has provided funds to set up ICTREC, Maharashtra government has given the 20-acre land in Khopoli. With ICTREC, TMC will become the first cancer hospital in India to offer cultivation and conservation of medicinal plants with potential benefits in cancer care. The facility, expected to be operational by 2026, will also offer standard cancer treatments such as radiotherapy and chemotherapy.

ICTREC will cultivate over 500 plants, some of which require climate control. It will collaborate with Central Ayurvedic Clinical Research Institute for Cancer (CARIC), Indian Institute of Integrative Medicine, Council of Scientific and Industrial Research in Jammu, Agharkar Research Institute in Pune, Podar Ayurvedic Hospital in Mumbai, IIT Bombay, Banaras Hindu University and many other institutes already researching Ayurveda and cancer treatment.

Dr Shripad Banavali, director, academics, at TMC, also said they are not rushing to prove anyone wrong or right. "A single randomised trial can take up to 10-15 years. We have just begun. We will only assert the anti-cancer potential of medicinal plants if a trial indicates so".

He said there is considerable international interest in ICTREC's work: "There will be multi-centre trials. Multiple global cancer treatment centres have expressed interest in long-term research on medicinal plants... we aspire to collaborate with such centres worldwide.

Source: *The Times of India,* 4th February 2024

3 Commonly Used Pain, Cough and Cold Medicines Under Scanner

The central drug regulator has asked companies manufacturing two commonly prescribed cough and cold medications and one painkiller drug available in fixed dose combinations (FDCs), which have been on sale for more than 30 years, to carry out trials to review their safety and efficacy. FDC refers to combining two or more drugs in a fixed ratio to develop a single dosage form.

One of the cough and cold medications suggested for a fresh trial to assess safety includes drugs containing Paracetamol (antipyretic), Phenylephrine Hydrochloride (nasal decongestant) and Caffeine Anhydrous (processed caffeine)

The other one contains Caffeine Anhydrous, Paracetamol, Hydrochloride (salt) and Chlorpheniramine Maleate (anti-allergic medication) in different compositions.

Central Drug Regulatory Authority (CDSCO) has advised post-marketing surveillance to generate safety and efficacy data on a third FDC that belongs to a class of painkillers called non-steroidal anti-inflammatory drugs. It contains Paracetamol, Propyphenazone (an analgesic and antipyretic) and Caffeine.

In the case of the painkiller drug, the committee recommended continued manufacturing and marketing of the FDC for mild to moderate headache with the conditions that it should not be taken for more than five to seven days.

The CDSCO order is based on the suggestions of an expert committee formed in 2021 to examine certain pre-1988 FDCs that were given fresh approval for manufacturing for sale without due approval from the licensing authority.

FDCs are justified when they demonstrate clear benefits in terms of potentiating the therapeutic efficacy, reducing the incidence of adverse effects of drugs, better compliance by reducing the pill burden and decreasing development of resistance among others.In an editorial published in Indian Journal of Pharmacology, Dr Y K Gupta, former head of pharmacology at All-India

Institute of Medical Sciences & Dr Suganthi S Ramachandra, classified the available FDCs in India as 'The Good, the Bad and the Ugly'.

The 'Good FDCs' were defined as the ones having strong justification, for example, combination of carbidopa, levodopa, sulfonamides and trimethoprim. The 'Bad FDCs' were the ones formulated primarily with marketing interests and do not add any value to the therapeutic usefulness and whose justification is debatable.

The 'Ugly FDCs' were defined as ones that have neither evidence nor theoretical justifications like formulations having cough syrups with two or more antihistamines alongwith decongestant, bronchodilator, cough suppressant, expectorant and antifungal, antibiotic, steroid and topical local anaesthetic.

Source: *The Times of India,* 6th February 2024

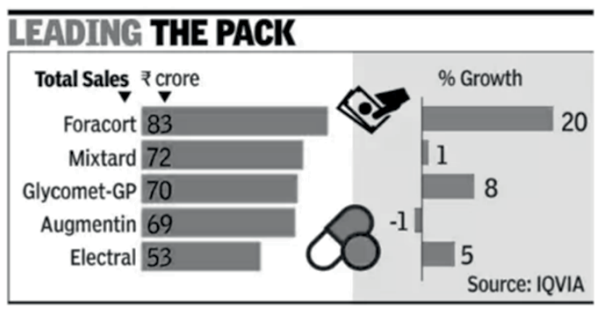
Anti-Asthma Drugs Drive Pharma Market Growth

Respiratory therapies led the growth during Jan in the pharma market, which seemed to have started the year with a bang, growing nearly 8% to Rs 17,937 crore.

Anti-asthma drugs (Foracort and Budecort) continued to post a double-digit growth each during the month, pointing to our struggle with growing across the country. Typically, the domestic pharma market has been largely driven by either antibiotics or anti-diabetics in the past.

Jan becomes the third month in which respiratory drugs posted some of the highest increases in recent times, latest data culled by TOI from market research firm IQVIA showed. The pharma retail market had closed the year with a lacklustre 5% growth in December

Among top rankers, Foracort, used for asthma and respiratory issues, assumed the top slot with a growth of 20% in January, netting Rs 83 crore sales. Other top drugs - antidiabetes therapies Mixtard and Lantus registered sluggish sales during the month. Overall, the organised pharma retail market, valued over Rs 214,476 crore, grew just over 10% as of MAT (moving annual total) January



Therapies including Udiliv, Liv 52, Telma and Zerodol-SP registered a strong double-digit growth, while Electral gained 128 ranks to reach 5th position with a growth of 5%. Further, the acute segment, which includes cough and cold medications, showed an upswing of 6%, whereas chronic has grown nearly double to 11%.

Meanwhile, the growth in domestic companies and MNCs was nearly neck-and-neck with 8% and 7% each for January. Growth for most domestic companies is being driven by sales in emerging markets including India, and the US business. The US has always been a lucrative market, accounting for a significant share of their revenues.

Also, certain companies, including MNCs, are facing headwinds by regulatory price controls, undertaken as part of inclusion of their drugs in National List of Essential Medicines. Analysts expect revenue growth of companies to be around 7-9% in FY2024, supported by price increases and new product launches. During a major part of 2023, companies were negatively impacted by the price caps, besides an uneven monsoon, which affected acute therapy.

Source: *The Times of India,* 15th February 2024

India has Rejected Demand for Data Exclusivity in Drug Development in FTA Talks: Commerce Secretary

India's generic drug industry has over the years made affordable versions of expensive drugs and become a large, global supplier itself, and such a clause could hamper the industry.

India has rejected the demand for 'data exclusivity', as part of ongoing discussions with the European Free Trade Association (EFTA) towards a free trade agreement, Sunil Barthwal, Secretary, Department of Commerce, said on the sidelines of a press briefing.

Data exclusivity pertains to a clause in the draft agreement that puts a minimum six-year embargo on clinical trial data generated during the testing and development of a drug. Thus, manufacturers interested in making a copy-cat product would have to generate such data on their own, which is an expensive proposition, or wait out that period before applying to register and sell their version in India. Crucially, this could also apply to drugs that are not patented in India.

India's generic drug industry has over the years made affordable versions of expensive drugs and become a large, global supplier itself, and such a clause could hamper the industry.

"We rejected their demand. We are with our generic industry. There is no fear for any generics industry in India. It is our very important objective for the country as a whole to see that generic drug industry is flourishing. It is contributing significantly in our exports [as] they are also growing. So, we are there to protect the interests of the generic drug industry throughout, so there is no FTA agreement in which we will be going against the industry's interest," Mr. Barthwal told reporters.

Concerns that such a clause would affect the availability of new drugs had prompted medical rights group Medicins Sans

Frontiers (MSF) to write to Prime Minister Narendra Modi earlier this week on the potential harm from India accepting data exclusivity provisions.

"We welcome the Indian Commerce Ministry's strong stand against the inclusion of data exclusivity in its trade talks with EFTA," Farhat Mantoo, Executive Director, MSF South Asia, said in a statement. "We appeal to India to continue to reject all harmful intellectual property provisions in this and other trade deals that may limit India's supply of affordable generic medicines for millions of people in India and around the world," Dr. Mantoo said.

"For MSF in particular, these possible changes to India's national patents and drug regulatory laws could have a significant impact for the future supply of potentially lifesaving medicines. This is because MSF relies on quality-assured vaccines and medicines made in India to treat the people in our care, with its spending on generic medicines procured from India estimated at 95% for HIV, 90% for hepatitis C antivirals, 36% on TB treatments, and 30% on vaccines," their letter had noted.

Source: *The Hindu,* 15th February 2024

Drug Regulator Warns About Meropenem, Disodium

The Central Drugs Standard Control Organisation (CDSCO) has cautioned against the manufacture and sale of unapproved drugs specifically warning against drugs falling under the category of "New Drugs".

The organisation citing the example of drugs – Meropenem (antibacterial agent) and Disodium EDTA (to treat calcium overload) – noted that they have got information that some manufacturers are involved in manufacturing/marketing of unapproved drugs which CDSCO does not yet approve.

In its communication to all zonal/sub-zonal offices of CDSCO and the Indian Drugs/Pharmaceutical Association forum, it said that no new drug shall be manufactured for sale unless the licensing authority approves it and additionally a person who intends to manufacture a new drug in the form of Active pharmaceutical ingredients (API) or Pharmaceutical formulation – as the case may be for sale or distribution – shall make an application for grant of permission to the central licensing authority as per the specifications.

CDSCO has now directed that all manufacturers be made aware of the two drugs – Meropenem and Disodium EDTA. "The matter should be conveyed to all manufacturers and the product permission granted by these drugs should be cancelled," it noted.

Source: *The Hindu,* 13th March 2024

Centre Seeks More Time to Frame Policy on Online Sale of Medicines

The Centre has urged the Delhi High Court to grant some time to frame a policy on the online sale of medicines on the grounds that the issue was "complex" and any modification in the manner of sale of drugs would have far-reaching consequences.

The high court granted the Union Ministry of Health and Family Welfare four months as a last and final opportunity to frame the policy.

A bench of Acting Chief Justice Manmohan and Justice Manmeet PS Arora made clear that "if the draft policy is not prepared before the next date of hearing, this court will have no other option but to proceed ahead with the matter".

The high court, which was hearing several petitions seeking a ban on the "illegal" sale of drugs online and challenging the draft rules published by the ministry to further amend the Drugs and Cosmetics Rules, listed the matter for further hearing on July 8.

It had earlier asked the Centre to file a status report on the petitions.

During the recent hearing, the joint secretary of the ministry was present in court in pursuance of its November last year order in which the bench observed that more than five years had lapsed and the Union of India has had sufficient time to frame the policy.

The officer sought four months more to frame the policy for the online sale of drugs as per the draft notification of August 28, 2018.

The central government submitted that the subject of the online sale of drugs is of a complex nature and any modification in the manner of sale of drugs will have far-reaching consequences.

It said this will involve changes in many other Acts and rules apart from the Drugs and Cosmetics Act, Pharmacy Act, Pharmacy Practice Regulations, Indian Medical Act, Code of Ethics Regulations and the Drugs and Magic Remedies (Objectionable Advertisement) Act.

Challenging the August 2018 notification, the petitioner, South Chemists and Distributors Association has said that the draft rules are being pushed through in "serious violation" of the law, ignoring the health hazards caused by to sale of medicines online without proper regulations.

Petitioner Zaheer Ahmed has sought contempt action against e-pharmacies for continuing to sell drugs online despite a high court order staying such activity.

The high court had on December 12, 2018, stayed the sale of drugs without licence by online pharmacies while hearing Ahmed's PIL.

The petition also sought contempt action against the central government for allegedly not taking action against the defaulting e-pharmacies.

Some of the e-pharmacies had earlier told the high court that they do not require a licence for the online sale of drugs and prescription medicines as they do not sell them and instead, they are only delivering the medications akin to the food delivery app Swiggy.

The court had earlier sought responses from the Centre, Delhi government, Central Drugs Standard Control Organisation and the Pharmacy Council of India to the petition.

The petitioner had said the "illegal" sale of medicines online will lead to a "drug epidemic", drug abuse and misutilisation of habit-forming and addictive drugs.

The PIL said since there was no mechanism to control the sale of medicines online, it puts the health and lives of people at a high risk and affects their right to a safe and healthy life under Article 21 of the Constitution.

It claimed the Ministry of Health and Family Welfare, Central Drugs Standard Control Organisation, and an expert committee appointed by the drug consultative committee have already concluded the online sale of medicines is in contravention of the provisions of the Drugs and Cosmetics Act, 1940 and other allied laws.

Source: *Business Standard,* 17th March 2024

Desi Sickle Cell Anaemia Drug to Cost Less than 1% of Imported Versions

Hydroxyurea, a drug used to treat sickle cell anaemia, will now be accessible in India for Rs 600 per vial, a fraction of the cost of imported versions. Unlike the global brands priced at around Rs 77,000 per vial, needing specific storage at 2-8 degrees Celsius, the Indian variant by Delhi-based Akums Drugs and Pharmaceuticals Ltd. remains stable at room temperature.

NEW DELHI: Hydroxyurea, a medicine used for treating sickle cell anaemia patients, will now be available in India for Rs 600 per vial — less than 1% of the price of its imported versions.

Unlike the versions sold by global brands for around Rs 77,000 per vial, which need a storage temperature of 2-8 degrees Celsius, the Indian variant remains stable at room temperature, claimed its manufacturer Delhi-based Akums Drugs and Pharmaceuticals Ltd.

The company said Hydroxyurea will be available to govt at less than Rs 600, “thus embodying the spirit of Make In India and fostering widespread benefit to the masses”

Congratulating the company, Union health minister MansukhMandaviya wrote on X, “PM NarendraModi had in 2023 launched National Sickle Cell Elimination Mission. This medicine will prove to be a blessing for our tribal brothers, sisters and children and we can make India free from sickle cell soon.”

Sickle cell disease is a genetic disorder mostly prevalent in districts with high tribal populations. About one in 86 births among STs have sickle cell disease that affects haemoglobin in red blood cells, resulting in morbidity and mortality

The exercise to encourage Indian companies to manufacture generic versions of drugs used in treatment of rare diseases, also referred to as orphan drugs, had started in July 2022 and discussions were held.

Source: *The Times of India,* 18th March 2024

AstraZeneca Pharma Gets CDSCO Nod for Trastuzumab deruxtecan Use for 2 More Indications

AstraZeneca Pharma India has received permission from the Central Drugs Standard Control Organisation (CDSCO)to import for sale and distribution of Trastuzumab deruxtecan lyophilized powder for concentrate for solution for infusion 100 mg (Enhertu) for two additional indications.

HER2-low metastatic breast cancer and HER2 positive gastric / gastro-oesophageal cancer are the additional indications for which CDSCO has given approval, the company said recently.

"With this approval, we have the potential to significantly enhance outcomes for patients battling advanced or metastatic low HER-2 and HER-positive gastric cancers, especially those who have exhausted standard treatment options," country president and MD SanjeevPanchal said. The Drugs Controller General of India (DCGI) had earlier approved Trastuzumab deruxtecan for the treatment of adult patients with unresectable or metastatic HER2-positive breast cancer who have received a prior anti-HER2-based regimen.

The latest permission paves way for launch of Trastuzumab deruxtecan lyophilized powder for concentrate for solution for infusion 100mg (Enhertu) in India for the specified additional indications, subject to receipt of related statutory approvals, if any, the company said.

Source: *The Hindu,* 29th March 2024

10% of Prescriptions from Hospitals had 'Unacceptable Deviations': Govt Study

Around 10 per cent of prescriptions from tertiary care and teaching hospitals analysed as part of a yearlong government study had "unacceptable deviations" such as inappropriate prescription of medications or more than one diagnosis. The potential consequences of these deviations could have led to increased cost for patients and probability of increase in the number of adverse drug reactions or even treatment failure, according to the study.

'Evaluation of prescriptions from tertiary care hospitals across India for deviations from treatment guidelines and their potential consequences' analysed 4,838 prescriptions which was published in the Indian Journal of Medical Research (IJMR).

The multicentric study which was carried out from August 2019 to August 2020, was conducted by 13 ICMR Rational Use of Medicines Centres (RUMCs) located in tertiary care teaching hospitals and medical colleges across India including Delhi AIIMS and Safdarjung Hospital.

A deviation that could result in a drug interaction, lack of response, increased cost, preventable adverse drug reaction (ADR) and/or antimicrobial resistance was labelled as an 'unacceptable deviation'.

"Against all the prescriptions assessed, about one tenth of them (9.8 per cent) had unacceptable deviations," the study said.

All the prescribers were postgraduates in their respective disciplines and on average were in practice for four to 18 years.

Of the 475 prescriptions that had deviations, 102 had stated more than one diagnosis and in some of them drugs were prescribed inappropriately.

The drugs identified in prescriptions with unacceptable deviations were pantoprazole, rabeprazole and domperidone combination, trypsin/chymotrypsin, serratiopeptidase, ranitidine, azithromycin, cefixime, amoxicillin and clavulanic acid combination and aceclofenac.

"It appears that the above drugs were prescribed to not only treat the symptoms but also to treat potential side effects of the drugs prescribed.

"For patients with pain as a presenting symptom, analgesics were co-prescribed with pantoprazole. Gastroprotective drugs are to be prescribed if the patient has a risk for developing peptic ulcer.

"Unnecessary prescribing of pantoprazole may lead to potential side effects such as abdominal bloating, oedema and rash," the study stated.

Similarly, it was observed that rabeprazole and domperidone combination along with antacids was prescribed for functional dyspepsia which is not recommended in national/international guidelines.

In this study, participants presenting with bilateral knee pain (osteoarthritis) were prescribed trypsin/chymotrypsin along with analgesics and/or serratiopeptidase with antibiotics. Existing scientific evidence for serratiopeptidase is not sufficient to support its use, it said.

Further, the study said the FDC (trypsin plus chymotrypsin) prescription is irrational and increases the cost of therapy. Azithromycin and the FDC (fixed dose combinations)

amoxicillin plus clavulanic acid were co-prescribed in upper respiratory tract infections (URTI), which was inappropriate and can contribute to antimicrobial resistance (AMR) in the long run.

Furthermore, cefixime was prescribed to patients suffering from acute otitis media (not the first choice as per STGs) along with an antihistaminic, an analgesic and an anti-ulcer drug resulting in an unacceptable deviation, the study found.

Most of the physicians followed the disease-specific ICMR guidelines and the adherence to it was found to be around 55 per cent.

For those conditions where there were no Indian guidelines or recent updates in the guidelines, physicians used the international guidelines as these are not only updated regularly but also easily accessible in the public domain, the study stated.

In this study, outpatient prescriptions by physicians of various specialities in tertiary care, teaching government and private hospitals across India were analysed.

Prescriptions of eligible patients exiting from OPD or hospital pharmacy were captured and analysed their prescriptions.

To minimise the deviations, clinicians recommended online training on rational prescribing and administrative directives as potential interventions.

Inappropriate prescribing of medicines is a major clinical concern and can negatively impact upon efficacy, safety and economic issues for the patients. Hence, the treatment of patients in clinical practice should be individualised and based on principles of rational prescribing, the study asserted.

The present definition of rational use was drafted by the World Health Organisation (WHO) more than three decades ago at an international conference in Kenya in 1985.

However, inappropriate prescribing is still a problem and worldwide over 50 per cent of the medications may be prescribed or dispensed inappropriately and 50 per cent of the patients may be non-compliant to their medication.

Inappropriate prescriptions can lead to an increase in adverse drug reactions, hospitalisation and increase in cost of treatment.

Inappropriate use of medicines includes, but is not limited to, selecting injectable forms or expensive drugs when cheaper alternatives are available, polypharmacy, unwarranted antibiotic use, failure to adhere to clinical guidelines and non-compliance by patients to prescribed drug regimens.

Source: *ET Healthworld,* 13th April 2024

Essential Med Prices Set to See Marginal Rise After Govt Nod

National Pharmaceutical Pricing Authority (NPPA) has allowed pharma companies to marginally increase prices of scheduled formulations included in National List of Essential Medicines (NLEM) from April 1. The drugs include commonly used painkillers, antibiotics, diabetes medications, and anti-rabies immunoglobulin, among others, reports DurgeshNandanJha.

Each unit of anti-rabies immunoglobulin (injection 150 IU/ml) will now be available for maximum Rs 3,454.

Ceiling price of anti-tetanus immunoglobulin was fixed at Rs 1,383.6. A unit of Amikacin (injection 250 mg/ml) will cost maximum Rs 54.2, as per NPPA order.

Quantum of increase in prices of scheduled formulation included in NLEM is based on change in Wholesale Price Index of formulation for the preceding year, as decided in Drug (Pricing Control) Order 2013. Unlike the previous year, when WPI change was in excess of 10%, this year the movement is significantly low leading to a marginal increase in prices of scheduled formulations. Indian Pharmaceutical Alliance secretary general Sudarshan Jain said the price increase is per norms laid down by govt.

Source: *The Times of India,* 2nd April 2024

Director Among 4 Killed in Blast at Pharma Plant in Telangana

A blast in a chemical reactor at a pharmaceutical company's plant in Telangana's Sangareddy district killed at least four persons, including the firm's director, and left 16 others grievously injured.

According to fire officials, the blast occurred around 4.45pm, and triggered a massive fire at the factory of S B Organics Ltd, located at Chandapura village in Sangareddy, about 100 km from Hyderabad.

While one of the deceased was identified as the pharma company's director D Ravi, the identity of three others was yet to be ascertained. The injured, all of whom have suffered third degree burns, have been admitted to different hospitals. At least five workers are said to be critical.

A case has been registered against the company at Hathnoora police station. Sangareddy SP ChRupesh said the victims were employees of the company, working at different levels.

A police officer said overheating of the reactor and the defunct sensors were suspected to have caused the explosion, but a joint probe by police and fire departments had begun to ascertain the exact cause.

The fire department received a call around 5 pm, following which five fire tenders were rushed to the site.

"While we managed to contain the fire from spreading out of the factory, some casualties had already occurred by then. It took over three hours to bring the situation under control," said V Srinivas, district fire officer. Officials said there were 20 people at the factory at the time of the incident, and dismissed reports about more employees being trapped inside the premises. Telangana CM ARevanth Reddy, former CM K Chandrasekhar Rao and other leaders expressed condolences to the bereaved families.

Source: *The Times of India,* 4th April 2024

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Health Ministry Notifies Revised Pharma Manufacturing Rules Under Schedule M to Ensure Quality Control

Aimed at ensuring robust quality control for pharma and biopharmaceutical products, the Union Health Ministry on January 6 notified revised rules under Schedule M of the Drugs and Cosmetics Rules, 1945.

Schedule M prescribes the Good Manufacturing Practices (GMP) for pharmaceutical products and the revised Schedule M has been notified as rules to ensure GMP is adhered to, and requirements of premises, plant, and equipment for pharmaceutical products.

GMP is mandatory standards which builds and brings quality into a product by way of control on materials, methods, machines, processes, personnel, and facility/environment, etc. GMP was first incorporated in Schedule M of the Drugs and Cosmetics Rules, 1945 in the year 1988 and the last amendment was done in June, 2005.

With the amendment, the words 'Good Manufacturing Practices' (GMP) has been replaced with 'Good Manufacturing Practices and Requirements of Premises, Plant and Equipment for Pharmaceutical Products'.

'On par with global benchmark'

"To keep pace with fast-changing manufacturing and quality domain, there was a necessity to revisit and revise the principles and concept of GMP mentioned in current Schedule M. This would bring our GMP recommendations at par with global standards, especially to those of World Health Organization (WHO), and ensure production of globally acceptable quality of drug," said a senior Health Ministry official about the recent move.

The changes introduced in the revised Schedule M include introduction of a pharmaceutical quality system (PQS), quality risk management (QRM), product quality review (PQR), qualification and validation of equipment, and a computerised storage system for all drug products.

The notification, dated December 28, 2023 states that manufacturers must assume responsibility for the quality of the pharmaceutical products to ensure that they are fit for their intended use, comply with the requirements of the licence, and do not place patients at risk due to inadequate safety, quality, or efficacy.

It adds that companies must market a finished product only after getting "satisfactory results" on tests of the ingredients and retain a sufficient quantity of the samples of intermediate and final products to allow repeated testing or verification of a batch.

Speaking about the revision, Sudarshan Jain, secretary general, Indian Pharmaceutical Alliance (IPA) said, "The revision of Schedule M by the government is a positive step and an important milestone for

the Indian pharmaceutical sector. This will elevate and update the quality standards of medicines, reinforcing the reputation of our industry and improving patient outcomes. We welcome this initiative helping India's journey to become a global benchmark in quality."

"The revised regulations of Schedule M will help ensure compliance with international quality standards and will benefit both patients and the industry by promoting the manufacturing of safe, effective, and high-quality drugs. The focus on risk management, qualification and validation of equipment, and self-inspection will be vital contributions."

Earlier in August, the Ministry had set a six-month deadline for small manufacturers and 12 months for large units to get their World Health Organization-Good Manufacturing Practices (WHO-GMP) certification.

The revised rules is to be implemented on the basis of company turnovers where the medium and small manufacturers include those with an annual turnover of less than ₹250 crore who will have to implement the revised rules within 12 months from its date of publication, whereas large manufacturers with an annual turnover of over ₹250 crore will be given six months to do so.

The revised Schedule M has 13 parts which provide GMP guidelines for the specific requirements for manufacturing pharmaceutical drugs. The revised rules has five new categories of drugs including pharmaceutical products containing hazardous substances such as sex hormones, steroids (anabolic and androgenic), cytotoxic substances, biological products and radio pharmaceuticals.

Source: *The Hindu,* 6th January 2024

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