ISSUE No. 65

SILVER JUBILEE YEAR 2016

TAMILNADU PHARMACEUTICALS SCIENCES WELFARE TRUST

25 Years

Pharma Web

Newsletter of Tamilnadu Pharmaceutical Sciences Welfare Trust

Jul. 2025 - Dec. 2025

Sai Mirra
Innopharm

MOVING GLOBALLY

PIC/S
Approved Facility

WHO-GMP
CERTIFIED

Formulation R & D and Manufacturing | **International Marketing** | **Domestic Marketing**

"We develop and manufacture medicine the way a mother prepares food for her child."

www.saimirra.com

NURAY CHEMICALS PVT. LTD.
API R & D and Manufacturing

HIBROW
Formulation R & D and Manufacturing

Tamilnadu Pharmaceutical Sciences Welfare Trust

Pharma Web

Newsletter of Tamilnadu Pharmaceutical Sciences Welfare Trust

ISSUE : 65 Jul. 2025 - Dec. 2025

CONTENTS **Page No.**

TAMILNADU PHARMACEUTICAL SCIENCES WELFARE TRUST
No. 608A, 6th Floor, Phase I, Spencer Plaza, 768 / 769, Anna Salai, Chennai – 600002
Ph: 044 - 28491232
e-mail : pictrust89@gmail.com Website : www.pictrust.com

EDITORIAL

Dear Readers,

It is with great pleasure that we present the 65th edition of the *Pharma Web Newsletter*, covering the period from Jul to Dec 2025. This issue is packed with valuable content, including program highlights and insightful presentations by distinguished experts from the pharmaceutical industry:

- **Indian Pharmacopoeia Reference Standards - Dr. Manisha Trivedi,** Scientific Officer, Indian Pharmacopoeia Commission, Ghazibad
- **Pharmacopeial Standards, Regulatory Standards & Quality Consideration Challenges Associated in Testing of Oral Liquids / OSD Manufacturing - Mrs. B.Jayashree**, Head-Corporate Quality, The Madras Pharmaceuticals, Chennai
- **Role of the Indian Pharmacopoeia Commission in Medical Products' Quality & Safety - Dr. V. Kalaiselvan,** Secretary-cum-Scientific Director, Indian Pharmacopoeia Commission, Ghazibad

Additionally, this edition features a collection of **Gazette Notifications** related to amendments in the Drugs & Cosmetics Act and Rules, as well as key circulars from the DCGI concerning drugs and pharmaceuticals. We've also curated significant news articles from national publications, providing a well-rounded perspective on recent developments in the pharmacy sector. Furthermore, pertinent *Parliamentary Questions and Answers* relevant to our profession are included to keep you informed of legislative updates.

We extend our sincere gratitude to **M/s. Delvin Formulations**, **M/s. Medopharm**, and **M/s. Tablets (India) Ltd.** for their unwavering support through advertisements, which play a vital role in sustaining this publication.

A special acknowledgment goes to **M/s. Fourrts (India) Laboratories Pvt. Ltd.** for their invaluable contributions to *Pharma Web* advertising and their dedication to nurturing talent in the field through the meritorious awards granted to B.Pharm students of *The Tamilnadu Dr. MGR Medical University*, Guindy, Chennai. Their commitment to fostering excellence in our profession is truly commendable.

We trust this newsletter will serve as a useful resource for our pharmaceutical professionals. Your feedback and suggestions for improvement are always welcomed and greatly appreciated.

With Best Regards,

R. NARAYANASWAMY

Chief Editor

ARTICLES

Indian Pharmacopoeia Reference Standards

by
Dr. Manisha Trivedi
Scientific Officer, Indian Pharmacopoeia Commission, Ghazibad

Presented at the IPC & IDMA, Tamilnadu interactive session held on 8th November 2025 at Hotel Hablis, Guindy, Chennai

Agenda

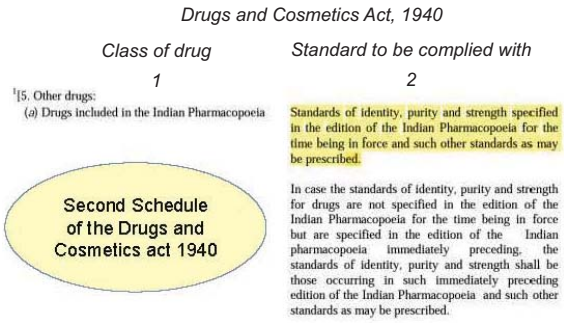
1.What is IPRS
2.Legal and Regulatory Status
3.Applications of IPRS
4.Development, Characterization Process and Certification
5.Amendments related to DEG and EG &IPRS
6.Comparison: IPRS vs. Working Standards
7.Outreach and Global Recognition
8.Procurement/Purchase
9.Challenges
10.Key Takeaways

Reference Standards -IPRS

- A **reference standard** is a substance of **known purity and identity** established through comprehensive testing using validated analytical methods, and used for calibrating analytical instruments, validating methods, or assessing the performance of a test sample Reference Standards IPRS
- In India, **pharmaceutical reference standards are officially governed, established, and distributed by the Indian Pharmacopoeia Commission (IPC)** in the form of **Indian Pharmacopoeia Reference Standards (IPRS)**
- These serve as the **primary and legally recognized standards** for all analytical procedures described in the Indian Pharmacopoeia (IP)

Legal Status of IPRS

- IP is published by the IPC to fulfill the requirements of the Second Schedule of the Drugs and Cosmetics Act 1940 and Rules thereunder
- These standards carry official status meaning all analytical tests described in IP must use IPRS or materials standardized against them for compliance
- In 2022 2023 a regulatory notification by the ministry emphasized that the use of authentic IPRS and IMP RS issued by IPC is mandatory for quality control and compliance



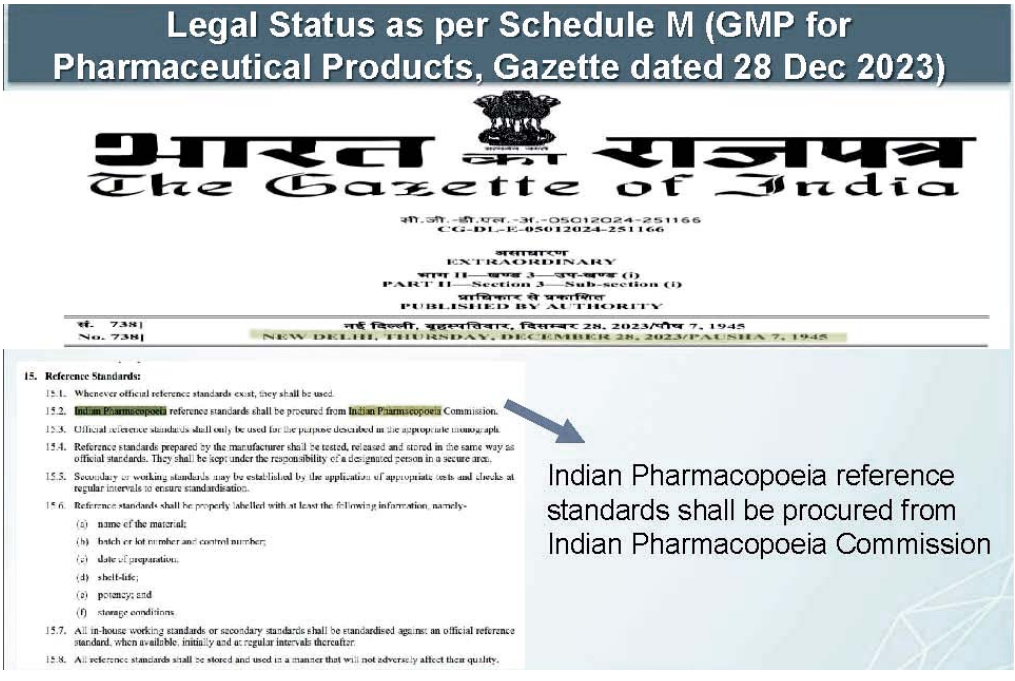
IP Reference Substances (IPRS)

Indian Pharmacopoeia Reference Substance abbreviated, as IPRS in the individual monographs, are issued by the Indian Pharmacopoeia Commission (IPC) or by laboratories authorized by the IPC and assume the official status in India. Where an IPRS is referred to in an official TP monograph, it becomes a part of the official standard that is alone authoritative in case of doubt or dispute to determine compliance with the TP.

Legal Notices

In India, under the Drugs and Cosmetics Act 1940, the current edition of Indian Pharmacopoeia is a book of standards for drugs included therein and the standards as included in the Indian Pharmacopoeia would be official. Also, in several other laws of India, the Indian Pharmacopoeia is recognised as the standard book. It is expedient that enquiry be made in each

Legal Status as per Schedule M (GMP for Pharmaceutical Products, Gazette dated 28 Dec 2023)



IPC Notice Regarding IPRS & Impurity Standards

A.11020/05/2023-DR

13/13

भारतीय फार्मेकोपिया आयोग
स्वास्थ्य एवं परिवार कल्याण मंत्रालय, भारत सरकार
सेक्टर 23, राज नगर
गाजियाबाद 201002 (उ.प्र.), भारत

INDIAN PHARMACOPOEIA COMMISSION
Ministry of Health & Family Welfare, Government of India
Sector 23, Raj Nagar
Ghaziabad 201002 (U.P.), INDIA

डा. राजीव सिंह रघुवंशी
सचिव-सह-वैज्ञानिक निदेशक

Dr. Rajeev Singh Raghuvanshi
Secretary-cum-Scientific Director

No. T.11013/02/2018-AR&D

Dated: October 7, 2022

Subject: Ensuring Use of Indian Pharmacopoeia Reference Standards (IPRS) and Impurity Standards for Quality Testing of Drugs-reg.

Sir,

This has reference to your letter No. 29/Misc/14/2022-DC dated 11.03.2022 on the subject mentioned above. In this regard, I am happy to share that IPC has recently achieved the milestone of developing a total of 1000 IPRS and Impurity Standards. Currently there are 660 IPRS and 345 Impurity Standards listed in the IPC catalogue and the details are available on our website www.ipc.gov.in. In addition, IPC has also come with the publication of 9th edition of IP 2022 which will be effective from 1st December, 2022.

2. IPC is also making efforts to promote the use of authentic copies of IP 2022 along with IPRS and Impurity Standards by the pharmaceutical manufacturers and drug testing laboratories for which awareness programmes for stakeholders are being oragnised by IPC across India.

3. It is brought to your kind notice that IPC is the only supplier of IPRS and Impurity Standards and IPC has not authorised any other party for their disctribution. Using unauthorised Reference Standards is violation of provisions of the Drugs and Cosmetics Act 1940.

4. This subject was discussed during the 21st meeting of the Governing Body of IPC held on 28th April, 2022 and minuted as Item No. 4 in the minutes (copy enclosed). As advised by the Governing Body Chairman, CDSCO had to write to State Regulators to support promotion of IPRS/Impurity Standards and use by stakeholders in their respective States. The status of the action has to be updated in the forthcoming 22nd meeting of the Governing Body scheduled for 14th October, 2022.

Please send us the current status of the action.

Thanking you,

Yours sincerely,

(Dr. Rajeev Singh Raghuvanshi)

CDSCO Notice Regarding IPRS & Impurity Standards

F. no. 29/Misc./14/2022-DC
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
(DTAB-DCC Division)

FDA Bhawan, Kotla Road,
New Delhi-110002
Date: 10 OCT 2022

To
All States /UT Drugs Controllers

Subject: Ensuring use of Indian Pharmacopoeia Reference Standards (IPRS) and Impurity Standards for Quality Testing of Drugs-regarding.

Sir/ Madam,

Please find herewith the attached letter no. T.11013/02/2018-AR&D dated 07.10.2022 issued by the Indian Pharmacopoeia Commission (IPC) to ensure use of Indian Pharmacopoeia Reference Standard (IPRS) and Impurity Standards for Quality Testing of Drugs, which is self-explanatory.

As informed by the IPC, they have recently achieved the milestone of developing a total of 1000 IPRS and impurity standards. Currently there are 660 IPRS and 345 impurity standards listed in the IPC catalogue and the details are available in IPC website www.ipc.gov.in.

Earlier, *vide* letter no. 29/Misc./14/2022-DC dated 11.03.2022 you were requested to do the needful for the use of Reference Standards and Impurity Standards of Indian Pharmacopoeia Commission by pharmaceutical manufacturers and testing laboratories.

You are requested once again to do the needful for the use of Reference Standards and Impurity Standards of Indian Pharmacopoeia Commission (IPC) as per the Drugs and Cosmetics Act 1940 and Rules thereunder, for Quality Testing of Drugs by pharmaceutical manufacturers and testing laboratories in the country.

Yours faithfully,

(Dr. V.G. Somani)
Drugs Controller General (India)

D.O Letter Issued by MOH&FW

G20 भारत 2023 INDIA

राजेश भूषण, आईएएस
सचिव
RAJESH BHUSHAN, IAS
SECRETARY

सत्यमेव जयते

आज़ादी का अमृत महोत्सव

भारत सरकार
स्वास्थ्य एवं परिवार कल्याण विभाग
स्वास्थ्य एवं परिवार कल्याण मंत्रालय
Government of India
Department of Health and Family Welfare
Ministry of Health and Family Welfare
D.O. No. A.11020/05/2023-DR
5th May, 2023

Dear Colleague,

The Indian Pharmacopoeia Commission (IPC) functions as an autonomous Institute under the Ministry of Health & Family Welfare (MoHFW). In order to fulfill the requirements of the Drugs and Cosmetics (D&C) Act, 1940 and Rules 1945 there under, MoHFW, Government of India has entrusted IPC with mandates of publishing the Indian Pharmacopoeia (IP) at regular intervals along with the certification and distribution of IP Reference Standards (IPRS) and Impurity Standards. An IPRS, being an integral and essential component of the IP standard, is an official standard that alone is authoritative in assessing the quality of drugs and use of any unauthorised Reference Standard is a noncompliance of the IP standards.

As per Schedule M of the D&C Act, Part I, Quality Control System (16.14) - "Pharmacopoeia reference standards, working standards, references, spectra, other reference materials and technical books, as required, shall be available in the Quality Control Laboratory of the licensee". IPC has been making efforts to promote the use of authentic copies of the IP, IPRS, and Impurity Standards by the manufacturers and testing laboratories. In this regard, a letter no. 29/Misc./14/2022-DC dated 10-10-2022 was also issued from Central Drugs Standard Control Organisation (CDSCO) to ensure the availability of authentic copies of IP and to promote the use of IPRS and Impurity Standards during quality control analysis of drugs. (copy enclosed)

It has come to the notice of the Ministry that counterfeit copies of the IP and unauthorised Reference Standards are being referred to and used for laboratory work in violation of the provisions of the D&C Act 1940. Such malpractices may lead manufacturing and marketing of counterfeit/spurious drugs in India which may lead to hazardous health consequences in the Country.

I would, therefore, request you to take necessary steps and issue directions to the Drugs Controllers of your States/UTs to ensure the use of authentic IP, IPRS, and Impurity Standards by the drug manufactures and testing laboratories under their control. Details for purchasing IP, IPRS, and Impurity Standards are available on IPC website (www.ipc.gov.in). These requirements may also be included in the checklist of the ongoing joint inspections planned by the CDSCO and States/UTs Drug Regulators.

Your support in this drive is highly solicited for ensuring availability of quality medicines and strengthening the overall drug regulatory framework of India.

Warm regards.

Yours sincerely,

Encl : as above

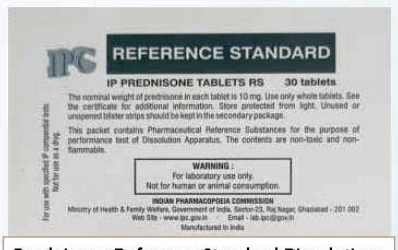
(Rajesh Bhushan)

Reference Substances available at IPC

IP Reference Substances (IPRS)

Impurity Reference Substances (IMP-RS)

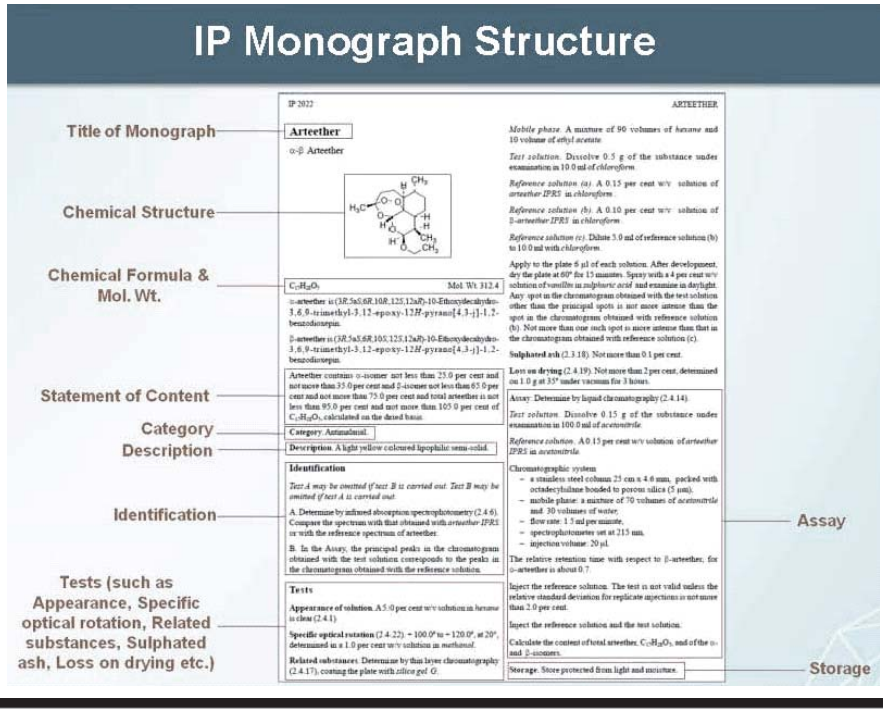
Phytochemical Reference Substances (IPPRS)



Prednisone Reference Standard Dissolution

Various uses of IPRS

Qualitative	Identification (IR), peak identification (By HPLC,GC,UV)
Quantitative	Assay, related substances, Dissolution and Content Uniformity
System Suitability	Resolution, S/N Ratio, peak to valley, theoretical plates, tailing factor, RSD, RRT
Verification / Calibration	• **Caffeine (IPRSC050)** is available at IPC which is recommended to use in Calibration of HPLC. • **IP Prednisone Dissolution Calibrator Tablet (IPRSP088)** is available at IPC which is recommended to verify the performance of Dissolution apparatus. • **Nicotinic Acid (IPRSN018)** is also developed by IPC and is mentioned in IP 2022 for use in calibration of UV. • **primary reference materials** for the **qualification of in-house working standards**



Example: Rifampicin Reference Standard

Identification

A. Determine by infrared absorption spectrophotometry (2.4.6). Compare the spectrum with that obtained with *rifampicin IPRS* or with the *reference spectrum* of rifampicin.

B. In the Assay, the principal peak in the chromatogram obtained with the test solution corresponds to the peak in the chromatogram obtained with the reference solution.

Tests

pH (2.4.24). 4.5 to 6.5, determined in a 1.0 per cent w/v suspension.

Related substances. Determine by liquid chromatography (2.4.14)

NOTE – Prepare the solutions immediately before use.

Solvent mixture. A mixture of 10 volumes of a 21.01 per cent w/v solution of *citric acid* 23 volumes of a 13.61 per cent w/v solution of *potassium dihydrogen phosphate*, 77 volumes of a 17.42 per cent w/v solution of *dipotassium hydrogen phosphate*, 640 volumes of *water* and 250 volumes of *acetonitrile*.

Test solution. Weigh a quantity of powder containing 20 mg of Rifampicin, add 10 ml of *acetonitrile*, shake and filter. Dilute 5 ml of the filtrate to 50 ml with the solvent mixture.

Reference solution. A solution containing 0.02 per cent w/v of *rifampicin quinone IPRS* in *acetonitrile*. To 1 ml of the solution, add 1 ml of the test solution and dilute to 100 ml with the solvent mixture.

Chromatographic system

- a stainless steel column 10 cm x 4.6 mm, packed with octylsilane bonded to porous silica (5 µm),
- mobile phase: a mixture of 65 volumes of a solution containing 0.1 per cent w/v of *orthophosphoric acid*, 0.19 per cent w/v of *sodium perchlorate*, 0.59 per cent w/v of *citric acid* and 2.09 per cent w/v of *potassium dihydrogen phosphate* and 35 volumes of *acetonitrile*,
- flow rate: 1.5 ml per minute,
- spectrophotometer set at 254 nm,
- injection volume: 20 µl.

Rifampicin Quinone IMP-RS used in RS testing

Rifampicin IPRS used in Identification test by IR

Example: 4 FDC Reference Standard

Rifampicin, Isoniazid, Pyrazinamide and Ethambutol Tablets

Rifampin, Isonicotinylhydrazid, Pyrazinamide and Ethambutol Hydrochloride Tablets

Rifampicin, Isoniazid, Pyrazinamide and Ethambutol Tablets contain not less than 90.0 per cent and not more than 110.0 per cent of the stated amounts of rifampicin, $C_{43}H_{58}N_4O_{12}$, isoniazid, $C_6H_7N_3O$, pyrazinamide, $C_5H_5N_3O$ and ethambutol hydrochloride, $C_{10}H_{24}N_2O_2.2HCl$.

Usual strength. Rifampicin 150 mg, Isoniazid 75 mg, Pyrazinamide 400 mg and Ethambutol 275 mg.

Identification

A. In the Assay for rifampicin, isoniazid and pyrazinamide, the principal peaks in the chromatogram obtained with the test solution correspond to the peaks in the chromatogram obtained with the reference solution.

B. In the Assay for ethambutol hydrochloride, the principal peak in the chromatogram obtained with the test solution corresponds to the peak in the chromatogram obtained with the reference solution.

Tests

Dissolution (2.9.3).

Apparatus No. 2 (Paddle).

Medium: 900 ml of *sodium phosphate buffer pH 6.8* prepared by dissolving 7 g of *dibasic sodium phosphate anhydrous* in 5000 ml of *water* and adjusting to pH 6.8 with *orthophosphoric acid*.

Speed and time: 100 rpm and 45 minutes.

Withdraw a suitable volume of the medium and filter through a membrane filter disc with an average pore diameter not greater than 0.8 µm. Reject the first few ml of the filtrate. Determine the amounts of rifampicin, $C_{43}H_{58}N_4O_{12}$, isoniazid, $C_6H_7N_3O$, pyrazinamide, $C_5H_5N_3O$ and ethambutol hydrochloride, $C_{10}H_{24}N_2O_2.2HCl$ by using the methods described under Assay for rifampicin, isoniazid, pyrazinamide and ethambutol hydrochloride.

Q. Not less than 75 per cent of the stated amounts of $C_{43}H_{58}N_4O_{12}$, $C_6H_7N_3O$, $C_5H_5N_3O$ and $C_{10}H_{24}N_2O_2.2HCl$.

Related substances. Determine by liquid chromatography (2.4.14).

NOTE – Prepare the solutions immediately before use.

Solvent mixture. A mixture of 10 volumes of a 21.01 per cent w/v solution of *citric acid* 23 volumes of a 13.61 per cent w/v solution of *potassium dihydrogen phosphate*, 77 volumes of a 17.42 per cent w/v solution of *dipotassium hydrogen phosphate*, 640 volumes of *water* and 250 volumes of *acetonitrile*.

Test solution. Weigh a quantity of powdered tablets containing 200 mg of Rifampicin, dissolve in 100 ml of *acetonitrile* and filter. Dilute 5 ml of the solution to 50 ml with the solvent mixture.

Reference solution (a). Dissolve 20 mg of *rifampicin IPRS* in 100 ml of *acetonitrile*. Dilute 1.0 ml of the solution to a 100.0 ml with the solvent mixture.

Reference solution (b). A solution containing 0.01 per cent w/v each of *rifampicin IPRS* and *rifampicin quinone IPRS* in *acetonitrile*. Dilute 5.0 ml of the solution to 50.0 ml with the solvent mixture.

Assay. *For Rifampicin, Isoniazid and Pyrazinamide* – Determine by liquid chromatography (2.4.14).

Test solution. Weigh and powder 20 tablets. Weigh a quantity of the powdered tablets containing about 40 mg of Isoniazid, dissolve in 100 ml of *methanol*, dilute to 500 ml with the buffer solution pH 6.8, mix and filter.

Reference solution. A solution containing 0.08 per cent w/v of *rifampicin IPRS*, 0.04 per cent w/v of *isoniazid IPRS* and 0.2 per cent w/v of *pyrazinamide IPRS* in *methanol*. Dilute 10.0 ml of the solution to 50.0 ml with the buffer solution pH 6.8.

For Ethambutol Hydrochloride – Determine by liquid chromatography (2.4.14).

Test solution. Weigh a quantity of the powdered tablets containing about 60 mg of Ethambutol Hydrochloride and dissolve in 100 ml of the solvent mixture.

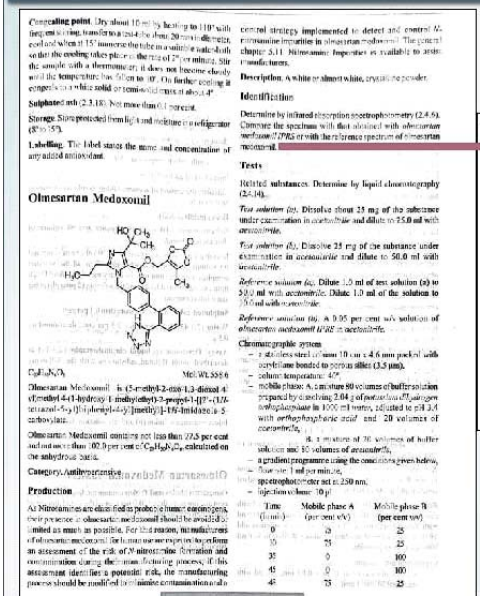
Reference solution. A 0.06 per cent w/v solution of *ethambutol hydrochloride IPRS* in the solvent mixture.

Chromatographic system

1. Rifampicin IPRS,
2. Isoniazid IPRS,
3. Pyrazinamide IPRS
4. Ethambutol IPRS

used in Assay testing

IPRS in Identification



Olmesartan Medoxomil

Olmesartan Medoxomil is (5-methyl-2-oxo-1,3-dioxol-4-yl)methyl 4-(1-hydroxy-1-methylethyl)-2-propyl-1-[[2′-(1*H*-tetrazol-5-yl)[1,1′-biphenyl]-4-yl]methyl]-1*H*-imidazole-5-carboxylate.

Olmesartan Medoxomil contains not less than 97.5 per cent and not more than 102.0 per cent of $C_{29}H_{30}N_6O_6$, calculated on the anhydrous basis.

Category: Antihypertensive.

Production

As Nitrosamines are classified as probable human carcinogens, every precaution to olmesartan medoxomil should be avoided or limited as much as possible. For this reason, manufacturers of olmesartan medoxomil for human use are required to perform an assessment of the risk of *N*-nitrosamine formation and contamination during their manufacturing process; if this assessment identifies a potential risk, the manufacturing process should be modified to minimise contamination and to control strategy implemented to detect and control *N*-nitrosamine impurities in olmesartan medoxomil. The general chapter 5.11 Nitrosamine Impurities is available to assist manufacturers.

Description. A white or almost white, crystalline powder.

Identification

Determine by infrared absorption spectrophotometry (2.4.6). Compare the spectrum with that obtained with *olmesartan medoxomil for IPRS* or with the reference spectrum of olmesartan medoxomil.

Tests

Related substances. Determine by liquid chromatography (2.2.46).

Test solution (a). Dissolve about 25 mg of the substance under examination in *acetonitrile* and dilute to 25.0 ml with *acetonitrile*.

Test solution (b). Dissolve 25 mg of the substance under examination in *acetonitrile* and dilute to 50.0 ml with *acetonitrile*.

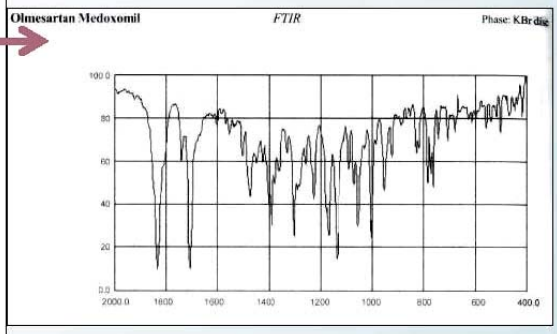
Reference solution (a). Dilute 1.0 ml of test solution (a) to 50.0 ml with *acetonitrile*. Dilute 1.0 ml of the solution to 10.0 ml with *acetonitrile*.

Reference solution (b). A 0.05 per cent w/v solution of *olmesartan medoxomil IPRS* in *acetonitrile*.

Chromatographic system

- a stainless steel column 10 cm × 4.6 mm packed with octylsilane bonded to porous silica (3.5 µm),
- column temperature: 45°,
- mobile phase: A, a mixture 80 volumes of buffer solution prepared by dissolving 2.04 g of *potassium dihydrogen orthophosphate* in 1000 ml water, adjusted to pH 2.5 with *orthophosphoric acid* and 20 volumes of *acetonitrile*; B, a mixture of 70 volumes of buffer solution and 30 volumes of *acetonitrile*,
- a gradient programme using the conditions given below,
- flow rate: 1 ml per minute,
- spectrophotometer set at 250 nm,
- injection volume: 10 µl.

Time (minutes)	Mobile phase A (per cent v/v)	Mobile phase B (per cent v/v)
0	25	25
35	75	25
35	0	100
45	0	100
46	75	25

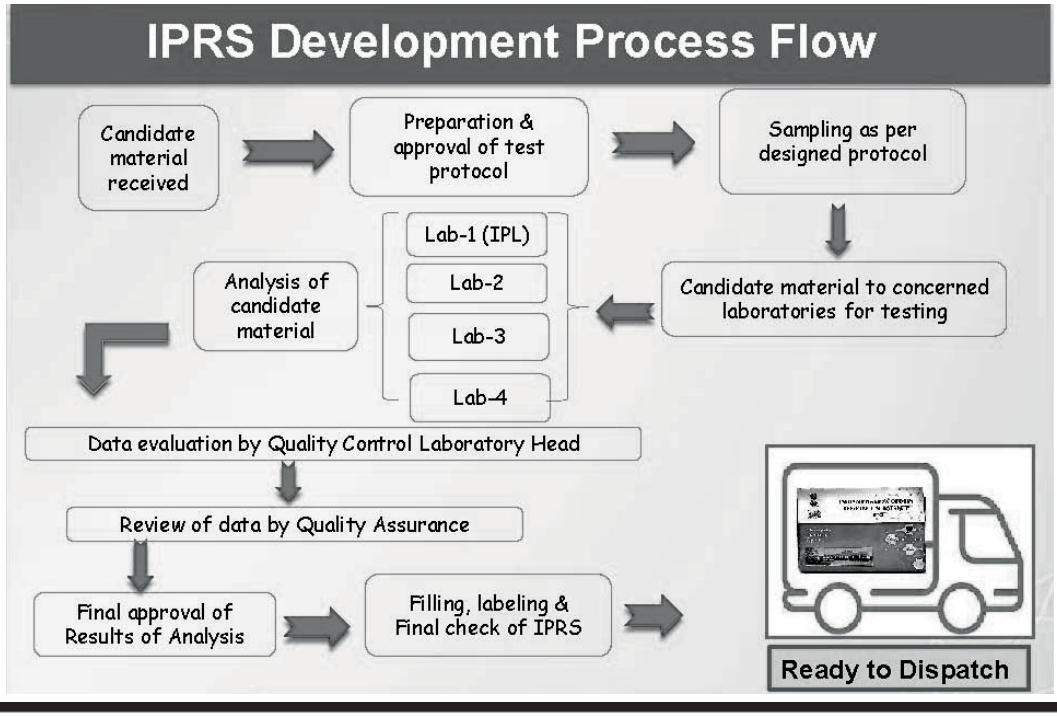


Production Planning of IPRS

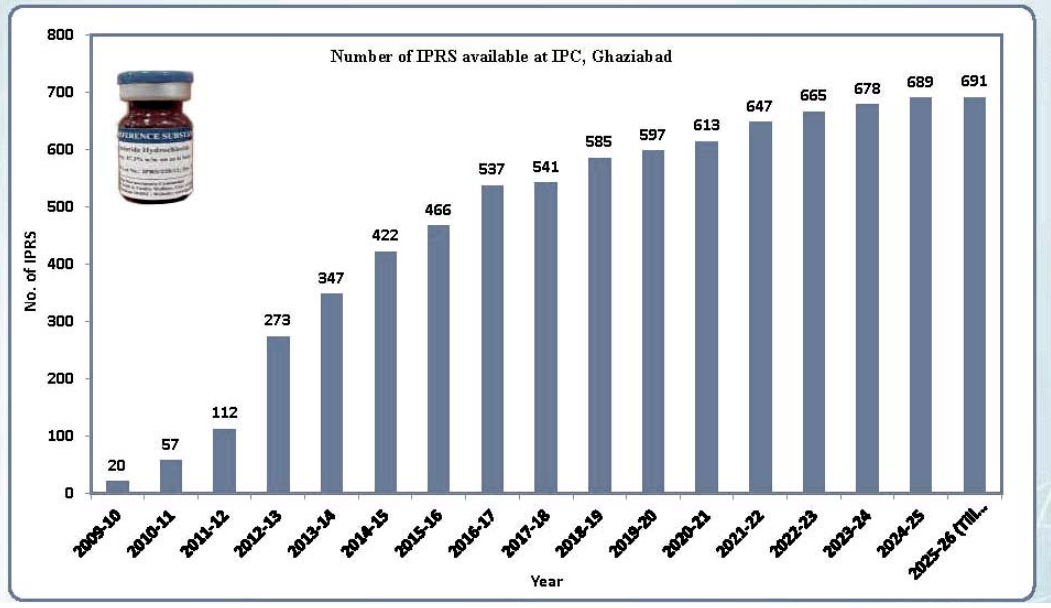
1. Source of selected reference material as per IP
   - WHO qualified
   - FDA approved Lab
   - Procurement as per GFR rules
2. Selection of certified material (Purity NLT 99.0%)
3. Verification of material (Purity, identity and stability)
4. Material processing and characterization across multiple laboratories using validated analytical methods (HPLC, GC, NMR, IR, MS, elemental analysis)
5. Measurement Testing (IP/B.P/U.S.P) & Statistical evaluation of results
6. Adequate storage, packing, labeling and distribution / transport

Development and Standardization of IPRS

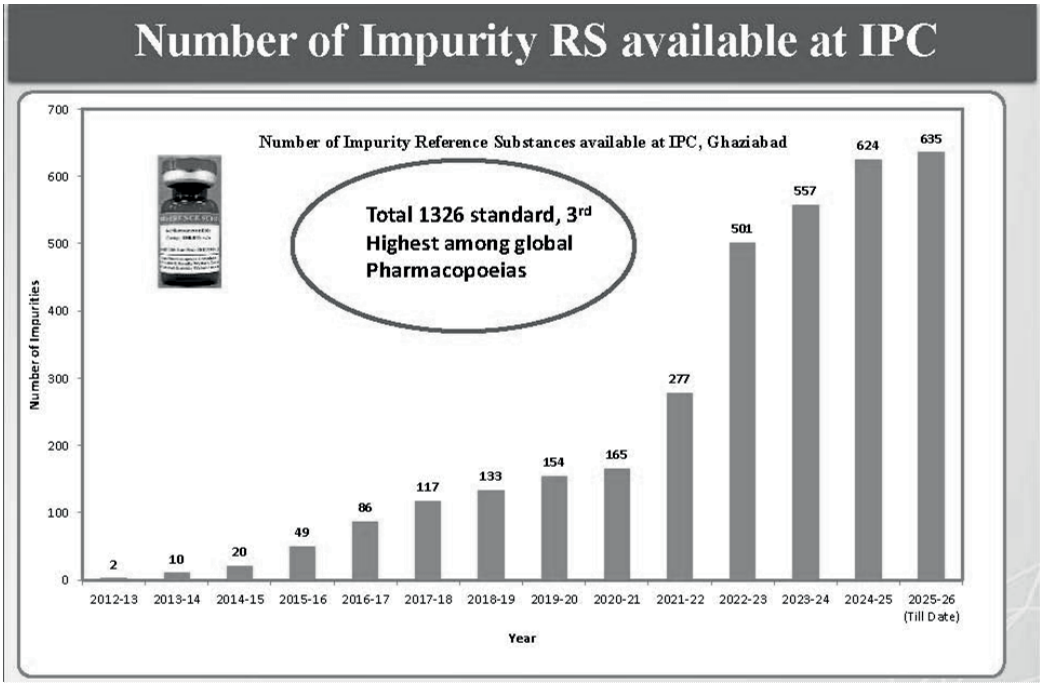
- IPRS characterization done by multiple method such as MS, NMR, CHNS
- IPRS developed by using mass balance method
- The potency/purity of IPRS shall be assigned on the basis of chromatographic purity, LOD/Water, Residual solvents and Sulphated ash



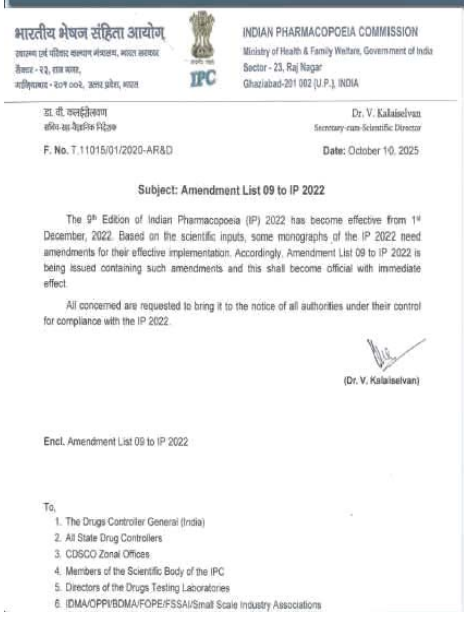
Number of IPRS available at IPC



Number of Impurity RS available at IPC



Amendments related to DEG and EG



भारतीय भेषज संहिता आयोग
INDIAN PHARMACOPOEIA COMMISSION
Ministry of Health & Family Welfare, Government of India
Sector - 23, Raj Nagar
Ghaziabad-201 002 (U.P.), INDIA

Dr. V. Kalaiselvan
Secretary-cum-Scientific Director

F. No. T.11015/01/2020-AR&D
Date: October 10, 2025

Subject: Amendment List 09 to IP 2022

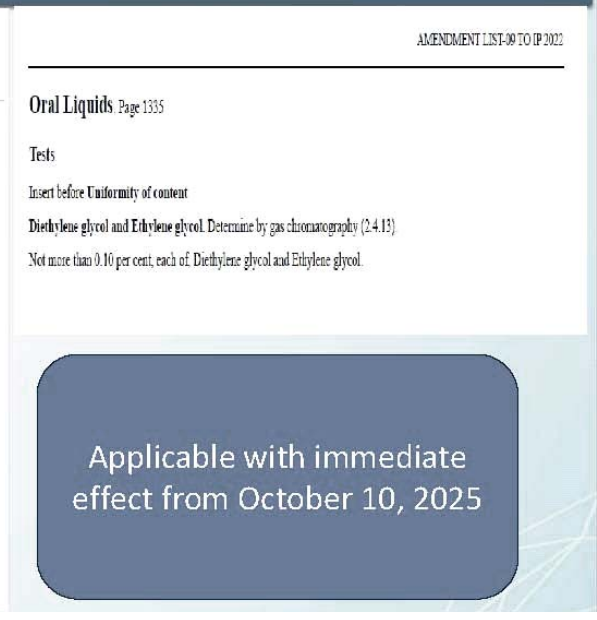
The 9th Edition of Indian Pharmacopoeia (IP) 2022 has become effective from 1st December, 2022. Based on the scientific inputs, some monographs of the IP 2022 need amendments for their effective implementation. Accordingly, Amendment List 09 to IP 2022 is being issued containing such amendments and this shall become official with immediate effect.

All concerned are requested to bring it to the notice of all authorities under their control for compliance with the IP 2022.

(Dr. V. Kalaiselvan)

Encl. Amendment List 09 to IP 2022

To,
1. The Drugs Controller General (India)
2. All State Drug Controllers
3. CDSCO Zonal Offices
4. Members of the Scientific Body of the IPC
5. Directors of the Drugs Testing Laboratories
6. IDMA/OPPI/BDMA/FOPE/FSSAI/Small Scale Industry Associations



AMENDMENT LIST-09 TO IP 2022

Oral Liquids Page 1335

Tests

Insert before **Uniformity of content**

Diethylene glycol and Ethylene glycol. Determine by gas chromatography (2.4.13)

Not more than 0.10 per cent, each of Diethylene glycol and Ethylene glycol.

Applicable with immediate effect from October 10, 2025

IPRS Availability of DEG and EG

Excipient Monographs of the IP

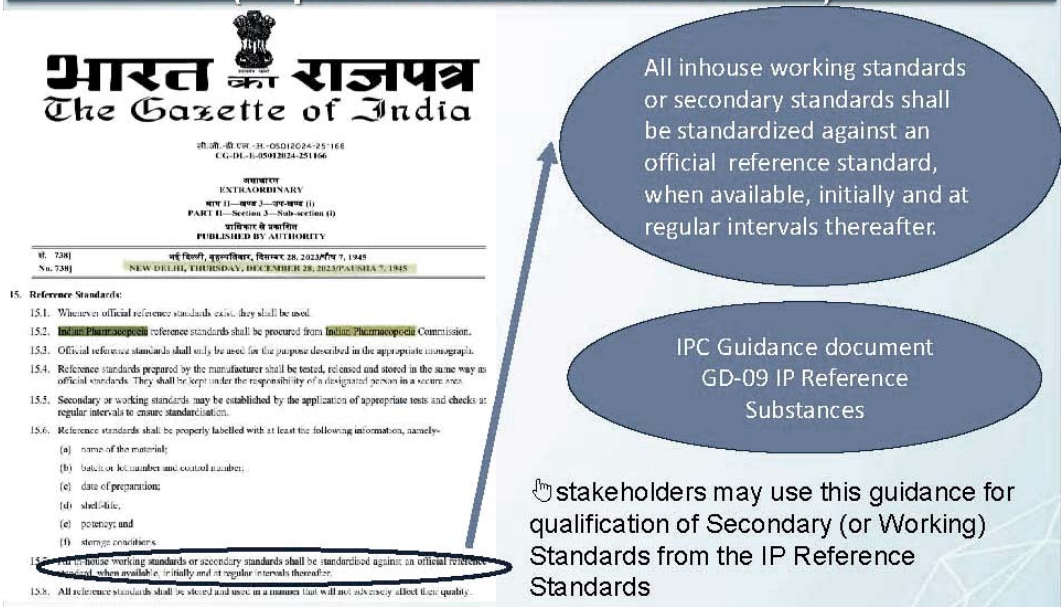
Glycerin
Propylene Glycol
Sorbitol solution (70 per cent crystallising)
Sorbitol solution (70 per cent non crystallising)
Liquid Maltitol

IPC Guidance document
GD-11 Testing of DEG and EG

To ensure analytical accuracy and traceability, the relevant IP Reference Standards (IPRS) materials are available through the IPC

→ Diethylene Glycol IPRS,
Ethylene Glycol IPRS,
Glycerin (Glycerol) IPRS,
Propylene Glycol IPRS,
Sorbitol IPRS

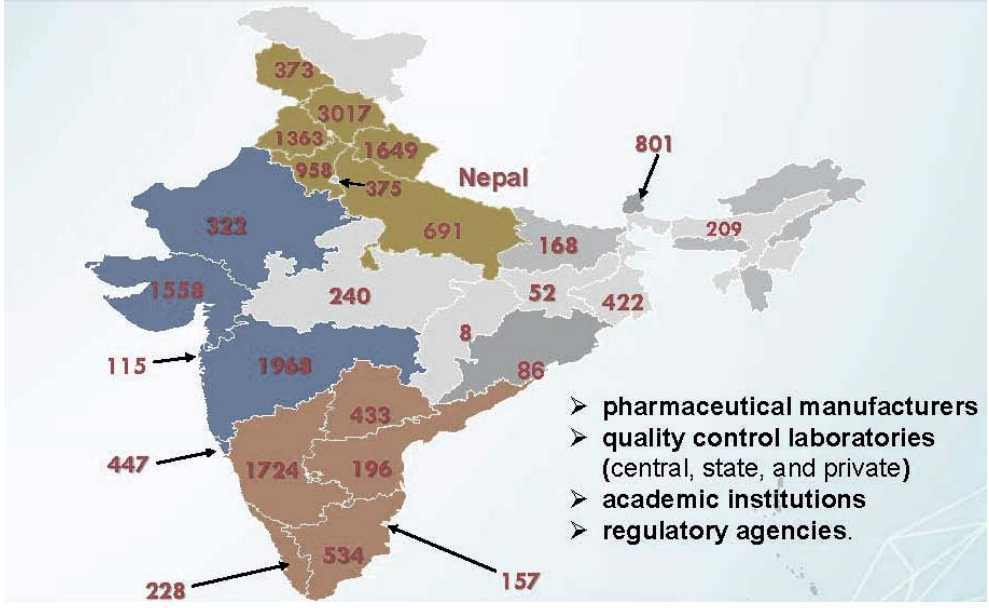
Use of working standards or secondary standards (as per Gazette dated 28 Dec 2023)



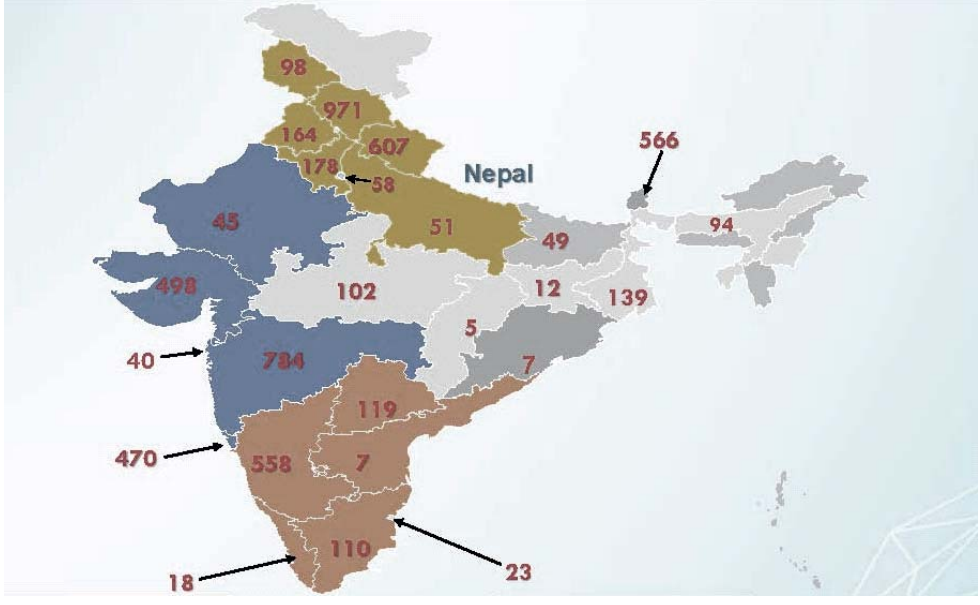
Comparison between IPRS & working standards or secondary standards

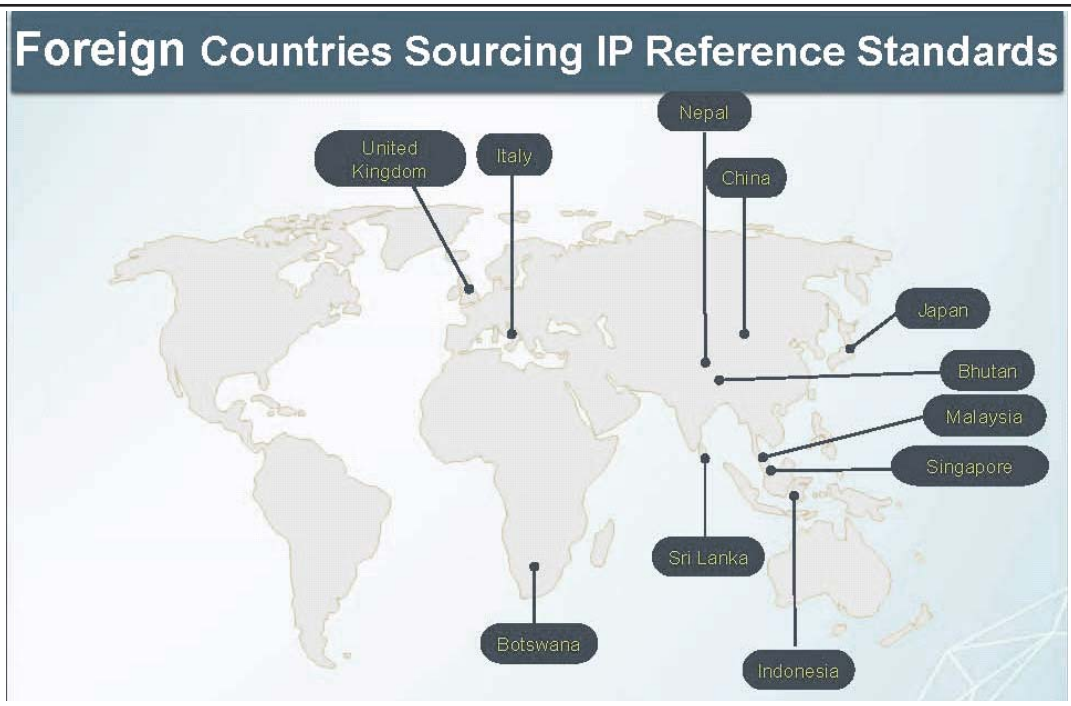
Parameter	IPRS	Working Standard (WS)
Purpose in QC	Ensuring metrological traceability and regulatory compliance	operational extensions of IPRS, allowing laboratories to maintain analytical accuracy and consistency in routine pharmaceutical testing
Governing body	Indian Pharmacopoeia Commission (IPC)	Individual laboratory / industry
Type	Primary Pharmacopoeial reference	Secondary laboratory reference
Basis of purity	Certified (mass balance/absolute method)	Standardlized against IPRS
Use	Method validation, identity confirmation, WS qualification	Routine testing
Traceability	Primary Standard	IPRS
Certification	Accompanied by IPC Certificate	Internal qualification report
Renewal Requalification	Continuous post-distribution monitoring, stability testing, and periodic recharacterization	defined intervals or when there is a change in batch, storage conditions, or analytical performance

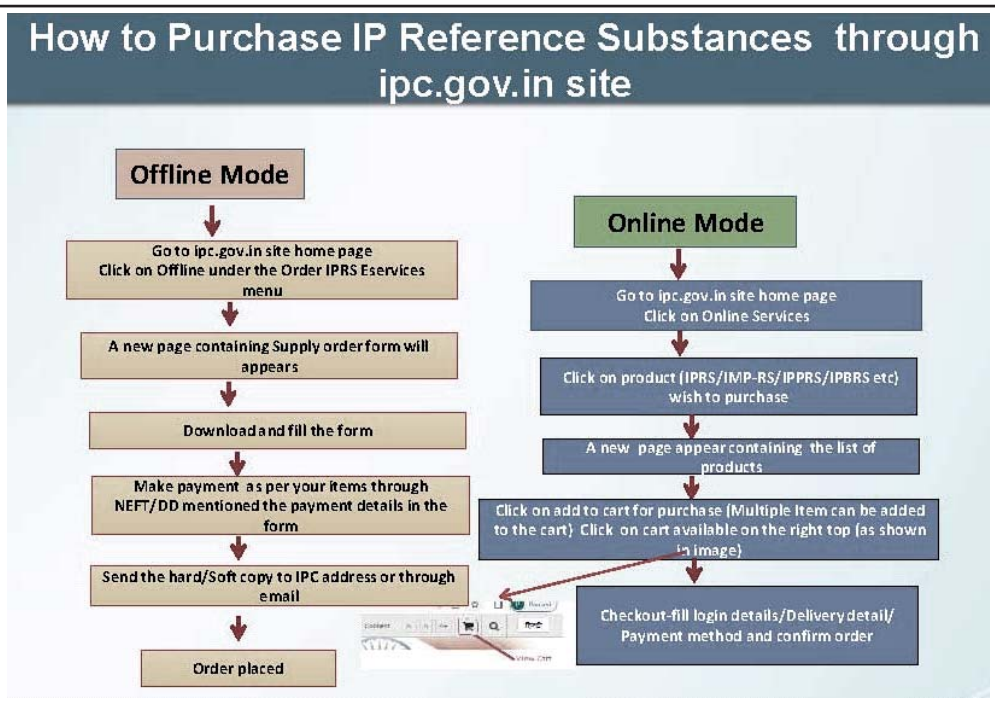
Number of IPRS Vials Sourced State wise for the FY 2024 – 2025



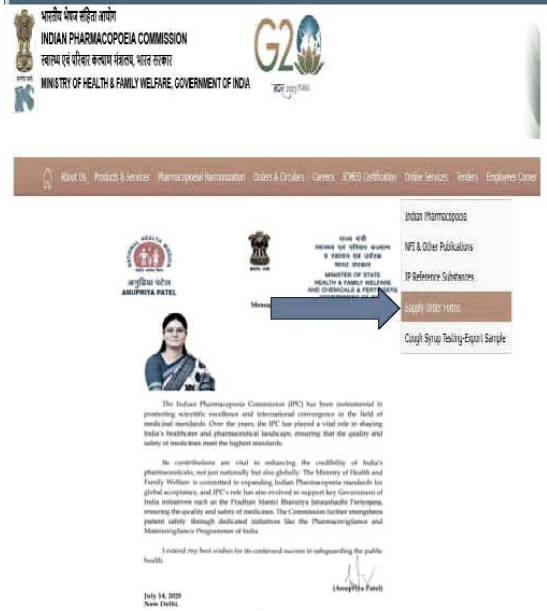
Number of Impurity Vials Sourced State wise for the FY 2024 – 2025

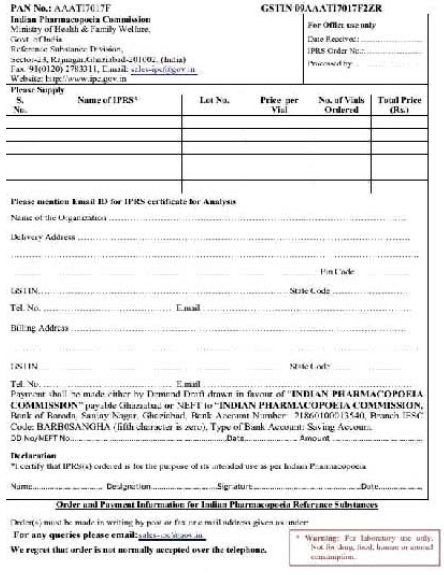



Foreign Countries Sourcing IP Reference Standards
Nepal
United Kingdom
Italy
China
Japan
Bhutan
Malaysia
Singapore
Sri Lanka
Botswana
Indonesia


How to Purchase IP Reference Substances through ipc.gov.in site
Offline Mode
Go to ipc.gov.in site home page
Click on Offline under the Order IPRS Eservices menu
A new page containing Supply order form will appears
Download and fill the form
Make payment as per your items through NEFT/DD mentioned the payment details in the form
Send the hard/Soft copy to IPC address or through email
Order placed
Online Mode
Go to ipc.gov.in site home page
Click on Online Services
Click on product (IPRS/IMP-RS/IPPRS/IPBRS etc) wish to purchase
A new page appear containing the list of products
Click on add to cart for purchase (Multiple Item can be added to the cart) Click on cart available on the right top (as shown in image)
Checkout-fill login details/Delivery detail/ Payment method and confirm order

Offline IPRS Purchase Procedure: www.ipc.gov.in & sales-ipc@gov.in




SUPPLY ORDER FORM

PAN No.: AAATI7017F GSTIN 09AAATI7017F2ZR

Indian Pharmacopoeia Commission
Ministry of Health & Family Welfare,
Govt. of India
Reference Substance Division,
Sector-23, Raipur, Ghaziabad-201002, (India)
Tel: 91(0120) 2783311, Email: sales-ipc@gov.in
Website: http://www.ipc.gov.in

For Office use only
Date Received: .....
IPRS Order No.: .....
Processed by: .....

Please Supply

S. No.	Name of IPRS*	Lot No.	Price per Vial	No. of Vials Ordered	Total Price (Rs.)

Please mention Email ID for IPRS certificate for Analysis

Name of the Organization .....

Delivery Address .....

Pin Code .....

GSTIN ..... State Code .....

Tel. No. ..... Email .....

Billing Address .....

GSTIN ..... State Code .....

Tel. No. ..... Email .....

Payment shall be made either by Demand Draft drawn in favour of "INDIAN PHARMACOPOEIA COMMISSION" payable Ghaziabad, or NEFT to "INDIAN PHARMACOPOEIA COMMISSION, Bank of Baroda, Sanjay Nagar, Ghaziabad, Bank Account Number: 21860100013540, Branch IFSC Code: BARB0SANGHA (fifth character is zero), Type of Bank Account: Saving Account.

DD No/NEFT No. ..... Date ..... Amount .....

Declaration

"I certify that IPRS(s) ordered is for the purpose of its intended use as per Indian Pharmacopoeia.

Name ..... Designation ..... Signature ..... Date .....

Order and Payment Information for Indian Pharmacopoeia Reference Substances

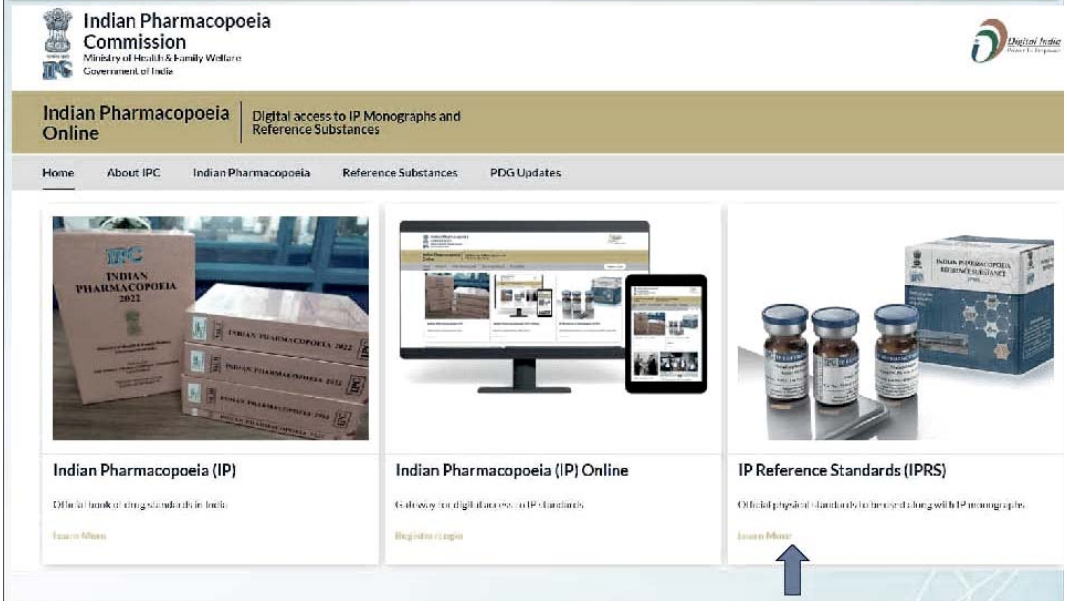
Order(s) must be made in writing by post or fax on e-mail address given as under:

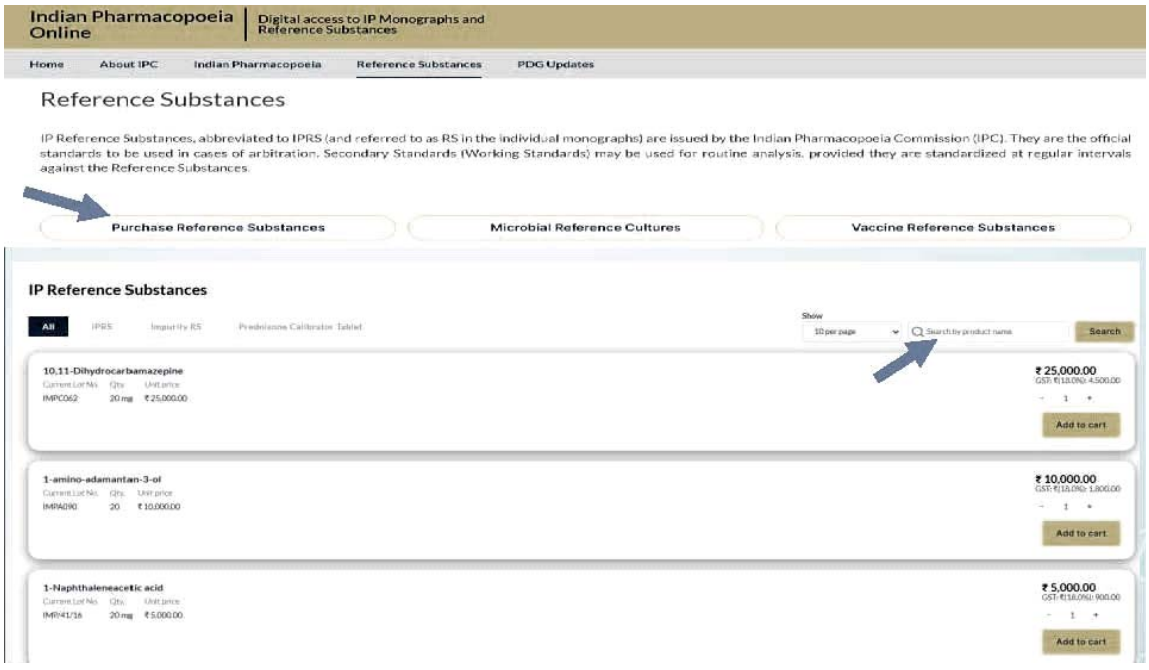
For any queries please email: sales-ipc@gov.in

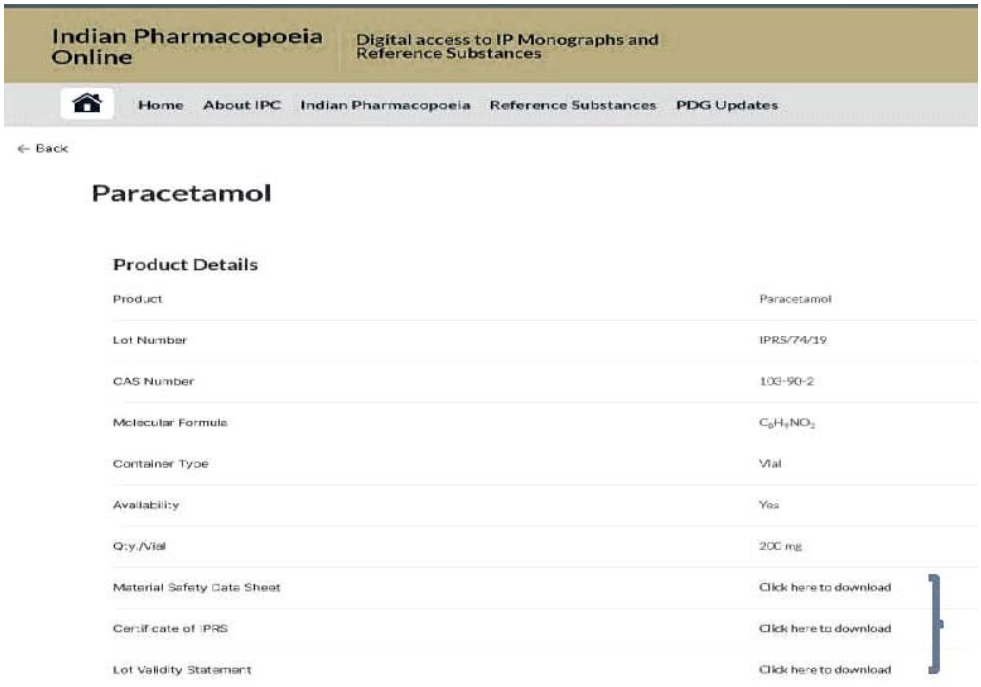
We regret that order is not normally accepted over the telephone.

* Warning: For laboratory use only. Not for drug, food, human or animal consumption.

Purchase IPRS by visiting https://onlinestore.ipc.gov.in




Indian Pharmacopoeia Online
Digital access to IP Monographs and Reference Substances
Home
About IPC
Indian Pharmacopoeia
Reference Substances
PDG Updates
Reference Substances
IP Reference Substances, abbreviated to IPRS (and referred to as RS in the individual monographs) are issued by the Indian Pharmacopoeia Commission (IPC). They are the official standards to be used in cases of arbitration. Secondary Standards (Working Standards) may be used for routine analysis, provided they are standardized at regular intervals against the Reference Substances.
Purchase Reference Substances
Microbial Reference Cultures
Vaccine Reference Substances
IP Reference Substances
All
Search
10,11-Dihydrocarbamazepine
₹ 25,000.00
Add to cart
1-amino-adamantan-3-ol
₹ 10,000.00
Add to cart
1-Naphthaleneacetic acid
₹ 5,000.00
Add to cart


Indian Pharmacopoeia Online
Digital access to IP Monographs and Reference Substances
Home
About IPC
Indian Pharmacopoeia
Reference Substances
PDG Updates
← Back
Paracetamol
Product Details
Product
Paracetamol
Lot Number
IPRS/74/19
CAS Number
103-90-2
Molecular Formula
$C_8H_9NO_2$
Container Type
Vial
Availability
Yes
Qty./Vial
200 mg
Material Safety Data Sheet
Click here to download
Certificate of IPRS
Click here to download
Lot Validity Statement
Click here to download

IPRS Certificate

Indian Pharmacopoeia Commission
Ministry of Health & Family Welfare, Government of India
Sector 23, Raj Nagar
Ghaziabad 201002 (U.P.) India
Email: lab.ipc@gov.in; Website: www.ipc.gov.in
Ph. No.: 0120-2783500, 2783400, 2783392

Format No.: IPC/CRE/STP/032/11/FMT/05

IP Reference Substance Certificate

Paracetamol
(N-(4-hydroxyphenyl)acetamide)

Molecular Formula	$C_8H_9NO_2$	Molecular Weight	151.16
Catalogue No.	P-012	Lot No.	IPRS/74/19
Unit Quantity	200 mg		
Assigned Value (Purity)	0.996 mg per mg on as is basis		

Storage
Store between 2°C to 8°C, protected from light and moisture.

Validity
Indian Pharmacopoeia Reference Substances (IPRS) are periodically tested by the Indian Pharmacopoeia Commission (IPC) to ensure their continuous fitness for the purpose. IPC does not assign any expiry date and a lot remains valid till the time it is available at IPC website (www.ipc.gov.in) or at IP Online Portal (www.onlinestore.ipc.gov.in). It is the responsibility of the user to ensure validity of the lot of IPRS at the time of testing, either from the IPRS catalog available at the IPC website or from the 'Lot Validity Statement' available at IP online portal.

Intended Use
IPRS are supplied by the IPC for laboratory tests and assay as defined in the Indian Pharmacopoeia. They are not intended for use in humans or animals as drugs, nutraceuticals, or food.

Instructions for Handling and Usage
Allow the sealed container to equilibrate at ambient temperature before opening for use. Once the container has been opened, its content must be used immediately. Do not dry and use "as is". Any further storage and reuse of the contents of opened vial are not warranted.

Safety Information
Refer to the "Material Safety Data Sheet".

Signature
This certificate is approved by

Dr Robin Kumar
Principal Scientific Officer
Approving Officer

Certificates are now available online on IPC website i.e. https://onlinestore.ipc.gov.in/ User can download the particular Certificate of IPRS

Purity is "on as is basis"

Frequently Asked Questions on IPRS

Usagee of Reference Standard Vial after Opening?

Once the vial is opened, the stability of content and value cannot be guaranteed. It is for immediate use.

Pack size of IPRS & Impurities

IPRS- 25 mg, 50 mg, 100 mg, 200 mg & 1 mL.

IMP RS- 10 mg, 20 mg & 1 mL

What is the validity of current lot of IPRS?

The current lot of IPRS/Impurity RS is valid till the lot is present in the list of IPRS and Impurity at the official website of IPC (www.ipc.gov.in) and the lot validity statement on https://onlinestore.ipc.gov.in/

How to download CoA of IPRS/Impurity Standards?

COA are now available online on IPC website i.e. https://onlinestore.ipc.gov.in/
User can download the particular COA of IPRS

Current Challenges in IPRS

- ✓ **Expansion of Reference Material Scope**

•Rapid emergence of **new drug molecules, impurities, metabolites, and degradation products** increases the demand for corresponding reference standards.

- ✓ Developing impurity standards requires high-purity isolation or synthesis, which is **technically complex and resource-intensive**.

- ✓ **Stability and Homogeneity Issues**
  Chemical degradation, polymorphic changes, and moisture sensitivity demand continuous requalification and controlled storage.

Key Takeaways

Official Standards of India:
Established and governed by the *Indian Pharmacopoeia Commission (IPC)* under the Ministry of Health & Family Welfare.

Legal Recognition: Mandated by the *Drugs and Cosmetics Act, 1940* and *Rules, 1945* for all compendial assays described in the *Indian Pharmacopoeia (IP)*.

Scientific Integrity: Serve as the **primary benchmarks** ensuring analytical accuracy, reproducibility, and traceability across laboratories.

Quality Assurance: Developed through **multi-laboratory characterization**, with verified stability and homogeneity before certification.

Pharmacopeial Standards, Regulatory Standards & Quality Consideration Challenges Associated in Testing of Oral Liquids / OSD Manufacturing

by
Mrs. B.Jayashree
Head-Corporate Quality, The Madras Pharmaceuticals, Chennai

Presented at the IPC & IDMA, Tamilnadu interactive session held on 8th November 2025 at Hotel Hablis, Guindy, Chennai

Challenges Associated with testing of Liquid orals / OSD(Oral Solid Dosage form):

- Testing Ensures Safety, Quality, Efficacy & consistency of Dosage forms.
- Testing of Liquids & Solid dosage form in pharmaceutical Products comes with Variety of Analytical & Regulatory Challenges.
- In Both dosage form unique Testing difficulties faced is in Chemical & Stability Testing.
- Whether the formulation is Pharmacopeial or Non Pharmacopeial the Method used should be Stability indicative & specific which can quantify accurately the API content for Assay & Its impurities Profile using instrumentation like High pressure Liquid Chromatography (HPLC)with Suitable Prevalent detector like UV, PDA,RI which ever is applicable.

Challenges Faced :

- The challenges faced is in the Analysis of Related Substances is for the unknown impurities.
- The Pharmacopeial requirements for unknown Impurity limit is < 0.2%.
- To achieve this, the Excipients Compatibility to be studied thoroughly to minimize the Impurity Generation.
- The formulation Matrix interference (ie) Placebo's play's a very critical Role & interference due to the Placebo has to be established well during each analysis.
- The Peaks due to the placebo/Blank should be ignored while calculating the Unknown impurities & this makes the point that each batch manufactured should have its respective placebo in place for this evaluation.

Challenges Faced :

- During Stability analysis also the placebo's requirement is there which has to be charged in the respective stability chamber suitably packed.
- The Main Challenge faced in RS testing is the Non Availability of the Known Impurities from IPRS sometimes.Recommmendation to use other pharmacopealimpurities is the challenge we face as it involves huge cost.
- In such event the Alternate Impurity standards which are sourced from third Party Supplier or Contract lab that performs synthesis should be acceptable by the Authorities.
- We request FDA & other regulatory authorities to bring them under their control by performing inspection which will support the industry in meeting the regulatory requirement.

Challenges Associated with testing of Liquid orals:

- In Liquid dosage form the much talked about Impurities now are **"Ethylene Glycol" &DiethyleneGlycol"** With the limit 0.1 %.
- These impurities are to be tested in solvents Glycerin ,Propylene Glycol, Sorbitol & sorbital solution ,Polyethylene Glycol, Poly sorbate (Tween) 20,40, 60,80.
- The Purchase of the above mentioned Solvents should be direct from the Manufacturer or his Approved Supplier.
- The Manufacturer of these solvents are to be audited for their GMP requirements by the Formulation unit who purchases the Material.
- The Pack purchased should be from the manufacturer & the authorized supplier should not be allowed for any Repacking as it leads Non GMP Practice which may lead to contamination.

- The Empty drums after usage should be Defaced properly to avoid Malpractice in scrap handling.
- As per the Notification from (Health & Family welfare Dept Himachal Pradesh dated 09.10.2025 Keeping Patients Safety in mind-Made testing for EG /DEG impurities container wise & also in all Oral liquid formulations as Mandatory requirement with Immediate effect.
- The Testing as per IP Guideline documents is by GC using FID Detector
- Now Gas Chromography has taken a important role along with HPLC instruments in QC labs.
- This Impurity evaluation also calls for placebo preparation as per the Formulation which has to be dispensed & formulated properly.
- The Placebo in Liquid Preparation calls for multiple combination like placebo without API, placebo without solvent 1,Placebo without solvent 2 as multiple solvents are used in the formulation.

- As the Analysis of Solvents drum wise as input material & also in Finished product the Industries who are not having GC has to get the Analysis outsourced by FDA Approved Commercial Lab.
- IDMA should support small scale manufactures by setting up additional LAB's where the required analytical support can be done with non profit model.
- We suggest **"CDSCO"** can initiate inspection of the Excipients Manufacturer's overseas which will help the industries by increasing the confidence level.
- The Next Challenge is the Elemental impurities which is going to be become Mandatory in IP 2026 & the Notification states that IPC's working committee is working on the same.
- The General Chapter 5.10 which covers this requirement for Class 1,2 & 3 with limits in line with ICHQ3D.
- The Analytical Method involves ICP MS or ICPMS OES.

- We request the IPC committee to consider offering industries the option to have skip for elemental impurity test, with the condition that these can be performed after analyzing trend results. This would be especially beneficial as many industries are forced to outsource their analysis due to the high costs associated with purchasing the necessary Instrument.
- While introducing any new monographs IPC can harmonise the same with the Existing BP or USP monographs which will support the regulatory dept for Dossier Filing .
- While Harmonizing Monographs of IP with USP –I suggest IPC to consider the inclusion of Multiple dissolution Tests as given in USP.
- As per drug Law Rule 124 If the monographs for the formulation is not available in IP we have to refer other official monographs.
- Harmonization should happen capturing the complete monograph, in particular the Dissolution Test as the formula we manufacture might meet one of the multiple dissolution test given in those pharmacopeia's & if only one method among the multiple is finalized change in Dissolution method might call for reformulation.

Role of the Indian Pharmacopoeia Commission in Medical Products' Quality & Safety

by

Dr. V. Kalaiselvan

Secretary-cum-Scientific Director, Indian Pharmacopoeia Commission, Ghazibad

Presented at the IPC & IDMA, Tamilnadu interactive session held on 8th November 2025 at Hotel Hablis, Guindy, Chennai

Indian Pharmacopoeia Commission (IPC)

- The Govt. of India has created a dedicated Institution, Indian Pharmacopoeia Commission (IPC), to be the custodian of the Indian Pharmacopoeia (IP), the official book of standards for drugs included therein, in terms of the Second Schedule to the Drugs and Cosmetics Act, 1940.

- Govt. of India published an official gazette on 8th May 2008 and *IPC came into existence on 1st January 2009 as an autonomous institute* of Ministry of Health & Family Welfare, Govt. of India.

MINISTRY OF HEALTH & FAMILY WELFARE
(DEPARTMENT OF HEALTH AND FAMILY WELFARE)

New Delhi, the 8th May 2008

RESOLUTION

The Government of India have had under consideration the question of formation of ... Indian Pharmacopoeia which is the official book of standards for drugs included therein, in terms of the Second Schedule to the Drugs and Cosmetics Act, ... manufactured for sale, stocked or exhibited for sale or distributed in India. With the above objective in view, the Indian Pharmacopoeia Commission (IPC) was registered as a society under the Societies Registration Act, 1860 (No.21 of 1860) under the Ministry of Health & Family Welfare with the mandate to perform, inter-alia, functions such as revision and publication of the Indian Pharmacopoeia and the National Formulary of India on a regular basis. ...

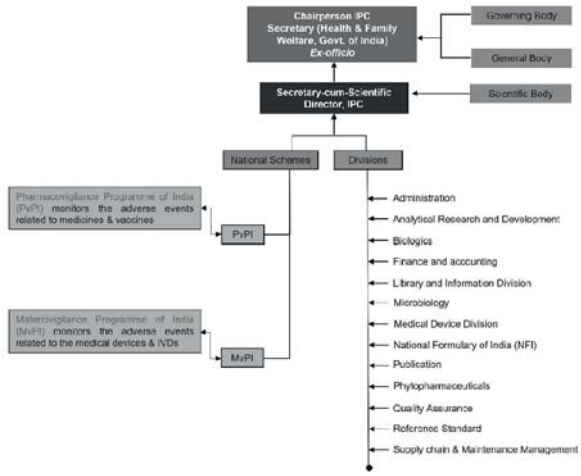
... have declared that the Central Indian Pharmacopoeia Laboratory, Ghaziabad (CIPL), a subordinate office of the Directorate General of Health Services which is primarily engaged in assisting the Central Drugs Standards Control Organization in the preparation of Indian Pharmacopoeia should be amalgamated/merged with the IPC with effect from the date to be appointed by the Ministry of Health & Family Welfare together with the staff, assets and liabilities including buildings and other existing infrastructure belonging to the CIPL and the IPC shall take over all the functions and tasks hitherto being performed by the CIPL. The existing officers and staff of the CIPL, irrespective of their grade shall be transferred on deputation to the strength of the IPC on terms of foreign service without any deputation allowance and will be given the option to be absorbed in the IPC permanently or to revert to the Parent cadre in the Indian Pharmacopoeia Commission will henceforth function as an autonomous body, fully financed by the Central Government with specific budgetary allocations under the administrative control of the Ministry of Health & Family Welfare. It has also been decided that during the amalgamation the CIPL shall function together with its staff and infrastructure as a constituent Laboratory of the IPC until both the institutions have settled/granted/merged themselves formally wherefore the CIPL shall cease to exist for all purposes.

ORDER

Ordered that a copy of the resolution be communicated to:

1. All Ministries/ Departments of the Government of India.
2. All Attached/ Subordinate Offices under the Ministry of Health and Family Welfare.
3. All autonomous/statutory organizations under the Ministry of Health and Family Welfare.

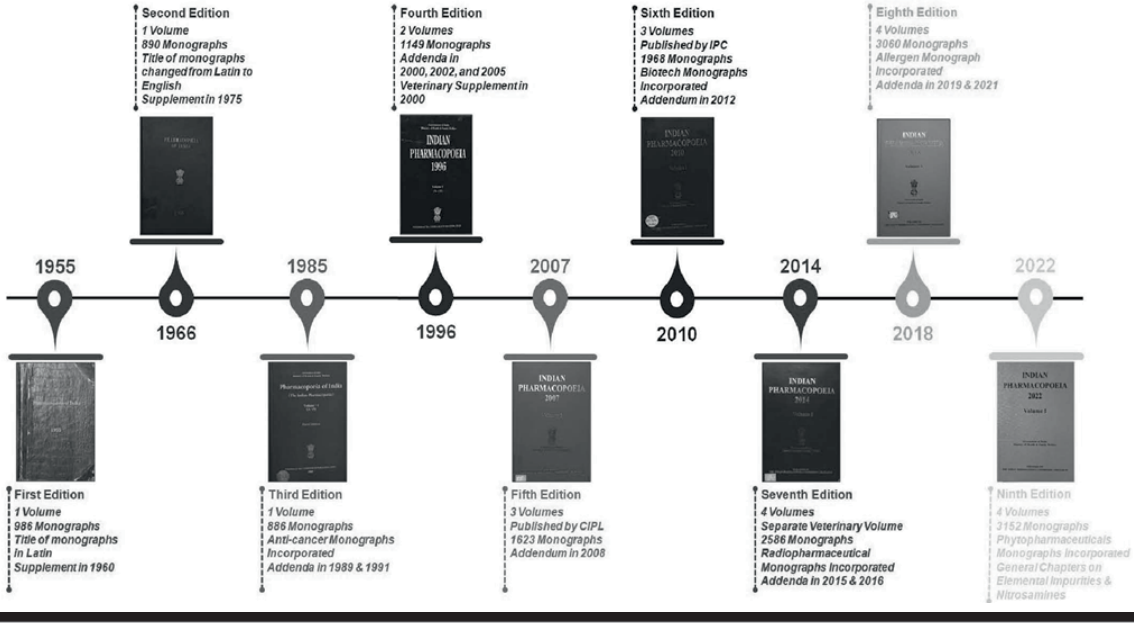
IPC Governance & Structure



Mandates & Functions

PHARMACOVIGILANCE PROGRAMME OF INDIA (PvPI)
WHO Collaborating Centre for Pharmacovigilance in Public Health Programmes and Regulatory Services

History of Indian Pharmacopoeia Editions



Global Recognition of the IP

Signing of MoUs for IP Recognitions across the Globe

- Signing of MoUs on recognition and acceptance of the IP Suriname and Malawi

- Exchange of MoUs on recognition and acceptance of the IP in Sri Lanka and Trinidad & Tobago.

15th International Meeting of World Pharmacopoeias (IMWP)

IPC hosted the 15th International Meeting of World Pharmacopoeias (IMWP) from 5th to 7th February 2025 with participation from 10 pharmacopoeial bodies

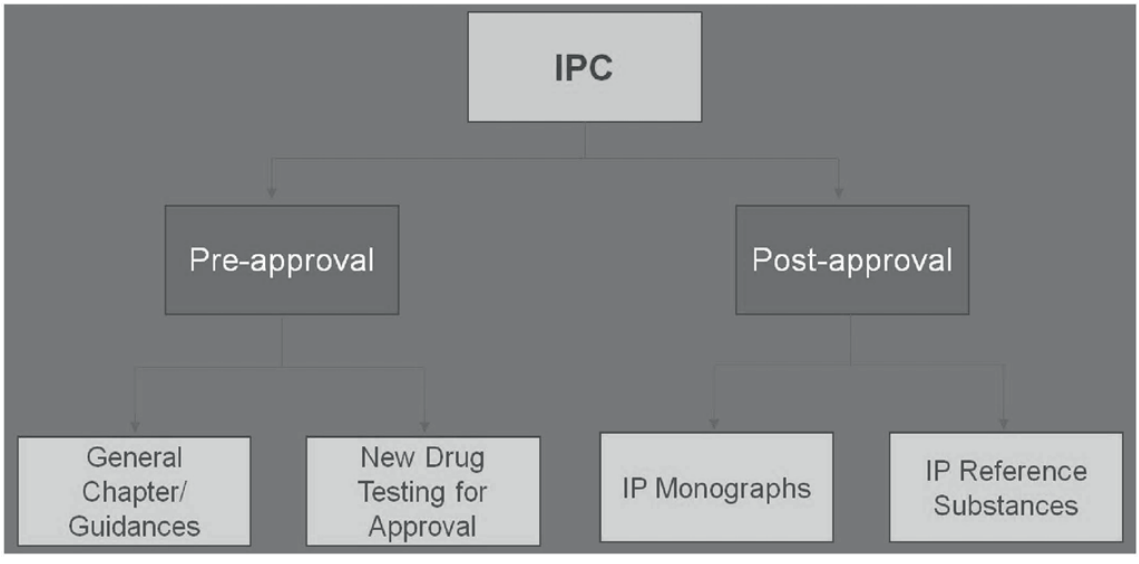
1st and 2nd Policymaker's Forums

IPC hosted 1st and 2nd Policy Makers Forums with participation of delegates from 37 countries across the world in August 2024 and June 2025, respectively.

IPC's Membership in the Pharmacopoeial Discussion Group

IPC became member of the PDG along with European Pharmacopoeia (EP), Japanese Pharmacopoeia (JP), and United States Pharmacopoeia (USP) during the PDG Annual Meeting held from 3rd-5th October 2023 at USP, Hyderabad

IPC's Role in Ensuring Quality of Pharmaceuticals



Indian Pharmacopoeia Reference Substances (IPRS)

- Indian Pharmacopoeia Reference Substances (IPRS) are highly-characterized physical specimens used in testing to help ensure the identity, strength, quality, and purity of drugs as given in the IP.
- These are specimens of drug substances, impurities, phytopharmaceuticals, excipients, and performance calibrators. IPRS are certified, maintained and distributed by the IPC.
- IPRS are authoritative standards for determining the quality of medicines in India.

IP Reference Substances (IPRS)

Indian Pharmacopoeia Reference Substances abbreviated, as IPRS in the individual monographs, are issued by the Indian Pharmacopoeia Commission (IPC) or by laboratories authorized by the IPC and assume the official status in India. Where an IPRS is referred to in an official IP monograph, it becomes a part of the official standard that is alone authoritative in case of doubt or dispute to determine compliance with the IP.

Types of Reference / Impurity Standards at IPC

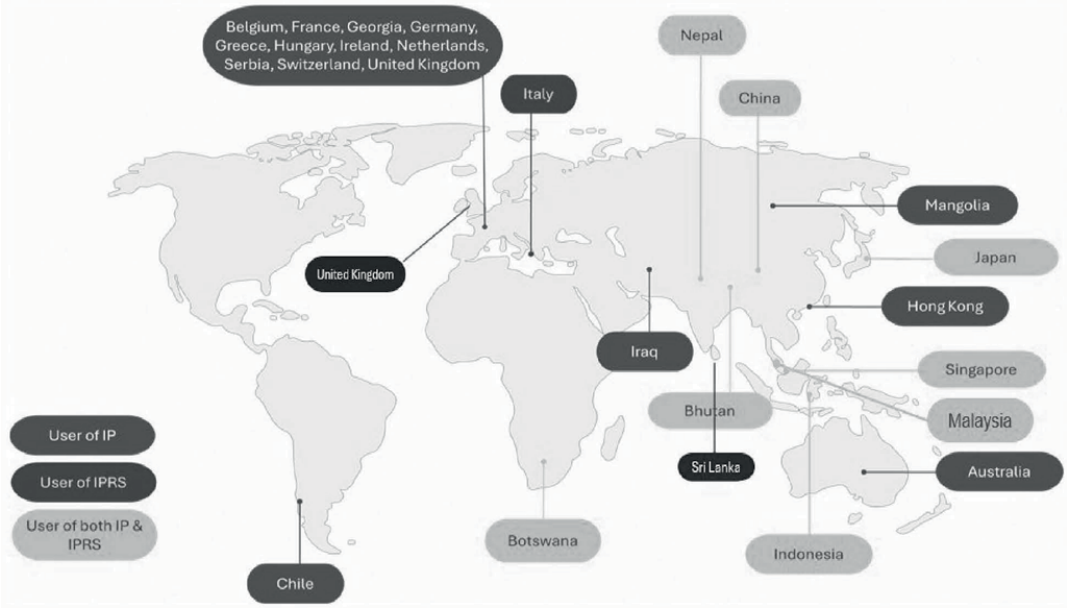
Abbreviation	Full Form	Representative Vial Image
IPRS	Indian Pharmacopoeia Reference Substances	
IMP-RS	Impurity Reference Substances	
IPPRS	Indian Pharmacopoeia Phytochemical Reference Substances	
Calibration Standards	IP Dissolution Apparatus Calibrator, Prednisone Tablets (Lot No: IPRSC050-Calibration of HPLC, Nicotinic Acid (Lot No IPRSN018)-Calibration of UV	

Availability of IPRS and Impurity RS

Total 1326 standards, 3rd highest among global pharmacopoeias

Particulars/ Item	No. of Standards Available at IPC Ghaziabad
IPRS	691
Impurity RS	635

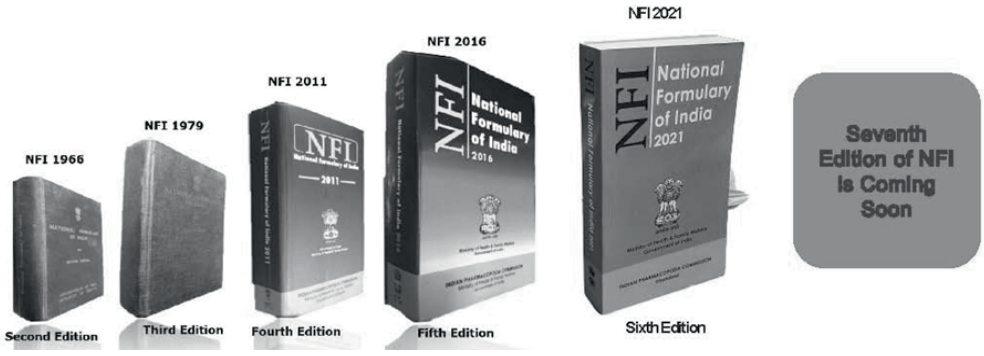
International Customers of IP and IPRS



National Formulary of India

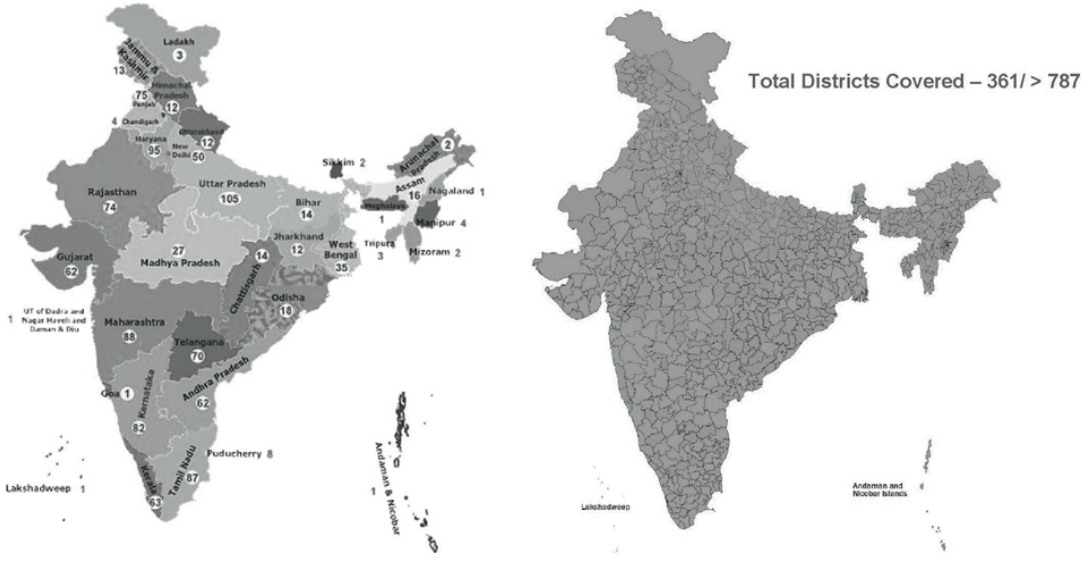
The Ministry of Health and Family Welfare, Govt. of India vide their Notification No. ***F.No.X.11035/2/06- DFQC*** dated 8th May, 2008 assigned this mandatory responsibility of publication of NFI to the IPC.

The NFI is a guidance document that gives balanced, unbiased information on medicines to promote rational use of medicines in the country.

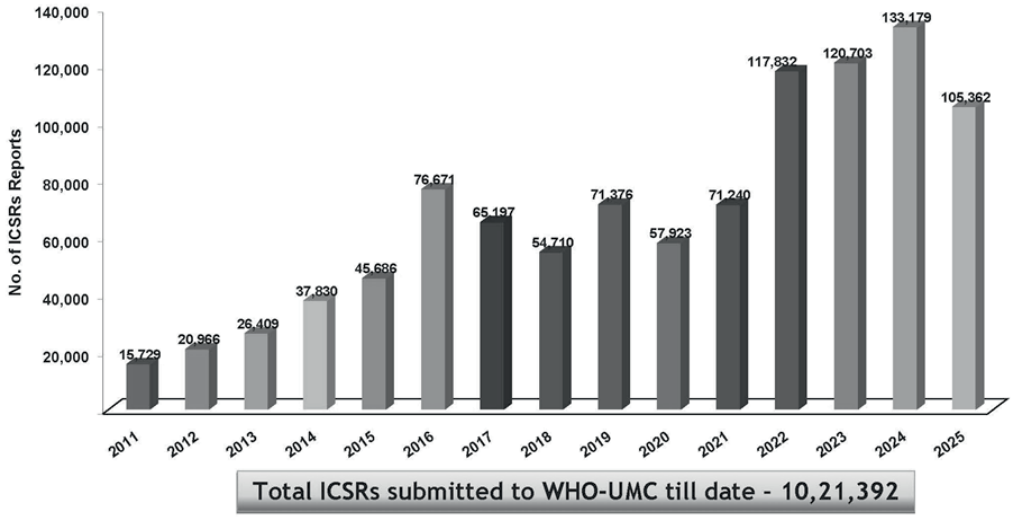


Pharmacovigilance Programme of India (PvPI) - Touchpoints in India

Adverse Drug Reaction Monitoring Centres (AMC) - 1120



PvPI Data Analysis Overview

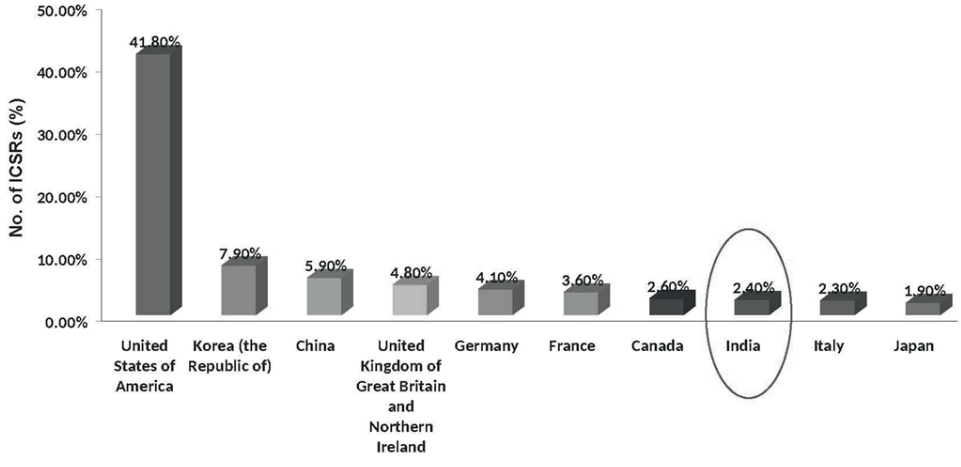


Total ICSRs submitted to WHO-UMC till date - 10,21,392

Source: VigiLyze
Data as on 04.11.2025

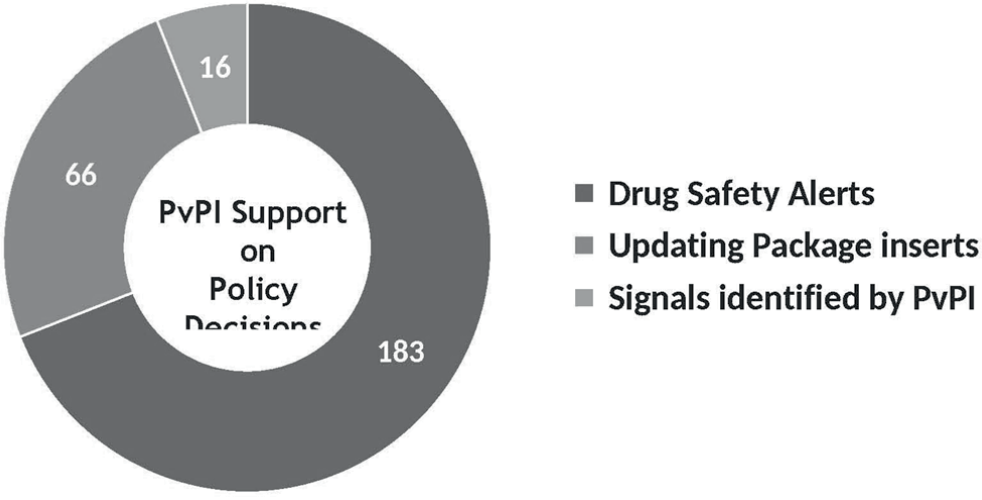
Global Contribution of India in ICSR's Submission

8th Largest Reporter of ICSRs
Total WHO-PIDM members - 182 members



PvPI Data Review Output

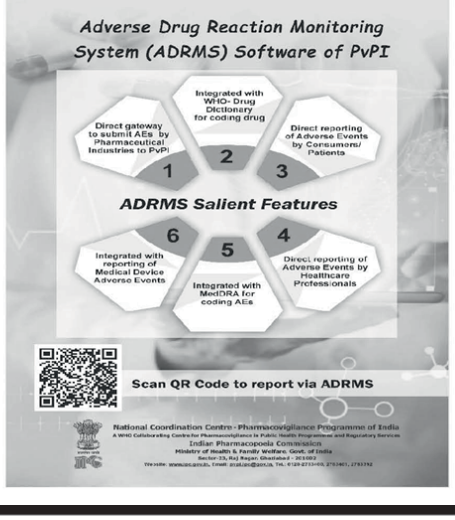
PvPI ensures Aatmanirbhar Bharat in Regulatory Decisions



IPC's Digital Tools to Promote Adverse event reporting

IVRS Facility for PvPI Toll-free helpline (1800 180 33024)
Launched on 3rd September 2025

ADRMS
Launched on 19th August 2024



Ease of doing post-market surveillance: ADRMS Account Setup Guide

Company User Registration

Indian Pharmacopoeia Commission

Materiovigilance Programme of India (MvPI)

ADRMS- Company User Registration

Registration Form for Marketing Authorization Holders (MAHs) under Materiovigilance Programme of India (MvPI)

We hereby submit the details of our company/institution for registration under the Materiovigilance Programme of India (MvPI) and request enrolment in the Adverse Drug Reaction Monitoring System (ADRMS). As a Marketing Authorisation Holder (MAH), we affirm our commitment to ensuring medical device safety and maintaining full compliance with applicable regulatory requirements.

Company Details

Company Name:

Company Category (Autonomous/Government/Private/Semi-Government):

Address:

Pin Code:

District: State:

Country:

Phone No.: Institute Email Address:

Coordinator Details

Coordinator First Name: Last Name:

Gender:

Mobile No.: Email Address:

Terms of Reference (TOR):

a) The Marketing Authorization Holder (MAH) shall ensure timely and accurate reporting of all observed or received Medical Device Adverse Events (MDAEs) as per the defined regulatory requirements.

b) The MAH must submit MDAE reports and completeness of the reports with all required details.

c) The MAH should cooperate with the National Coordination Centre-MvPI (NCC-MvPI), Indian Pharmacopoeia Commission (IPC) for any follow-up queries, additional investigations, or Root Cause Analysis (RCA), if needed.

d) In case of any change in the designated safety contact person or authorized representative, the MAH shall inform NCC-MvPI promptly through email communication to mvpi-ipc@gov.in

e) MAHs should actively participate in MvPI training sessions, workshops, or stakeholder meetings to strengthen vigilance practices and improve the quality of MDAE reporting.

Declaration:

We, the undersigned, have read and understood the above Terms of Reference and agree to undertake the responsibilities associated with reporting Medical Device Adverse Events under the Materiovigilance Programme of India (MvPI).

Signature
Proposed Coordinator of MvPI

Signature with Seal
Head of the Company

Filled user registration form can be sent to **mvpi-ipc@gov.in** or **shatrunjay.ipc@gov.in**

Review and verification

An autogenerated login credentials will be shared to the proposed focal person

PvPI Digital Initiative to facilitate Consumer Reporting

Global Impact

WHO-PIDM Endorses India's Initiative for Implementation in All Member States during the recently held 43rd WHO-PIDM meeting in Egypt (October 27–29, 2025)

National Impact

- The following States/UT have implemented this initiative - **Puducherry, Chhattisgarh, Goa, Odisha, Nagaland.**
- The Pharmaceuticals & Medical Devices Bureau of India (PMBI) have issued a circular to all Pradhan Mantri Bhartiya Janaushadhi Kendras (PMBJKs) to display the poster in prominent places in retail/wholesale stores to facilitate consumer reporting.

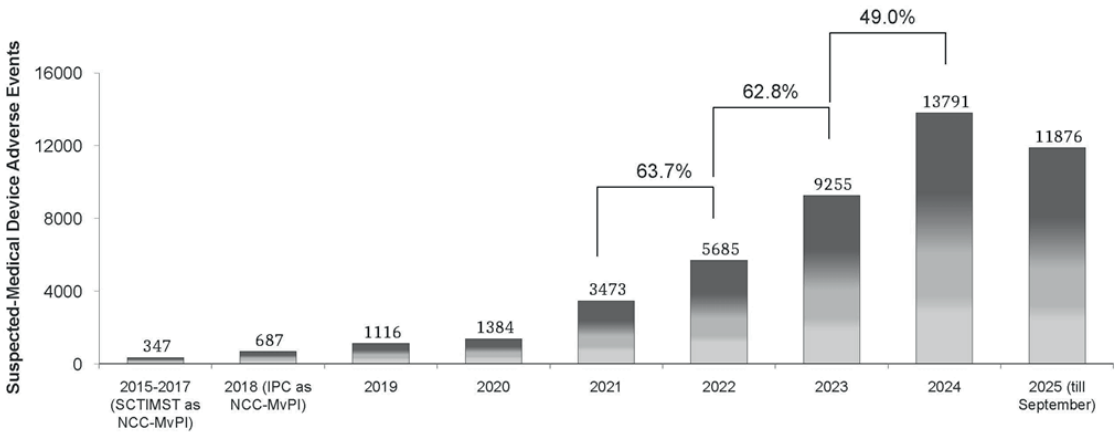
Materiovigilance Programme of India (MvPI) - Touchpoints in India

Medical Device Adverse Event Monitoring Centres

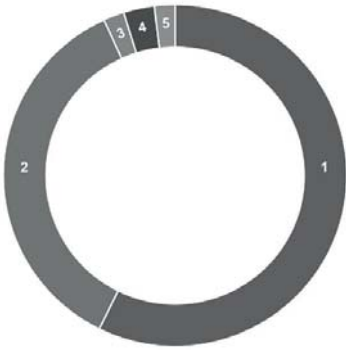
Regional training Centres

Pending approvals = >1190

MvPI Data Anslysis Overview



MvPI Data Review Output



1. Evidence-based recommendation shared to CDSCO = 59
2. Safety alerts shared to Monitoring Centres = 37
3. Joint-investigation conducted based on data-driven recommendations = 02
4. Changes incorporated in IFU/package inserts = 03
5. Counterfeit medical device/IVD identified = 02

Public Notice

National Medical Commission mandates each medical college to set up Medical Device Adverse Event Committee

CDN-20011/139/2025-COORDINATION-NMC

CDN-20011/139/2025-COORDINATION-NMC
Government of India
National Medical Commission
Policy & Coordination Division

Azadi Ka Amrit Mahotsav

Pocket- 14, Sector- 8,
Dwarka, Phase-1, New Delhi-77
Dated: 13 July, 2025

PUBLIC NOTICE

Subject:- Monitoring, assessing, and preventing adverse events associated with medical devices - Constitution of Medical Device related Adverse Event Committee in each Medical College.

****

Medical devices have become an indispensable part of modern healthcare, contributing significantly to the diagnosis, treatment, and management of diseases. Various incidents involving medical devices causing harm to the patients has created the need of a system to monitor these events and take necessary actions to prevent these from happening again.

2. In response to this the Ministry of Health and Family Welfare (MoHFW), launched the Materiovigilance Programme of India (MvPI) in 2015 at Indian Pharmacopoeia Commission, to monitor adverse events and risks associated with medical devices used across the country. This national initiative is designed to systematically collect, analyse, and respond to adverse events associated with medical devices, ensuring better patient safety and quality healthcare delivery. The program is coordinated by the IPC and operates through a growing network of Medical Device Adverse Events Monitoring Centres (MDMCs) in hospitals and medical colleges.

4. **Materiovigilance Programme of India (MvPI)**

The Materiovigilance Programme of India (MvPI) is a national initiative aimed at ensuring the safety of medical devices across their lifecycle. MvPI enhances device safety through systematic reporting and analysis of adverse events, providing data to CDSCO to support regulatory action and guide improvements in clinical practice.

5. **Advantages of Becoming a Medical Device Adverse Events Monitoring Centre (MDMC):**

Medical colleges serve as ideal hubs for Materiovigilance due to their diverse patient populations and access to advanced healthcare technologies. Becoming an MDMC offers multiple strategic advantages:

- **Academic Recognition:** Participation enhances the institution's stature as a contributor to national public health and regulatory science.
- **Professional Development**: Provides faculty and students hands-on exposure to post-market surveillance, risk assessment, and patient safety.
- **Infrastructure Enhancement**: Access to MvPI resources, training modules, and national-level collaboration.
- **Policy Influence:** Opportunities to contribute to evidence-based recommendations and medical device regulations.
- **Patient Safety**: Ensures early detection and response to device malfunctions, directly improving clinical outcomes.

- The National Medical Commission (NMC) has mandated the establishment of a "Medical Device related Adverse Event Committee" in every medical college across India.
- This directive aims to enhance patient safety by systematically monitoring, assessing, and preventing adverse events associated with medical devices.
- The committees are required to register with the Indian Pharmacopeia Commission (IPC) under the Materiovigilance Programme of India (MvPI).

Think Health, Think Pharmacist

by

Ms. Sneha. K
College of Pharmacy, SRIPMS, Coimbatore

Note: This article was awarded 1st prize in the Essay Competition conducted by our Trus

Health is the **greatest wealth of mankind** and among all healthcare professionals, pharmacists play a vital role in maintaining and improving public health. The phrase "Think health, Think pharmacist" highlights the **multifaceted nature** of the profession where one role encompasses many functions beyond dispensing medication. Their roles extend from community and clinical settings to research and industry, making them integral in ensuring safe, effective and rational medication use for the benefit of the individual patient and society as a whole.

For generations, the public image of a pharmacist has been that of a person standing behind the pharmacy counter, counting tablets and placing them into small containers with neat labels. This view, while not entirely incorrect, represents only a very small fraction of what pharmacists actually do today. Modern healthcare systems have evolved so far beyond the simple act of dispensing medicine and the pharmacy profession has grown with them. They are recognized as **medication experts, clinical advisors, researchers, public health educators and integral members of multidisciplinary healthcare teams**. They are often the **most accessible healthcare professionals** bridging the gap between physicians and patients.

Clinical and patient care roles:

One of the most visible transformations in modern pharmacy practice is the rise of clinical pharmacy. They directly work with the physicians, nurses and other health care providers to optimize medication therapy and improve patient outcomes. They are trained to review prescriptions not only for **accuracy** but also for **therapeutic appropriateness**. They assess the potential drug-drug interactions, contraindications, dosing error that could harm the patients. By collaborating with other health care professionals, they help select the most suitable medication regimen based on individual patient's need, lab res

Significant aspect of this role is **medication therapy management** where pharmacist evaluate the entire medication profile to identify the unnecessary or duplicate therapies. Studies have consistently shown that pharmacist led interventions **improve patient outcomes, lower healthcare costs, and enhance quality of life.**

Community and public health roles:

They often serve as the **1st point of contact** for patient seeking medical advices, minor ailment treatment or medication guidance. Community pharmacist play a crucial role in public health promotion and disease prevention. They educate the public about medication use and safety (For eg: Counselling patients on correct inhaler techniques in asthma or insulin injection methods in diabetes.)

Creating awareness about preventive healthcare measures like **immunization, sanitation and hygiene.** Informing public about importance, schedule and safety of vaccines. Addressing vaccine myths and building trust in immunization programs. They also teach patients how to **monitor and control chronic diseases** like diabetes, BP, asthma, dyslipidemia.

Passing awareness on the dangers of **antibiotic resistance** and promoting rational use of antimicrobials, provide counselling on **smoking cessation, Deaddiction programs, contraceptive methods, menstrual health and safe pregnancy medication use**

Pharmacists educate about drug-food interactions and balanced diet for disease prevention and also on safe disposal of unused medicines/expired medicines to prevent environmental contamination.

They also have vital role in pandemic and emergency preparedness by maintaining availability of essential drugs and managing drug shortages.

Research, innovation and technological roles:

Pharmacists participate in every stage of drug development from discovery and formulation to preclinical studies, clinical studies and post marketing surveillance.

In **Pharmaceutical research,** they work in labs to design new dosage forms, to improve drug stability and developing novel delivery systems such as nanoparticles, liposomes.

Another crucial field is **Pharmacovigilance** where pharmacists monitor, assess and report adverse drug reactions thereby ensuring that unsafe drugs are quickly identified and withdrawn from market.

In **Industrial research,** they are responsible for ensuring that medicines are manufactured under strict quality control standards and supervise production, packaging and labelling.

One of the most promising areas, **Pharmacogenomics** which combines pharmacy and genetics to personalize drug therapy. They interpret genetic data to predict how patients respond

to specific drugs, thus minimizing adverse drug reactions and improving treatment efficacy, this personalized approach represents future of precision medicine.

In **clinical research,** pharmacists serve as Clinical Research Associates (CRAs) overseeing the ethical conduct of trials, verifying data accuracy and compliance with regulatory standards.

Education, regulation policy roles:

Pharmacists are not only practitioners but also educators and regulators who shape future of the health care.

In academic setting, they train next generation of pharmacist, scientist and healthcare leaders In regulatory sphere, they ensure safe, quality and efficacious drugs are available in market. They work with drug control authorities like FDA and CDSCO to evaluate new drugs, inspect manufacturing facilities and monitor compliance with legal standards.

They serve on national and international committees that formulate guidelines on rational drug use, antimicrobial stewardship and public health strategies.

In hospital administration, they procure drugs, formulate hospital formularies and ensure cost effective use of medicines.

These regulatory and educational roles demonstrate the intellectual leadership that pharmacists bring into healthcare systems.

Conclusion:

Pharmacists are pillars of safe medication use. Pharmacist ensure that the patients receive right medicine in right dosage form and right doses at right time. They act as the final checkpoint in the healthcare chain identifying potential drug interactions, adverse effects and contraindications.

They are **unsung guardians** of health, the **silent partners** of physicians, **everyday educators** of patients-shaping healthier lives and safer communities.

Indeed, to think health is to think pharmacist

INFORMATION

G. Rangachari Memorial (PG Pharmacy Fellowship) Awards 2025

Tamil Nadu Pharmaceutical Scientific Welfare Trust (TNPSW Trust), a subsidiary of the **Indian Pharmaceutical Association (IPA), Tamil Nadu Branch**, was established in **1989** and has since been serving the **pharmacy profession** by supporting both students and the industry.

In addition to these initiatives, since **1998**, the Trust has been conferring the **Research Fellowship Awards** to selected **M.Pharm** students—and later extended to **Pharm.D (from 2013)** final-year students—from various colleges across Tamil Nadu, to support their ongoing project work.

Applications containing project synopses are received, codified, and sent to external evaluators outside Tamil Nadu for impartial assessment. Based on the evaluators' reports, cash awards are presented to the students securing **first, second, and third ranks**.

This year marks the **28th edition** of this initiative. A total of **301 applications** were received—**254 from M.Pharm** students across six branches and **47 from Pharm.D** students representing **17 institutions**. All synopses were codified and evaluated by **Dr. L. Sathiyanarayanan**, Vice Principal, **Poona College of Pharmacy, Bharati Vidyapeeth University, Pune**, and his team. Based on their evaluation, **21 students** have been selected for the awards as detailed below.

PHARMACEUTICS

Rank	Name	College	Prize Amount (Rs.)
1st	Ms. Ashwini. J	COP, Madurai Medical College, Madurai	12,000/-
2nd	Mr. Dharanikumar. S	COP, Sri Ramakrishna Institute of Paramedical Sciences, Coimbatore	10,000/-
3rd	Ms. Vidya UL	COP, Madras Medical College, Chennai	8,000/-

PHARMACEUTICAL CHEMISTRY

Rank	Name	College	Prize Amount (Rs.)
1st	Ms. Muskan Sharma	JSS College of Pharmacy, Ooty	12,000/-
2nd	Mr. Vasanth. R	JSS College of Pharmacy, Ooty	10,000/-
3rd	Ms. Priyadharshini. E	Adhiparasakthi College of Pharmacy, Melmaruvathur	8,000/-

PHARMACEUTICAL ANALYSIS

Rank	Name	College	Prize Amount (Rs.)
1st	Mr. S. Siva Ram	COP, Sri Ramakrishna Institute of Paramedical Sciences, Coimbatore	12,000/-
2nd	Ms. Sangavi. M.S	COP, Sri Ramakrishna Institute of Paramedical Sciences, Coimbatore	10,000/-
3rd	Ms. Sangavi. G	C.L. Baid Metha College of Pharmacy, Chennai	8,000/-

PHARMACOGNOSY

Rank	Name	College	Prize Amount (Rs.)
1st	Mr. Deepak Muthu. S	COP, Madurai Medical College, Madurai	12,000/-
2nd	Ms. M. Vinodhini	COP, Madurai Medical College, Madurai	10,000/-
3rd	Ms. Kavipriya. V	JSS College of Pharmacy, Ooty	8,000/-

PHARMACOLOGY

Rank	Name	College	Prize Amount (Rs.)
1st	Ms. Suganya. V	Swamy Vivekanandha COP, Tiruchengode	12,000/-
2nd	Ms. Santhiya. P	COP, Sri Ramakrishna Institute of Paramedical Sciences, Coimbatore	10,000/-
3rd	Ms. Preety Rani Gupta	JSS College of Pharmacy, Ooty	8,000/-

PHARMACY PRACTICE

Rank	Name	College	Prize Amount (Rs.)
1st	Mr. N. Veerasundaramoorthy	COP, Sri Ramakrishna Institute of Paramedical Sciences, Coimbatore	12,000/-
2nd	Ms. Varsha M	SRM COP, SRMIST, Chennai	10,000/-
3rd	Mr. N. Akilan	JSS College of Pharmacy, Ooty	8,000/-

PHARM D

Rank	Name	College	Prize Amount (Rs.)
1st	Mr. Sharagesh R, Mr. Akash Mohan, Mr. Mohana Krishna M, Mr. Rikash Kumar S	SRM College of Pharmacy, SRMIST, Chennai	15,000/-
2nd	Ms. Abigail James Raj, Ms. J M Rithanya, Ms. J Pruthvi, Ms. Thusita S	JSS College of Pharmacy, Ooty Coimbatore	12,000/-
3rd	Ms. Sangavi. A, Ms. Yashvi Ambrish Pathak	PSG College Pharmacy, Coimbatore	10,000/-

Shri. G. Swaminthan Memorial Award - Essay Competition 2025

TNPSW Trust initiated an Essay Competition in 2011 as part of its ongoing efforts to encourage and recognize the talents of pharmacy students. This year, the topic for the competition was **"Think Health, Think Pharmacist."** The award is presented in memory of **Shri. G. Swaminathan** and is **sponsored by M/s. Pharma Products Pvt. Ltd., Thanjavur.**

For this year's competition, we received **170 entries from 24 colleges** across the state. The essays were evaluated by **Dr. V. Prabakaran, Retd. Principal, Tirupathi, Andhra Pradesh.**

Based on the evaluation, the following students have been selected for the awards:

Rank	Name of the Student	College	Amount
1st	Ms. Sneha. K	COP, Sri Ramakrishna Institute of Paramedical Sciences, Coimbatore	10,000/-
2nd	Ms. T. Ramya	SSM College of Pharmacy, Jambai, Erode Dt	8,000/-
3rd	Ms. Kowsalya. M	Arulmigu Kalasalingam College of Pharmacy, Srivilliputhur	7,000/-

We extend our sincere thanks to **Mr. T. Ravichandran**, *M/s. Pharma Products Pvt. Ltd., Thanjavur*, for sponsoring these awards and supporting this academic initiative.

Fourrts University Merit Award 2025

Since 2015, **M/s. Fourrts (India) Laboratories Pvt. Ltd., Chennai**, has been sponsoring the **University Merit Awards** to recognize the top-performing students of **B.Pharm** examinations conducted by *The Tamil Nadu Dr. M.G.R. Medical University, Guindy, Chennai.*

For the year **2025**, the awards are presented to the topper candidates who secured the highest marks in the **B.Pharm examinations held in October 2024**. The prize distribution is as follows:

Rank	Name of the Student	College	Prize Amount (Rs.)
1st	Ms. Laxmipriya. G	K.M. College of Pharmacy, Madurai	10,000/-
2nd	Ms. Priyadharshini. K K	K.M. College of Pharmacy, Madurai	8,000/-
3rd	Mr. Abdul Fazith S	Arulmigu Kalasalingam College of Pharmacy, Srivilliputhur	7,000/-

We extend our heartfelt thanks to **Dr. S. V. Veerramani**, *Chairman & Managing Director*, **M/s. Fourrts (India) Laboratories Pvt. Ltd., Chennai**, for his continued support and encouragement towards this prestigious award.

EVENTS

AI in Pharma

The **"AI in Pharma"** webinar series was successfully conducted over multiple sessions by **Indian Pharmaceutical Association (IPA), Tamil Nadu State Branch**, in association with **Arachimedis Digital, Chennai**, with the objective of creating awareness on the rapidly growing impact of **Artificial Intelligence (AI)** in the pharmaceutical and healthcare sectors. The programme brought together industry experts, professionals, academicians, and students to explore both theoretical concepts and real-world applications of AI across the pharma value chain.

The **first session**, held on **19th September 2025**, focused on **AI Foundation**, providing participants with a clear understanding of core AI concepts, machine learning, data analytics, and their relevance to pharmaceutical sciences. The session laid a strong groundwork for subsequent discussions.

The **second session**, conducted on **26th September 2025**, addressed **Smart Factories – AI in Manufacturing and Supply Chain**, highlighting the role of AI in automation, predictive maintenance, inventory optimisation, and supply chain visibility to enhance operational efficiency and reduce costs.

On **10th October 2025**, the **third session** explored **AI in Pharmaceutical Sales and Marketing**, where speakers discussed customer analytics, digital engagement, demand forecasting, and AI-driven decision support systems for improving market reach and business performance.

The **fourth session**, held on **17th October 2025**, focused on **AI in Manufacturing Quality and Regulatory Compliance**, emphasizing quality assurance, process monitoring, risk management, data integrity, and compliance with evolving regulatory requirements.

The **final session**, conducted on **24th October 2025**, covered **AI in Drug Discovery and Clinical Research**, highlighting AI applications in target identification, molecule screening, clinical trial optimisation, and real-world evidence generation.

Overall, the **AI in Pharma** webinar series was highly informative and well received, reinforcing the importance of digital transformation and innovation in shaping the future of the pharmaceutical industry.

National Conference on
Enhancing Pharmaceutical Quality Assurance through Good Manufacturing Practices (GMP) & Revamped Pharmaceutical Technology Upgradation Assistance Scheme (RPTUAS)

A National Conference focusing on Pharmaceutical Quality Assurance through Good manufacturing Practices (GMP) & **Revamped Pharmaceutical Technology Upgradation Assistance Scheme (RPTUAS)** was successfully conducted on **8th August 2025** at **Ramada Plaza, Guindy, Chennai**, jointly organised with the **IPA, Tamil Nadu State Branch** as an Associate Partner. The conference brought together regulators, industry experts, and pharmaceutical professionals to deliberate on technology upgradation, GMP compliance and regulatory pathways for the Indian pharmaceutical sector.

The programme commenced by a formal **inauguration and lamp lighting ceremony**, setting a positive and collaborative tone for the event. **Mr. J. Jayaseelan**, President, IPA Tamil Nadu State Branch, delivered the welcome address, highlighting the importance of continuous technology upgradation and regulatory compliance to enhance the global competitiveness of Indian pharmaceutical manufacturers.

Key inaugural addresses were delivered by **Mr. Jan Nagpal**, Joint Secretary, PHDCCI, **Mr. S. Gurubharathi**, Deputy Director of Drugs Control and Controlling Authority, Tamil Nadu. The **Chief Guest**, **Dr. K. M. Srinivasan**, Deputy Drugs Controller (India), CDSCO South Zone, Chennai, emphasized the critical role of GMP implementation and regulatory preparedness in ensuring quality, safety and efficacy of medicines.

A detailed presentation on the **RPTUAS Scheme** was delivered by **Mr. C. V. K. D. Prabhu**, General Manager, SIDBI, who explained the objectives, eligibility criteria, financial assistance components, and benefits of the scheme in supporting MSME pharmaceutical units for technology upgradation.

One of the key highlights of the conference was the **panel discussion on "Foundations and Strategies for Effective GMP Implementation"**, which provided valuable insights into essential GMP principles such as quality assurance, process validation, and documentation practices. The panel, comprising **Thiru. N. C. Ravichandran**, Assistant Director of Drugs Control, Chengalpattu Zone; **Mr. Sanjay Dasmohapatra**, COO, Medopharm, Chennai; and **Dr. Tom Puthiaparampil**, Country Head, Syner-G BioPharma Group, discussed practical challenges faced by the industry and shared best practices to overcome resource and technical constraints while ensuring sustained compliance.

The technical session on the **WHO-GMP COPP application process through the ONDLS portal** was presented by **Mr. Mukesh K. Singh**, Principal Technical Officer, CDAC, Noida. The session offered a comprehensive overview of the Online National Drugs Licensing System (ONDLS), developed by CDAC in coordination with CDSCO and State Drug Regulatory Authorities, enabling participants to better understand the digital regulatory submission process.

The programme concluded with a **vote of thanks by Mr. Rajesh H. Bhandari**, Hon. Secretary, IPA Tamil Nadu State Branch. The conference served as an effective platform for knowledge sharing, regulatory awareness and industry-regulator interaction, reinforcing the collective commitment towards strengthening GMP compliance and technological advancement in the Indian pharmaceutical industry.

IPC–IDMA Interactive Meet on Pharmacopoeia Standards Held in Chennai

The **Indian Pharmacopoeia Commission (IPC)**, in collaboration with the **Indian Drug Manufacturers' Association (IDMA), Tamil Nadu–Puducherry–Kerala Sub-Branch**, successfully organised an **IPC Interactive Meet on "Pharmacopoeia Standards: Regulatory and Quality Considerations"** on **Saturday, 8th November 2025**, at **Hotel Hablis, Guindy, Chennai**.

The programme was designed to create awareness and facilitate dialogue on evolving **Indian Pharmacopoeia standards**, regulatory expectations, and quality compliance within the pharmaceutical industry. The meet witnessed enthusiastic participation from industry professionals, quality assurance experts, regulatory officials, academicians, and stakeholders from across the region.

The inaugural session began with a **welcome address by Shri J. Jayaseelan**, Chairman, IDMA (TnPK Sub-Branch). This was followed by special addresses from **Thiru S. Gurubharathi**, Deputy Director of Drugs Control, who shared regulatory perspectives and emphasized the importance of compliance with pharmacopoeial standards. A significant highlight of the inaugural session was the **signing of an MoU between the IPC and the Tamil Nadu Pharmacy Council**, reinforcing collaborative efforts towards strengthening professional standards.

The **keynote address** was delivered by **Dr. V. Kalaiselvan**, Secretary-cum-Scientific Director, IPC, on the **role of IPC in ensuring medicine quality and patient safety**. The technical sessions provided in-depth insights into updates on Indian Pharmacopoeia standards, digital initiatives, global harmonisation, reference standards, and challenges in testing liquid and oral solid dosage forms. The sessions were handled by **Dr. Gaurav Pratap Singh**, **Dr. Manisha Trivedi**, and **Ms. B. Jayasri**, bringing practical and regulatory clarity to participants.

The programme concluded with an interactive **Q&A session**, followed by a **vote of thanks by Shri S. Sivanandhan**, Hon. Secretary, IDMA (TnPK Sub-Branch). The meet served as a valuable platform for knowledge exchange, reinforcing the commitment of IPC and IDMA towards quality assurance, regulatory excellence, and patient safety in the pharmaceutical sector.

64th NPW Inauguration, Award Function of IPA & Tnpsw Trust and Dr. T. K. Ravi Memorial Lecture

The **Indian Pharmaceutical Association, Tamil Nadu State Branch (IPA–TNSB)**, in association with the **Sri Ramakrishna Institute of Paramedical Sciences (SRIPMS), College of Pharmacy, Coimbatore**, successfully inaugurated the **64th National Pharmacy Week (NPW)** on **14th November 2025** at **Velumani Ammal Hall**, Sri Ramakrishna Hospital Campus, Coimbatore. The grand programme comprised the **64th NPW celebrations**, a **prestigious awards ceremony** and the **Dr. T. K. Ravi Memorial Lecture**.

The event witnessed an overwhelming participation of **more than 800 delegates**, including eminent pharmacy professionals, academicians, and students from across Tamil Nadu. The celebrations revolved around the national NPW theme, **"Pharmacists as Advocates of Vaccination,"** highlighting the expanding role of pharmacists in public health and preventive care.

The inaugural session commenced with a warm **welcome address by Mr. J. Jayaseelan**, President, IPA–Tamil Nadu State Branch, who outlined the various professional and public health initiatives undertaken by IPA to strengthen the pharmacy profession. The programme was presided over by **Mr. R. Sundar Ramakrishnan**, Managing Trustee, SNR Sons Charitable Trust, who reflected on the invaluable professional contributions and enduring legacy of the late **Dr. T. K. Ravi**.

Subsequently, **Dr. S. Sriram**, Principal, College of Pharmacy, SRIPMS, elaborated on the NPW theme, emphasizing the growing responsibilities of pharmacists in vaccination advocacy and community health education.

As the **Guest of Honour**, **Dr. S. V. Veeramani**, Chairman, TNPSW Trust, and CMD, Fourrts India Laboratories Pvt. Ltd., addressed the gathering. He highlighted the extensive welfare and educational initiatives of the TNPSW Trust and shared insights into the current scenario and positive growth trajectory of the pharmaceutical industry in Tamil Nadu. The joint organization of the programme reflected a strong collective commitment to professional excellence and public service.

A key highlight of the event was the **Dr. T. K. Ravi Memorial Lecture**, delivered by the **Chief Guest, Dr. B. Suresh**, Pro-Chancellor, JSS Academy of Higher Education and Research, Mysuru. His address paid rich tribute to the remarkable academic and research contributions of the late Dr. T. K. Ravi, a revered stalwart of the pharmacy profession. A brief profile on Dr. Ravi's professional achievements was presented by **Mr. Ramanathan**, President, IPA–Coimbatore Local Branch.

The programme then progressed to the **TN IPA Professional Awards Ceremony**. The **TN IPA Best Pharmacist Award**, sponsored by **M/s. Lalchand Bhimraj, Chennai**, was announced by **Dr. K. Chinnaswamy**, President, Indian Association of Colleges of Pharmacy (IACP), and was conferred upon **Mr. G. Anandaselvam**, Director – Marketing, Icarus Health Care Pvt. Ltd., Chennai, and EC Member, IPA–TNSB.

IPA Recognition Awards were presented in the following categories:

Industrial Pharmacy Division – *Mr. Sanjay Kumar Dasmohapatra*, COO, Medopharm Pvt. Ltd., Chennai

Pharmacy Education – *Dr. M. Ramanathan*, Principal & Professor of Pharmacology, PSG College of Pharmacy, Coimbatore, and President, IPA–Coimbatore Local Branch

Regulatory Division – *Mr. A. M. Shabudeen*, Retired Assistant Director of Drugs Control, Tamil Nadu

Hospital Pharmacy & Pharmacy Practice – *Dr. S. Sriram*, Principal, College of Pharmacy, SRIPMS, Coimbatore

Community Pharmacy Division – *Mr. A. Kasiraman*, Thirumala Medicals, Coimbatore

The **IPA Special Recognition Award for Academic, Administrative, and Research Excellence** was presented to **Dr. S. P. Dhanabal**, Principal, JSS College of Pharmacy, Ooty.

The **TNPSW Trust Awards** segment recognized outstanding academic performance among pharmacy students. The **G. Rangachari Memorial Awards** were presented to M.Pharm students across six specializations—Pharmaceutics, Pharmaceutical Chemistry, Pharmaceutical Analysis, Pharmacology, Pharmacognosy, and Pharmacy Practice—with prize amounts of **₹12,000 (First Prize)**, **₹10,000 (Second Prize)**, and **₹8,000 (Third Prize)**. For **Pharm.D students**, prizes of **₹15,000 (First Prize)**, **₹12,000 (Second Prize)**, and **₹10,000 (Third Prize)** were awarded.

The programme also honoured winners of the **G. Swaminathan Memorial Essay Competition** on the topic **"Pharmacists as Advocates of Vaccination."** Cash prizes of **₹10,000 (First Prize)**, **₹8,000 (Second Prize)**, and **₹7,000 (Third Prize)** were distributed. This competition was sponsored by **M/s. Pharma Products Pvt. Ltd., Thanjavur**.

In addition, the **Fourrts University Merit Awards**, instituted by **M/s. Fourrts (India) Laboratories Pvt. Ltd., Chennai**, were conferred upon the **top three B.Pharm students** of the **October 2024 examinations**, with cash prizes of **₹10,000**, **₹8,000**, and **₹7,000**, respectively.

These awards reflect the Trust's continued commitment to nurturing academic excellence in pharmacy education.

The grand inauguration concluded with a **vote of thanks proposed by Mr. Rajesh Bhandari**, Secretary, IPA–Tamil Nadu State Branch, marking a successful and memorable beginning to the **64th National Pharmacy Week celebrations**.

Awareness Program on Vaccination

Periyar College of Pharmaceutical Sciences conducted an **Awareness Program on Vaccination** as part of the **64th National Pharmacy Week celebrations**. We are pleased to inform you that the awareness activity was successfully organised on **22.11.2025**.

As part of the programme, printed pamphlets containing information on vaccination in both **English and Tamil** were distributed to the general public. The pamphlets were shared with visitors in and around pharmacies, hospitals, and nearby public places to emphasise the importance of vaccination.

Our **D. Pharm students** actively participated in the initiative by interacting with the public, explaining the key points highlighted in the pamphlets, and creating awareness about the importance of timely vaccination.

NOTIFICATION

MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health and Family Welfare)

NOTIFICATION

New Delhi, the 29th July, 2025

G.S.R. 513(E).——Whereas a draft of certain rules to amend the Cosmetics Rules, 2020 was published, as required under sub-section (1) of section 12 and sub-section (1) of section 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940), *vide* notification of the Government of India in the Ministry of Health and Family Welfare (Department of Health and Family Welfare) number G.S.R. 371 (E), dated the 15th May, 2023, published in the Gazette of India, Extraordinary, Part II, Section 3, sub-section (i), dated the 17th May, 2023, inviting objections and suggestions from 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 Official Gazette were made available to the public on the 17thMay, 2023;

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

Now, therefore, in exercise of the powers conferred by section 12 and 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 to amend the Cosmetics Rules, 2020, namely:–

1. Short title and commencement.- (1) These rules may be called the Cosmetics (Amendment) Rules, 2025.

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

2. In the Cosmetics Rules, 2020 (hereinafter referred to as the said rules), in rule 3, in clause (w), the following explanation shall be inserted, namely:-

"*Explanation:*-For the purposes of this clause, the expression"use before" means, use before the first day of a month mentioned on label and the expression "date of expiry" mean the cosmetic expires on the last day of the month.".

3. In the said rules, in rule 6, for the words "controlling officer"at both the places, where they occur, the words "Controlling Authority" shall be substituted.

4. In the said rules, for rule 7, the following rule shall be substituted, namely:-

" 7. Government Analyst:- The Government Analyst appointed under section 20 of the Act (23 of 1940) shall be the Government Analyst for the purposes of these rules."

5. In the said rules, in rule 9, for the words "*controlling officer*", wherever they occur, the words "Controlling Authority" shall be substituted.

6. In the said rules, in rule 11, for the heading and sub-rule (1), the following heading and sub-rule shall respectively be substituted, namely:-

"11. ***Central Cosmetics Laboratory and its function.-*** (1) The Central Drugs Laboratory established under the Act shall function as the Central Cosmetics Laboratory for the purposes of,

(a) analysing or testing such samples of cosmetics as may be sent to it under sub- section (2) of section 11 or under sub-section (4) of section 25 of the Act; or

(b) functioning as an appellate laboratory; or

(c) carrying out any other function as may be specifically assigned to it by the Central Government."

7. In the said rules, in rule 26,-

(i) in clause (c), in sub-clause (ii), for the words 'Central Licensing Authority', the words "State Licensing Authority" shall be substituted;

(ii) for clause (f), the following clause shall be substituted, namely:-

"(f) The licensee shall keep record of the details of each batch of cosmetic manufactured and of the raw materials used therein as per the particulars specified in the Eighth Schedule either as hardcopy or through electronic means and such records shall be retained for a period of three years or six months after expiry of the batch whichever is later.";

(iii) for clause (h), the following clause shall be substituted, namely:-

"(h) The licensee shall test each batch or lot of the raw materials used for manufacturing the cosmetics and also each batch of final product and shall maintain records or registers, showing the particulars in respect of such tests and the records or registers either as hardcopy or through electronic means shall be retained for a period of three years or six months after expiry of the batch whichever is later.";

(iv) in clause (m), for the proviso, the following proviso shall be substituted, namely:-

"Provided that clauses (f) and (h) shall not apply to the manufacture of soap and the procedure for testing of raw materials and the records to be maintained by a manufacturer of soap shall be such as are approved by the Licensing Authority.".

8. In the said rules, in rule 31, in sub-rule (2), for the words "*Controlling officer*", the words "Controlling Authority" shall be substituted.

9. In the said rules, after rule 31, the following rule shall be inserted, namely:-

"**31A. Cancellation or suspension of licence**.− (1) If a licensee fails to comply with any of the conditions of license or with any provision of the Act or the rules made thereunder, the State Licensing Authority may, after giving the licensee an opportunity to show cause

as to why an order for cancellation or suspension of license should not be passed and after giving an opportunity of being heard, by an order in writing, stating the reasons thereof, cancel a licence issued under these rules or suspend it for such period as he thinks fit, either wholly or in respect of some of the substances to which it relates.

(2) A licensee whose licence has been suspended or cancelled, may, within a period of ninety days from the date of the order, appeal to the State Government which shall, after considering the appeal and after giving an opportunity of being heard to the said appellant for hearing, pass such order as it deems fit which shall be final".

10. In the said rules, in rule 34, for sub-rule (10), the following sub-rule shall be substituted, namely:-

"(10) In case, the cosmetic is meant for export, then the label on package or container of cosmetic shall comply with the law of the country to which the cosmetic is to be exported:

Provided that where a cosmetic is required by the consignee to be not labeled with the name and address of the manufacturer, the label on package or container shall bear a code number as approved by the State Licensing Authority.".

11. In the said rules, in rule 49, -

(i) in sub-rule (1), the words "or by courier" shall be omitted;

(ii) in sub-rule (3), the words "or courier" shall be omitted.

12. In the said rules, in rule 53, in sub-rule (2), for the words "or adulterated cosmetic", the words

"or spurious cosmetics under section 17D or adulterated cosmetic" shall be substituted

13. In the said rules, in rule 60,-

(i) in sub-rule (1), (a) for the words "A licence issued", the words "An approval issued" shall be substituted;

(b) for the words "a licence retention", the words "approval retention" shall be substituted;

(ii) in sub-rules (2) and (3), for the word "licence", wherever it occurs, the word "approval" shall be substituted.

14. In the said rules, in rule 61,-

(i) for the words "premises licensed", the words "approved premises" shall be substituted;

(ii) for the word "licence", the word "approval"shall be substituted.

15. In the said rules, in rule 62, in clause (e), for the words “renewal of approval”, the words “end of retention period of approval”shall be substituted.

16. In the said rules, in rule 63, for the word “Part”, the word “Chapter”shall be substituted.

17. In the said rules, in rule 69, in sub-rule (2), for the words “Central Licensing Authority”, the words “Licensing Authority”shall be substituted.

18. In the said rules, in First Schedule, in paragraph (6), for the words “withdraw of this Power of Attorney”, the word “withdrawal of authorisation” shall be substituted.

[F. No. X.11014/16/2021-DR]
RAJIV WADHAWAN, Advisor (Cost)

Note: The principal rules were published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (I) *vide* notification number G.S.R.763 (E), dated the 15th December, 2020.

MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health and Family Welfare)

NOTIFICATION

New Delhi, the 1st August, 2025

S.O. 3551(E).— In pursuance of sub-rule (1) of rule 3 of the Drugs and Cosmetics (Compounding of Offences) Rules, 2025, the Central Government hereby appoints Additional Director General of Health Services dealing with the matters of Central Drugs Standard Control Organization, as compounding authority for the purpose of exercising powers and functions of the Central Government in respect of compounding of offences and for taking measures with respect to matters arising from the said rules.

2. This notification shall come into force from the date of its publication in the Official Gazette.

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

MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health and Family Welfare)

NOTIFICATION

New Delhi, the 18th August, 2025

G.S.R. 554(E).——Whereas a draft of certain rules further to amend the Drugs Rules, 1945 was published, as required under sub-section (1) of sections 12 and sub-section (1) of 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940) vide notification of the Government of India in the Ministry of Health and Family Welfare (Department of Health and Family Welfare), number G.S.R. 391 (E), dated the 12th July, 2024, in the Gazette of India, Extraordinary, Part II, Section 3, sub-section (i), inviting objections and suggestions from persons likely to be affected thereby, before the expiry of a period of thirty days from the date on which the copies of the Gazette containing the said notification were made available to the public;

And whereas copies of the said Gazette were made available to the public on the 12thJuly, 2024;

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

Now, therefore, in exercise of the powers conferred by sections 12 and 33 of the said Act, the Central Government, after consultation with Drugs Technical Advisory Board, hereby makes the following rules further to amend the Drugs Rules, 1945, namely:—

1. (1) These rules may be called the Drugs (2nd Amendment) Rules, 2025.

(2) They shall come into force from 1st March, 2026.

2. In the Drugs Rules, 1945, in rule 96, in sub-rule (7), —

(a) In clause (vii), for the words “date of expiry; and”, the word “date of expiry” shall be substituted;

(b) After clause (viii), the following clause shall be inserted, namely:-

“(ix) qualitative details of excipients.”

[F. No. X.11035/44/2024-DRS]
NIKHIL GAJRAJ, Jt. Secy.

Note: The principal rules were published in the Official Gazette *vide* notification No. F. 28-10/45-H(1) dated the 21st December, 1945 and last amended *vide* notification number G.S.R. 127(E), dated 11th February, 2025.

MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health and Family Welfare)

NOTIFICATION

New Delhi, the 31st October, 2025

G.S.R. 810(E).— In the draft notification of the Government of India, Ministry of Health and Family Welfare, published in the Gazette of India, Extraordinary Part II, Section 3, Sub-Section(i) vide G.S.R. 587 (E) dated the 27th August, 2025—

(i) In para 2 under the draft rules, the condition no. 3 of the Proviso **for the words** "The samples size should not be more than 48" **the following shall be substituted as,** :- "The samples size should be more than or equal to 18".

Objections and suggestions which may be received from any person within 15 days of the publication of this corrigendum will be considered by the Central Government.

Objections and suggestions, if any, may be addressed to the Director (Drugs), Ministry of Health and Family Welfare, Government of India, Room No. 407, A Wing, Nirman Bhavan, New Delhi - 110011 or emailed at drugsdiv-mohfw@gov.in.

[F. No. X.11014/06/2025-DR]
NIKHIL GAJRAJ, Jt. Secy.

MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health and Family Welfare)

NOTIFICATION

New Delhi, the 23rd September, 2025

S.O. 4338(E).—WHEREAS, the Central Government has published a draft notification, in exercise of the powers conferred by section 26A of the Drugs and Cosmetics Act, 1940 (23 of 1940), *vide* notification of the Government of India in the Ministry of Health and Family Welfare (Department of Health and Family Welfare) number S.O. 2298 (E), dated the 22nd May, 2025, in the Gazette of India, Extraordinary, Part II, section 3, sub-section (ii), inviting objections and suggestions from persons likely to be affected thereby, before the expiry of a period of thirty days from the date on which the copies of the Gazette of India containing these draft notification are made available to the public;

AND WHEREAS, copies of the said Official Gazette were made available to the public on the 22nd May, 2025;

AND WHEREAS, no objections and suggestions were received from the public on the said rules;

AND WHEREAS, safer alternatives to the said drugs for animal use are available;

AND WHEREAS, the Central Government is satisfied that it is necessary and expedient in the public interest to prohibit the import, manufacture, sale, and distribution of any antimicrobial medicinal products for animal use as specified in this notification;

Now, therefore in exercise of the powers conferred by sections 10A & 26A of the Drugs and Cosmetics Act, 1940 (23 of 1940), after consultation with the Drugs Technical Advisory Board, the Central Government hereby prohibit the import, manufacture, sale and distribution of the following antimicrobials and group of such antimicrobials and their formulations for animal use namely: -

1. Antibiotics
i. Ureidopenicillins
ii. Ceftobiprole
iii. Ceftaroline
iv. Siderophore cephalosporins
v. Carbapenems
vi. Penems
vii. Monobactams
viii. Glycopeptides
ix. Lipopeptides
x. Oxazolidinones
xi. Fidaxomicin
xii. Plazomicin
xiii. Glycylcyclines
xiv. Eravacycline
xv. Omadacycline

2. Antivirals
i. Amantadine
ii. Baloxavir marboxil
iii. Celgosivir
iv. Favipiravir
v. Galidesivir
vi. Lactimidomycin
vii. Laninamivir
viii. Methisazone/ Metisazone
ix. Molnupiravir
x. Nitazoxanide
xi. Oseltamivir
xii. Peramivir
xiii. Ribavirin
xiv. Rimantadine
xv. Tizoxanide
xvi. Triazavirin
xvii. Umifenovir
xviii. Zanamivir

3. Antiprotozoals
I. Nitazoxanide

[F. No. X.11035/125/2024-DR]
NIKHIL GAJRAJ, Jt. Secy.

NEWS

Apollo Hospitals to Hive off Pharmacy, Digital Biz

Apollo Hospitals Enterprise, controlled by the Prathap Reddy family, has announced a significant reorganisation where its pharmacy distribution and digital health operations will be carved out into a separate entity.

This new entity, Apollo Healthtech, will seek listing on stock exchanges over the next 18 to 21 months, with current Apollo Hospitals shareholders receiving proportionate shares in the new company. The deal will create a leading omni-channel pharmacy distribution and digital health platform in India with revenues of Rs 16,300 crore ($1.9 billion), Apollo Hospitals said in a statement.

Currently, Apollo Healthco (AHL) manages the wholesale pharmaceutical trading and Apollo 24/7 digital platform, while Keimed oversees wholesale distribution of pharmaceuticals and wellness products. Apollo Hospitals holds about 79% ownership in AHL, and Keimed operates as a related party to Apollo Hospitals.

The share allocation structure stipulates that for every 100 shares held in Apollo Hospitals, shareholders will receive 195.2 shares in the new company. AHL shareholders will get 89.5 shares for every 100 shares owned, while Keimed shareholders will receive 3045.2 shares for every 100 shares held. Following the completion of this demerger, both AHL and Keimed will cease to exist.

Under the agreement terms, Apollo Hospitals shall restrict its pharmaceutical operations exclusively to hospital-based pharmacies, refraining from any involvement in e-commerce, retail or wholesale pharmacy ventures. Veda Corporate Advisors was the exclusive financial advisor to the transaction.

The new company, Apollo Healthtech, will subsequently acquire 74.5% stake in Apollo Medicals, consolidating the front-end pharmacy business. Apollo Hospitals will own a 15% stake in Apollo Healthtech and will have one nominee director on the board, the Chennai-based company said.

Apollo Hospitals chairman Prathap C Reddy, said: "Today's developments mark the beginning of the next chapter of Apollo Hospitals. The omnichannel pharmacy business and integrated digital healthcare ecosystem will be a unique model to enable access to high-quality healthcare for millions of Indians."

Source: *The Times of India,* 1st July 2025

Rs 1L cr R&D Scheme to Boost Pvt Sector Innovation Gets Nod

The Union Cabinet on Tuesday cleared the Research, Development and Innovation (RDI) Scheme with a financial commitment of Rs 1 lakh crore. Designed to strengthen India's private research and innovation ecosystem, the scheme will provide long-term, low-cost financing to catalyse investment in emerging and strategic sectors.

Briefing the media, Union minister Ashwini Vaishnaw described the scheme as a pivotal initiative to drive high-impact R&D, particularly in areas critical to India's economic resilience, strategic autonomy and global competitiveness. The scheme targets the funding shortfall faced by private enterprises working on cutting-edge technologies, offering support through low or zero interest loans and equity funding.

The RDI Scheme's objectives include scaling up private sector research in emerging technologies, supporting high technology readiness level projects with transformative outcomes and facilitating access to strategically significant technologies. It also envisages the creation of a 'Deep-Tech Fund of Funds'.

The initiative will be steered by the Anusandhan National Research Foundation, with its governing board chaired by the PM. The executive council will operationalise the scheme by finalising guidelines and selecting fund managers, while an empowered group of secretaries, headed by the cabinet secretary, will monitor performance and approve changes when needed. The science and technology department will serve as the nodal agency for implementation.

Funding will be disbursed through a two-tier structure. A special purpose fund within the foundation will hold the corpus, which will then be deployed by selected fund managers to offer concessional financing or equity support, especially targeting start-ups and deep-tech enterprises.

Source: *The Times of India,* 2nd July 2025

Lupin Gets U.S. FDA Nod for Loteprednol Etabonate Ophthalmic Gel

Generic drugmaker Lupin has received U.S. Food and Drug Administration approval for its abbreviated new drug application for Loteprednol Etabonate Ophthalmic Gel, 0.38%

The approved product is bioequivalent to Lotemax SM Ophthalmic Gel of Bausch & Lomb Inc. Lupin is the exclusive first-to-file for the product and consequently eligible for 180 days of generic drug exclusivity. The product will be manufactured at its Pithampur facility, the company said.

Loteprednol Etabonate Ophthalmic Gel, 0.38% (RLD Lotemax SM) had an estimated annual sale of $29 million in the U.S., it said citing IQVIA MAT May 2025 numbers. A corticosteroid, the drug is indicated for treatment of postoperative inflammation and pain following ocular surgery.

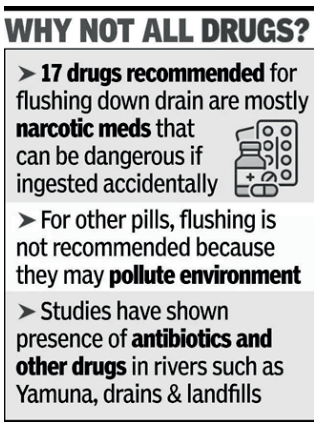
Source: *The Hindu,* 1st July 2025

Drug Regulator Issues List of 17 Drugs Which Should be Flushed Down if Unused or Expired

India's top drug regulatory body, Central Drugs Standard Control Organisation (CDSCO), has released a list of 17 drugs which, it says, should be flushed down the sink if lying unused or expired at home.

This includes fentanyl, Tramadol and several other painkiller drugs and Diazepam which is an anti-anxiety medication.

According to the CDSCO, these drugs may be especially harmful and, in some cases, fatal with just one dose if they are used by someone other than the person for whom the medicine was prescribed. If these drugs are kept unwanted, unused or expired, the drug regulatory body says, they should be flushed down the sink or toilet to prevent danger to people and pets in the home. However, for most other medications used commonly by people, the drug regulatory body in its latest guidelines on disposal of unused/expired drugs recommends that scientific disposal is needed to prevent environmental pollution.PMBJP is cruising towards new heights as more and more people are resorting to generic



For that, it suggests the initiation of 'drug take back' initiative that could be led by either the state drug control department or local chemists initially but eventually, the CDSCO recommends, the state govt in coordination with local bodies needs to establish the methodology and facility for the collection of and disposal of unused or expired drugs as per the provision of Biomedical Waste Management Rules.

"Initially, state drugs control departments and concerned chemists and druggists' associations may jointly launch 'drug take back' site programme at designated locations, where people can drop expired or unused drugs from their homes and that can be disposed finally by such associations under intimation to concerned state drug licencing authority with the help of registered/licenced external agencies.

The CDSCO guideline follows multiple reports and studies that show how unscientific disposal of unused or unexpired drugs is causing environmental pollution, eventually affecting human life.

A study by led by Dr T Velpandian of AIIMS' ocular pharmacology division that analysed water samples from seven places in Yamuna river, including the entry and exit points, 35 bore wells in Delhi NCR and the water percolating from waste at Ghazipur landfill site in 2018 showed drugs thrown in the waste bins end up in the environment and contribute to the emergence of multi-drug resistant pathogens.

The study showed presence of antibiotics

and other drugs in the surface water of river Yamuna and in areas adjacent to the Ghazipur landfill. “The govt move to formulate a guideline on disposal of unused or expired drugs is commendable indeed. We also plan to develop a pamphlet on how to dispose of drugs that will be given to all patients while being discharged from the hospital to create more awareness on the subject,” Devarati Majumdar, director and chief of pharmacy at Max healthcare said. She added that the drugs mentioned by the CDSCO in the 'flush list' contain mostly the narcotic drugs that are addictive and vulnerable for misuse and that's why the govt may have suggested they be flushed down.

Source: *The Times of India,* 8th July 2025

Centre Fixes Prices of 71 Key Drug Formulations, Including Cancer Medicines

The Centre has fixed the price of 71 key drug formulations, including medicines approved for treating metastatic breast cancer, allergies and diabetes, among others.

Also, the notification issued by the National Pharmaceutical Pricing Authority (NPPA) states that the manufacturer may add Goods and Services Tax (GST) only if they have paid or it is payable to the government on the retail price.

The drugs for which prices have been fixed include Trastuzumab by Reliance Life Sciences. It is used in the treatment of metastatic breast cancer and gastric cancer. The NPPA has fixed its price at Rs 11,966 per vial.

The price of a combination drug containing clarithromycin, esomeprazole and amoxicillin which is used to treat peptic ulcer disease - a sore on the lining of the stomach - manufactured by Torrent Pharmaceuticals has been fixed at Rs 162.5 per tablet.

The price of a combipack of ceftriaxone, disodium edetate and sulbactam powder used to treat life-threatening infections has been fixed at Rs 626 per vial. Another key drug combination used for treating infections containing ceftriaxone, disodium edetate and sulbactam powder for solution for Infusion from Tyykem has been priced at Rs 515.5 per vial, according to the NPPA notification.

The NPPA has also notified the retail price of 25 anti-diabetes formulations containing sitagliptin as a component, apart from several other antidiabetic formulations containing empagliflozin as a combination in its latest notification. NPPA, a government regulatory agency, is responsible for controlling and revising the prices of pharmaceutical products in India.

In February, the regulatory body issued an order stating that drug manufacturers must issue a price list to the dealers, state drug controllers and the government, indicating reference to such price fixation or revision as covered by the order or gazette notification issued by the government from time to time. "The order to display the price list is to allow citizens to cross-check whether the pharmacies are selling at the price fixed by NPPA or not," said an official.

"Every retailer and dealer shall display the price list and the supplementary price list, if any, as furnished by the manufacturer, on a conspicuous part of the premises where he carried on business in a manner so as to be easily accessible to any person wishing to consult the same," the NPPA's February order stated. It added that the directive also covers the virtual/online premises where the retailer or dealer carries on business.

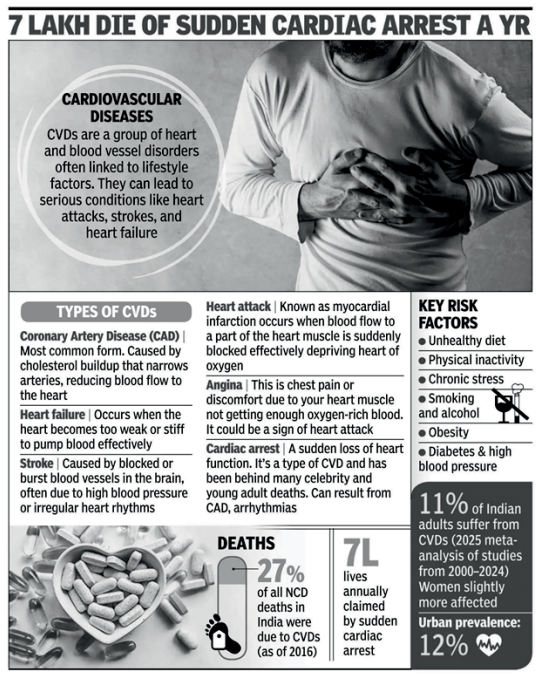
Source: *The Times of India,* 15th July 2025

Cardiac Medication Sales Shoot Up 50% in Five Years

India's heart disease burden is evident not only from the spate of heart attacks among young celebrities in the past five years, but also in the over-50% rise in cardiac medication sale in the same period.Be they lipid-lowering drugs, heart-failure medications or anti-anginal treatments, cardiac medications sell more than drugs meant for any complications, including the gastro-intestinal tract, infections or diabetes.

According to June report of Pharmarack, which analyses sales figures from 17 prominent Indian pharmaceutical companies representing more than half of the sector, sales of cardiac medicines rose from Rs 1,761 crore in June 2021 to Rs 2,645 crore by June 2025. There has been a consistent yearly growth rate of 10.7% in this sector, showed the report.

Experts offer a slew of reasons for this rise, ranging from better awareness of heart diseases, new parameters for measuring hypertension as well as the increasing population of senior citizens. “There is no doubt that cardiovascular diseases are on the rise, but at the same time, access to care and diagnostic tools has improved," said Dr Ajay Mahajan, head of the cardiology department at KEM Hospital.



Centre's data suggests that 63% of total deaths in the country were due to non-communicable diseases (NCDs), with cardiovascular diseases (CVDs) accounting for 27%.

Dr Suraj Nagre, associate professor at JJ Hospital's cardiovascular and thoracic surgery department, offers another reason: “A few years ago, the threshold for hypertension was a reading of 130-140. Medical guidelines have since changed and even readings above 120 are considered hypertensive.”

While heart care until a few years back mainly meant lipid-lowering medications, the prescriptions for other drugs meant to control unstable heart rhythm or heart failure have also increased. “Cardiovascular medications are interrelated because they target different but connected pathways of disease,” said senior cardiac surgeon Dr Ramakanta Panda. “For example, anti-hypertensives lower blood pressure to reduce the strain on arteries and the heart. Lipid-lowering drugs like statins reduce cholesterol helping prevent arterial blockages. Anti-anginals improve blood flow to the heart muscle, relieving chest pain caused by narrowed arteries. These medications are often prescribed together," said Dr Panda.

Referring to the frequent reports of cardiac arrest deaths among common people as well as celebrities and fitness enthusiasts, KEM cardiologist Dr Charan Lanjewar said underlying factors are almost always involved. “There's a lack of data to identify a single cause in many cardiac arrest cases. The reasons are multifactorial, but lifestyle, stress, and consumption habits play a vital role,” Dr Lanjewar said.

The aging population is more prone to heart conditions. Senior cardiologist Dr Akshay Mehta said, “The lifespan of the Indian population has increased and with a growing aging population, we are seeing a higher incidence of heart disease. Along with rising incidence, we also have better diagnostic tools now.”

Source: *The Times of India,* 21st July 2025

Study Recommends Two Half-Dose Combination of Drugs in A Single Pill for Good Blood Pressure Control in Indians

With evidence lacking thus far for guiding optimal combination hypertension therapy in South Asian patients, a recent study has recommended half doses of two drugs in a single pill combination right from the start of treatment for hypertension.

The paper, ‘Comparison of dual therapies for hypertension treatment in India’, published in the journal *Nature Medicine*, investigated the blood pressure (BP)-lowering efficacy and safety of three commonly-recommended antihypertensive combinations in a single pill in a multi-centre trial across 32 sites in India. Nearly 2,000 adults with uncontrolled or untreated hypertension were studied, and interventions included three single-pill dual combinations: Amlodipine + Perindopril, Perindopril + Indapamide and Amlodipine + Indapamide.

All three combinations, in patients aged 30–79, delivered equivalent BP reductions and similar rates of BP control, researchers said. All combinations were equally safe and effective with high tolerability over six months, they wrote in the paper.

”It must be noted that we are not recommending a multi-drug regimen. Polypharmacy will only lead to discontinuation of treatment,” says Prabhakaran Dorairaj, principal investigator of the study, from the Centre for Chronic Disease Control, New Delhi. “What we are recommending is to start with half doses of two drugs in a single pill combination. If BP control does not happen, then it is important to titrate to full doses. Despite this, if BP continues to be higher than 140/90, then additional drugs are to be added,” he explains.

“It is really astounding that we have been basing treatment on Western guidelines, so far,” Dr.Prabhakaran adds. This study tests the global guidelines for hypertension treatment among

patients in India, since these combinations are already available here. These drugs work through multiple pathways and are synergistic, with low side effects, he says.

"Many physicians, even cardiologists, think that they should start with a low dose and then keep escalating it," says Nagendra Boopathy, co-author and interventional cardiologist, Sri Ramachandra Medical Centre, Chennai. "Even patients are reluctant to start on drugs, but these combinations we have tested are really effective in bringing down BP, and the side effects are minor," he adds. The side effects observed during the trial included cough, swelling of feet and lower potassium in some subgroups, and not statistically significant.

Dr. Prabhakaran adds, "The biggest problem in India is poor control of hypertension. Only around 20% of individuals with hypertension are treated to target in urban areas, and it is even lower in rural areas. It is estimated that a 10 mm reduction in BP among people with hypertension can prevent 40% of strokes. A vibrant pharmaceutical industry, which makes these single combinations and pooled procurement via the public health system, should help drive down prices, making this a key strategy in the battle against hypertension."

Source: *The Hindu,* 27th July 2025

PhD Scholar Gets Rs 17.5L CM Grant for Cancer Research

A PhD scholar from Thanthai Periyar Govt Arts & Science College has been granted 17.5 lakh under the chief minister's research grant for a cancer research project that explores a medicinal plant-based drug as an alternative to treat breast and colon cancer.

P Backya Lakshmi, a PhD scholar with the biochemistry department, is investigating anti-cancer potential of Caesalpinia bonducella (kalarchikaai) extract in breast (MCF-7) and colon (HT-29) cancer cell lines. The grant for 2024-25 was approved by Directorate of Technical Education.

Backya Lakshmi has been chosen as the principal investigator for the project that can be taken up for three years. Assistant professor C Aiyavu will be the co-principal investigator. "The proposal I sent is regarding usage of a drug made using a medicinal plant to treat particularly breast and colon cancer. I believe such drugs would help patients from side effects of cancer treatment such as chemotherapy," P Backya Lakshmi, who also pursues a PhD programme on a different topic, said.

Last year, Aiyavu received 39.9 lakh from the CM's research grant for a project involving finding medicinal plant-based drugs to treat oral and colon cancer. Aiyavu said out of the sanctioned grant, 20 lakh has been spent to develop an advanced cancer research lab. "The lab will be completed soon. It could be the-first-of-a-kind lab inside a govt college in TN. The aim is to find plant-based alternatives for cancer treatment," he said.

Source: *The Times of India,* 9th August 2025

ICMR Offers Indigenous Tech to Replace CT/MRI Scans for Traumatic Brain Injuries, Seeks Support from State Governments

Aimed at reducing mortality and disabilities caused by traumatic brain injuries (TBI), especially in rural areas where advanced diagnostic tools, including CT (computerised tomography) or MRI (magnetic resonance imaging) scans are inaccessible or delayed, the Indian Council of Medical Research (ICMR) is offering CEREBO, a portable, non-invasive brain injury diagnostic tool which has been developed using advanced near-infrared spectroscopy technology powered by machine learning.

The ICMR is now seeking support from State governments to leverage this indigenous, relatively low-cost technology.

The handheld machine is safe for infants and pregnant women, too. It can be used by paramedical staff as well as unskilled personnel with just 30 minutes of training.

"TBI is a significant public health challenge, particularly in emergency settings. Traditional methods, such as the Glasgow Coma Scale, are prone to errors and subjective interpretations, while imaging techniques require specialised infrastructure, trained personnel, and are cost-intensive," Dr. Rajiv Bahl, head, ICMR, said.

The new device could detect intracranial bleeding and edema within a minute, he added, and provided colour-coded, radiation-free, and cost-effective results.

"Designed for deployment in ambulances, trauma centres, rural clinics, and disaster response units, it enhances early TBI detection and patient outcomes," Dr. Bahl said.

Developed in a collaboration between the ICMR's Medical Device and Diagnostics Mission Secretariat (MDMS); All India Institute of Medical Sciences (AIIMS), Bhopal; the National Institute of Mental Health and Neurosciences (NIMHANS), Bengaluru; and Bioscan Research, CEREBO has undergone clinical validation, regulatory approvals, and feasibility studies, "paving the way for global adoption in emergency and military healthcare systems," Dr. Bahl said.

Additionally, the ICMR noted that multi-centre clinical performance evaluation, and utility trials supported by the ICMR-MDMS's mPRiDE scheme, were conducted at leading trauma care and neurosurgical centres to generate robust, prospective evidence on diagnostic accuracy, time-to-decision benefits, and integration feasibility within emergency care pathways.

The ICMR is now seeking to enhance the device's adoption in tertiary care to accelerate emergency diagnosis, optimise triage, and reduce imaging costs.

India has the highest incidence of head injuries in the world, according to the Indian Head Injury Foundation, with more than 100,000 lives lost to head injuries every year, and over one million persons suffering from serious head injuries.

Half of those who die from TBI do so within the first two hours of injury. It's now known that only a portion of neurological damage occurs because of impact (the primary injury), and damage progresses during the ensuing minutes, hours, and days. The secondary brain injury can result in increased mortality and disability. Consequently, early and appropriate management of TBI is critical in securing better outcomes for patients.

Source: *The Hindu,* 23rd August 2025

Microbes that Digest Plastic May Also Fuel Antibiotic Resistance

Plastic is cheap, versatile, and used almost everywhere, from packaging and textiles to medical supplies. But unlike natural materials, 'plastic doesnt simply decay; instead, it breaks down into smaller fragments called microplastics (<5 mm) and nanoplastics (<1 µm).

These particles persist for decades or longer, accumulate in water bodies, and attract other pollutants like heavy metals, antibiotics, and toxic chemicals. They provide sticky surfaces where bacteria thrive, and recent research shows such surfaces can even host microbes carrying antibiotic resistance genes (ARGs). This raises fears that plastic waste may not only choke ecosystems but also help spread antimicrobial resistance (AMR).

Biodegradation offers a potential way forward. Some microbes produce enzymes capable of disintegrating the strong chemical bonds in plastic polymers. A famous example is PETase, discovered in *Ideonella sakaiensis*, which can degrade polyethylene terephthalate (PET), a common plastic used in bottles. Yet despite such exciting discoveries, natural microbial communities with this ability remain poorly understood, especially in environments where plastic pollution is constant and intense.

The Sundarbans, stretching across India and Bangladesh, is one such environment. It's the world's largest mangrove forest and receives around three billion microplastic particles every day through the rivers that feed into the Bay of Bengal. With such heavy exposure, microbes in this ecosystem may have evolved new ways to handle plastic waste. At the same time, because microplastics can carry antibiotics and metals, the same microbes may also acquire resistance traits. This two-faced possibility — plastic breakdown plus resistance — is at the heart of new work by scientists at the Indian Institute of Science Education and Research (IISER), Kolkata. Published in *FEMS Microbiology Letters*, it shows that the floating bacterial community in the Sundarbans possesses the genetic tools to degrade plastics and that these tools are also linked with genes for AMR and metal resistance.

The scientists collected one litre of surface water each month for nearly a year (2020-2021) from a site in the Mooriganga estuary, a branch of the Sundarbans. The water samples were filtered to capture microbial cells, and the DNA from these microbes was extracted. Using a technique called metagenomic sequencing, the researchers read the genetic material of the entire microbial community.

Then they compared the DNA sequences to specialised databases. PlasticDB was used to identify plastic-degrading enzyme (PDE) genes while other resources helped detect ARGs, metal resistance genes (MRGs), and mobile genetic elements — pieces of DNA that allow genes to move between microbes.

The analysis revealed an impressive 838 hits for plastic-degrading enzymes, representing the ability to act on 17 different plastic polymers. Most hits (73%) targeted synthetic plastics such as polyethylene glycol (PEG), polylactic acid, PET, and nylon, while the rest targeted natural polymers like polyhydroxyalkanoates. The single most abundant set of enzymes were those breaking down PEG, suggesting a strong contamination input from biomedical and industrial sources.

The PDEs were more abundant during the monsoon. “HpB reflects the occurrence of PDEs and ARGs per season,” IISER Kolkata biologist and study coauthor Punyasloke Bhadury said this is because “freshwater flow from inland to the coast during monsoon brings in nutrients, bacteria, and other materials including microplastics.”

Crucially, however, the study found that microbes carrying PDEs also often carried resistance genes. Genes for zinc resistance and for resistance to aminoglycoside antibiotics were particularly common among plastic degraders. A co-occurrence network analysis revealed strong associations between PDEs, ARGs, and MRGs, hinting that the same selective pressures — plastic additives, metals, and pollutants — are shaping microbial adaptation.

The findings paint a complex picture. On one hand, the discovery of such a diverse and abundant set of plastic-degrading enzymes is promising. It shows the Sundarbans' microbial community has already adapted to deal with the flood of plastic waste, potentially offering natural solutions to one of the world's most pressing environmental challenges.

On the other hand, the very microbes capable of breaking down plastics are also reservoirs of antibiotic and metal resistance genes. If such microbes were deliberately released or enriched in natural settings, they may contribute to the spread of resistance traits, undermining efforts to control AMR. In fact, plastics themselves may serve as hotbeds where resistance genes accumulate and spread between microbes through horizontal gene transfer. This makes the application of plastic-degrading microbes more complicated than it first appears.

“Changing climate can potentially accelerate the transfer of ARGs among bacteria, which may ultimately end up in humans,” Bhadury said. “This could have consequences for One Health and public health in general.”

Source: *The Hindu,* 31st August 2025

Study by IIT-M, Danish Researchers Unlocks Personalised Treatment of Cancer, Diabetes

Two genetic variants can work together as "switches" to unlock hidden metabolic pathways, research by IIT Madras and Danish researchers has shown. The discovery, based on research in yeast, offers new insights into diseases such as cancer and diabetes, leading to personalised medical treatment and better outcomes.

"Some diseases or disorders, such as colour blindness, are caused by a single gene mutation. These diseases are often rare and have clear, predictable inheritance patterns," said Department of Biotechnology professor Himanshu Sinha. "They work like an on-off switch. If the gene mutates, it causes the disease, regardless of other genetic or environmental factors," he said.

In diseases such as diabetes, cardiac diseases, or cancer, there are mutations in multiple genes. "Individual genes may only have a small, almost unnoticeable effect, but when they act together, they significantly increase a person's susceptibility to the disease," he said. These conditions are also often influenced by environmental factors such as diet, lifestyle, and exposure to toxins.

For the research, scientists focused on two specific genetic variants in yeast, MKT1(89G) and TAO3(4477C). Independently, these genes took different pathways. "When present together, they activated a hidden metabolic pathway. This effect was not seen when either variant was present alone, demonstrating that genetic interactions can create new biological outcomes," he said.

This means if a patient with a disease is treated for one of the pathways, the treatment would be ineffective or redundant, he said while discussing the study published in the science journal Nature Communications.

This discovery has significant implications for medicine and biotechnology as it paves the way for personalised medicine–new diagnostic tests and drug targets that account for the combined effects of genetic variants. It could also offer new avenues for research into conditions such as cancer, diabetes, and neurodegenerative disorders, he said. It can also provide a framework for precision agriculture and microbial engineering by leveraging gene–gene interactions to design stress-tolerant crops or industrial microbes with optimised metabolic traits, he added.

Source: *The Times of India,* 2nd September 2025

WHO Includes Drugs for Diabetes and Weight Loss in Essential Medicines List

With the World Health Organization (WHO) updating its Model Lists of Essential Medicines (EML) to add the GLP-1 class of drugs for diabetes with associated comorbidities such as obesity, access to these drugs might just become easier. Listing a medicine on the EML is one step in a series of actions that can lead to lower costs, better affordability, and greater access.

The 25th meeting of the WHO Expert Committee on the Selection and Use of Essential Medicines was held from May 5 to 9, 2025. It reviewed scientific evidence showing that a group of medicines called glucagon-like peptide-1 (GLP-1) receptor agonists can help people with type 2 diabetes — especially those who also have heart or kidney disease — and concluded that semaglutide, dulaglutide, liraglutide, and tirzepatide would be added to the EML. These drugs are used as glucose-lowering therapy for adults with type 2 diabetes mellitus and cardiovascular disease or chronic kidney disease and obesity.

High price

According to the WHO, the rationale for including these drugs is very clear: diabetes and obesity are two of the most urgent health challenges facing the world today. According to statistics from 2022, over 800 million people live with diabetes, with half going untreated. At the same time, more than one billion people worldwide are affected by obesity, and rates are rising fast especially in low- and middle-income countries.

The prices of these drugs are so high that access is limited. “A large share of out-of-pocket spending on noncommunicable diseases goes toward medicines, including those classified as essential and that, in principle, should be financially accessible to everyone,” Deusdedit Mubangizi, WHO Director of Policy and Standards for Medicines and Health Products, says.

Good step forward

While appreciating the move, Anoop Mishra, head, Fortis C-DOC Hospital for Diabetes and

and Allied Sciences, New Delhi, lends a reality check: “It is a good move; however, in India these types of drugs will benefit only a small number of people, while other life-saving, low-cost essential medicines for diabetes, hypertension, and heart disease, applicable to a large number of people, remain largely unavailable.”

On the other hand, V. Mohan, chairman, Dr. Mohan's Diabetes Specialties Centre (DMDSC), provides an energetic response: “I'm very happy that the WHO has included the GLP-1 class of drugs. The fact that even a conservative organisation like the WHO has included these rather expensive drugs in their EML, shows how compelling the evidence is. Apart from the glucose lowering effect, they have tremendous effect on weight reduction and obesity management.” He points out that, recently, injectible semaglutide has been approved for metabolic dysfunction-associated steatotic liver disease, associated with weight, and for improving cardio-metabolic health.

R.M. Anjana, managing director, DMDSC, says: “It will definitely help improve access and affordability. But will it be useful as a first line drug? This maybe not for everyone…as there are various subtypes of diabetes. But for those in whom it is indicated, it's a good step forward.”

The Model Lists are updated every two years by an Expert Committee, made up of recognised specialists from academia, research, and the medical and pharmaceutical professions, to address new health challenges, prioritise highly effective therapeutics, and improve affordable access.

Source: *The Hindu,* 16th September 2025

Abortion Kit Network Busted; Trader Among Four Booked

The directorate of drugs control in Tamil Nadu has busted a network selling abortion kits that may have aided sex-selective feticide. A trader, impersonating a licensed vendor, bought online kits and sold them to three others.

None of them had a licence to buy or sell drugs. Officials seized 6,720 medical termination kits and booked cases against all of them.

On Sept 12, drug inspectors found that Bengaluru-based Dharnidharan Selvam supplied the abortion kits to unlicensed distributors in Salem, Erode, and Theni.

"He produced the certificate of another vendor online, ordered thousands of MTP (medical terminaton of pregnancy) kits, and paid for them online," said deputy director of drugs control S Gurubharathi.

"He did not wait for the courier to be delivered as it may be delivered to the office of the licence holder. He went directly to the courier office and collected it," he said.

A team of drugs inspectors from the Namakkal district tracked down Selvam and three others who purchased the kits from him.

“We are verifying his bank accounts to check his network," Gurubharathi said. "We are also investigating if they are being supplied for sex-selective abortion." People who purchased these drugs have been traditional hotspots of feticide," he said. Meanwhile, the licence holder has filed a police complaint for misuse of his licence and impersonation.

MTP pills, which include a combination of mifepristone and misoprostol, should be taken under medical supervision for several critical safety and health reasons.

Patients must be screened before being administered the drugs, and they should be under medical observation to prevent possible complications which include bleeding and death. Officials said many traders buy habit-forming, abortion pills, and painkillers online, which is illegal. The department has written to the govt seeking a ban on the online sale of such drugs and stringent regulations.

Source: *The Times of India,* 27th September 2025

Can an Ivermectin Pill Keep Malaria from Being Transmitted?

Between 2000 and 2015, the 'worlds fight against malaria made remarkable progress, with millions of lives saved through better prevention, diagnosis, and treatment. Of late, however, that momentum has slowed. In 2023 alone, malaria claimed nearly 6 lakh lives, with 95% of those deaths occurring in the African region.

India has made dramatic progress too, with malaria cases dropping by over 80% in the last decade, especially in urban and semi-urban areas. However, some districts in Odisha, Chhattisgarh, Jharkhand, and the Northeastern States continue to struggle with persistent transmission.

This lingering threat has drawn renewed attention to the mass drug administration (MDA) of endectocides, systemic insecticides that work from inside the human body, as a promising tool to reduce malaria transmission. Among these, ivermectin reportedly stands out as the most promising candidate.

From worms to mosquitoes

Ivermectin has been around since the 1970s. Originally developed to treat parasitic worms, it has been safely given to more than four billion people and is a cornerstone of global campaigns against river blindness and lymphatic filariasis. Dubbed a "wonder drug," it earned its discoverers the Nobel Prize.

However, a surprising discovery later expanded its potential: mosquitoes that bit people recently treated with ivermectin often died or didn't live long enough to spread malaria.

This finding sparked renewed interest in using ivermectin as a vector control tool in malaria-endemic regions. Subsequent modelling and pilot studies suggested that mass drug administration with ivermectin, especially when timed to seasonal transmission peaks, could help bring down infection rates by shrinking the mosquito population.

In malaria control, mass drug administration aims to eliminate the parasite from both symptomatic and asymptomatic individuals, reducing the human reservoir and interrupting transmission.

The BOHEMIA trial

To test this idea in the real world, scientists launched the BOHEMIA trial in Kenya and Mozambique and the findings were published on July 23 in *The New England Journal of Medicine*.

In Kenya, the trial was conducted in Kwale County, a coastal region with year-round malaria

transmission despite 85% bed net coverage. The villagers were randomly given either ivermectin or albendazole (an anti-parasitic drug that doesn't affect mosquitoes) once a month for more than three months, starting in October 2023. Children aged 5 to 15, who are among the most vulnerable, were then monitored for six months.

The result: malaria cases dropped by 26% in the ivermectin group. This figure exceeded the World Health Organisation's threshold of a 20% reduction to be considered a valuable public health tool. Notably, children living farther from untreated areas had even greater protection, suggesting a strong community-level impact.

More than 56,000 doses were administered during the study and the participants reported no serious side effects. However, the trial excluded pregnant women and children under 15 kg of body weight, which may limit the drug's broader applicability.

The Mozambique trial could not yield conclusive results as the research term's operations were severely disrupted by Cyclone Gombe and a subsequent cholera outbreak.

The MATAMAL trial

In November 2024, a study in Guinea-Bissau called the MATAMAL trial involved more than 25,000 people in 24 villages. It tested whether adding the drug ivermectin to an already strong malaria treatment program — which used the drug dihydroartemisinin–piperaquine, or DP — could make the program work better.

Contrary to expectations, there was no significant difference in malaria prevalence between villages that received ivermectin and those that received a placebo. In fact, there were slightly more malaria cases in the ivermectin group, with no clear impact on mosquito survival or infection rates.

Researchers concluded that the timing and dosing used in this trial may not have been sufficient to add value to existing interventions.

Ivermectin still matters

Despite mixed results, both trials reaffirmed ivermectin's safety in large-scale campaigns. Side effects were mild and temporary, mostly headaches and dizziness, with no serious adverse events reported.

Ivermectin also offered a distinct advantage over traditional malaria control tools. Bed nets, indoor spraying, and larvicides target mosquitoes that bite indoors and at night. But mosquitoes evolve: some now bite earlier, outdoors or even feed on livestock. This makes it harder to keep them at bay with conventional tools.

On the other hand, ivermectin kills mosquitoes from the inside after they bite humans, regardless of time or location. It can also be delivered through existing deworming or parasitic disease campaigns, making it a practical dual-use tool, particularly in remote or underserved areas.

The BOHEMIA team also found significant collateral benefits. In Mozambique, people who took ivermectin had fewer skin problems like scabies and head lice. In Kenya, many noticed a dramatic drop in bed bugs.

Resistance concern

As with all widespread interventions, resistance is a looming concern. A 2024 review in *Parasitology Research* highlighted the growing resistance to ivermectin in ectoparasites like ticks, lice, and scabies mites, mostly due to overuse in veterinary medicine.

While resistance among human parasites is still rare, there's little data on its impact on *Anopheles* mosquitoes. Only two out of 18 reviewed studies examined ivermectin's impact on mosquito populations, highlighting a critical gap in surveillance.

Should resistance emerge, the drug's value as a malaria control tool could diminish rapidly. And the drug's widespread use for scabies, lice, and livestock parasites may make resistance develop faster.

Researchers have also warned that as ivermectin's mass drug administration expands, resistance in non-target organisms must be closely monitored as this risk is often overlooked. Ivermectin affects many parasites, so targeting one species may accelerate resistance in others. In regions with multiple parasites, the chosen doses might favour the target but harm broader control efforts.

To stay ahead, researchers are exploring longer-lasting formulations, higher doses, and combining ivermectin with malaria vaccines or genetically modified mosquitoes. Upcoming trial data and resistance tracking will shape its future role in malaria control programs.

Source: *The Hindu,* 28th September 2025

Pharmexcil Mulls SOP to Deal With Trade Payment Defaults

Pharma exporters body Pharmexcil is exploring the scope of evolving a standard operating procedure (SOP) to assist members grappling with payment defaults by buyers.

Though limited to certain cases, delayed payments or non-receipt of dues from overseas buyers is a challenge, impacting cash flows and posing significant hurdles to seamless export operations, the Pharmaceuticals Export Promotion Council of India said.

Seeking information from members on payment defaults to facilitate development of the SOP, the body under the Union Commerce Ministry said the development of the procedure will be in undertaken in collaboration with Indian Missions abroad, ECGC, DGFT as well as reputed payment collection agencies.

"This SOP aims to streamline the process of addressing payment-related grievances and enhance our ability to intervene constructively," Pharmexcil said in a communication to its members.

Member companies often approach Pharmexcil for assistance in resolving matters around delay and default in payments. "We wish to reiterate that as an export promotion council, our role is primarily facilitative. We do not possess statutory authority to enforce payment recovery. Nevertheless, we are committed to exploring structured mechanisms to support our members more effectively," Director General Raja Bhanu K said.

The Council is also in receipt of complaints from overseas buyers on payment default by India side, which would also be taken into account for ensuring seamless trade, Pharmexcil said, assuring confidentiality of the data and its use solely for the purpose of designing the SOP and engaging with relevant authorities.

Source: *The Hindu,* 5th October 2025

WHO Issues Medical Product Alert on Three Contaminated Oral Liquid Medicines in India

World Health Organisation (WHO) has issued medical product alert on three contaminated oral liquid medicines identified in India and reported to WHO on October 8, 2025. The contaminated oral liquid medicines have been identified to be specific batches of COLDRIF, Respifresh TR and ReLife, manufactured by Sresan Pharmaceutical, Rednex Pharmaceuticals, and Shape Pharma.

The U.N. agency said that the Indian National Regulatory Authorities (NRAs) has been advised to consider targeted market surveillance, with particular attention to informal and unregulated supply chains where products may circulate undetected. NRAs are also advised to carefully evaluate the risks associated with any oral liquid medicines originating from the same manufacturing sites — particularly those produced since December 2024.

"The CDSCO has informed WHO that none of the contaminated medicines have been exported from India and there is currently no evidence of illegal export," it said adding that the affected products are oral liquid medicines containing active ingredients commonly used to relieve symptoms of the common cold, flu, or cough.

Giving details about the syrups WHO maintained that the products identified in this alert are considered substandard as they fail to meet their quality standards and their specifications.

WHO in its statement noted that on October 8, 2025 the Central Drugs Standard Control Organization (CDSCO) of India reported presence of Diethylene Glycol (DEG) in at least three oral liquid medicines.

This followed information identified by WHO on September 30, 2025 of localized clusters of acute illness and child fatalities in India. CDSCO informed WHO that the contaminated products were reportedly consumed by the affected children.

CDSCO has confirmed that relevant State authorities have ordered an immediate halt to production at implicated manufacturing sites and have suspended product authorizations. In addition, a recall of the contaminated products has been initiated by relevant state authorities.

"WHO continues to collaborate closely with Indian health authorities to monitor the situation, identify the source of the contamination and mitigate any potential public health risks," it said.

The agency further said that contaminated products pose significant risks to patients and can cause severe and potentially life-threatening illness.

Diethylene glycol is toxic to humans when consumed and can prove fatal. The contaminated oral liquid medicines referenced in this alert are unsafe and their use, especially in children, may result in serious injury or death. Toxic effects can include abdominal pain, vomiting, diarrhoea, inability to pass urine, headache, altered mental state and acute kidney injury which may lead to death. To protect patients, it is essential to detect and remove these contaminated products from circulation.

It has also advised health-care professionals, regulatory authorities and the public to report the detection of these substandard products and any incident of adverse effects, or lack of expected effects to their National Regulatory Authorities or National Pharmacovigilance Centre.

"We advises increased surveillance and diligence within the supply chains of countries and regions likely to be affected by these substandard products. Increased surveillance of the informal/unregulated market is also advised," it said adding that all medical products must be obtained from authorized/licensed suppliers and that any information about the manufacture or supply of these products can be shared to WHO via rapidalert@who.int.

Source: *The Hindu,* 14th October 2025

Risk of Antibiotic Resistance Rises as Pharmas Skirt Prescription Law

As monsoon triggers a seasonal spike in both viral and bacterial infections, lack of enforcement is allowing antibiotics to be sold over the counter, accelerating the risk of antimicrobial resistance (AMR) — a condition where medicines designed to treat bacterial infections become redundant.

Several pharmacies including centre's PM Jan Aushadhi Kendra and state's Mudhalvar Marundhagam sold antibiotics such as Azithromycin (used for respiratory diseases) and Ciprofloxacin (used for urinary tract infections) without a valid doctor's note although they are listed as prescription only drugs.

Doctors say with every monsoon, there is spike in self-prescription of antibiotics. "Symptoms of most upper respiratory infections resemble that of a common cold. While most of them caused by viruses are self-limiting, some may require symptomatic treatment or medicines for secondary infections," said Stanley Govt Hospital professor Dr J Ganesh, who is the director of Institute of Social Paediatrics. "If patients take the wrong antibiotic, and if the infection becomes severe, it can be fatal. Also many stop the antibiotic course midway once symptoms ease. This can cause drug resistance," he said.

For this reason, selling schedule H antibiotics without a valid prescription is illegal under Rule 65(9)(a) of the Drugs and Cosmetics Rules, 1945, said deputy director of Drugs Control in the state, K Nandhakumar. "We cancel and suspend licences for this. This is all we can do," he said. Between Jan and Sept this year, the Directorate of Drugs Control in the state suspended 369 licenses, and cancelled 39.

Experts say it is impossible for the drugs control to stop the menace in a city, which has more than 3,200 independent pharmacies.

On Thursday, chemists at Prime Minister Jan Aushadhi Kendra in T Nagar, a chief minister's Mudhalvar Marundhagam in Sowcarpet, and a private pharmacy, and many other pharmacies across the city, dispensed these antibiotics to TOI solely on symptoms described.

At the chief minister's pharmacy in Sowcarpet, the pharmacist handed out nitrofurantoin, the drug of choice for urinary tract infections without a prescription. He, nevertheless, noted down the name and address of the buyer.

Former WHO chief scientist Soumya Swaminathan said weak enforcement and poor health literacy continue to fuel mindless popping of pills, she said. "Pharmacists often dispense a mix of antibiotics and antipyretics to patients who may not know what they're taking. Some states such as Kerala have implemented strict enforcement at the grassroots level. TN can move in that direction," she said.

Round-the-clock functioning of some pharmacies sustain the trend, say chemists. "People come directly to pharmacies also because they don't want to pay 500 or more as doctors' consultation fee. This is wrong," said Tamil Nadu Chemists and Druggists Association president S A Ramesh.

Source: *The Times of India,* 24th October 2025

Google's New AI for Drug Discovery is A Win for Scientific Discovery

Google's launch of a suite artificial intelligence (AI) tools, which its researchers reported to be successful at not only suggested a new drug combination for cancer therapy but even stood up to early tests in the laboratory, is a signal that research-scientists ought to be integrating AI into the process of scientific discovery.

Built on the Gemma family of open models, the Cell2Sentence-Scale 27B (C2S-Scale) is a 27-billion-parameter foundation model designed to “understand” the language of individual cells.

“This announcement marks a milestone for AI in science,” Shekoofeh Azizi and Brian Perozzi, staff scientists at Google DeepMind and Google Research respectively, in a post accompanying the announcement.

“C2S-Scale generated a novel hypothesis about cancer cellular behaviour and we have since confirmed its prediction with experimental validation in living cells. This discovery reveals a promising new pathway for developing therapies to fight cancer,” they added.

A novel use

The C2S-Scale model was trained on a large dataset of real-world patients and cell-line data, based on which it suggested a drug called silmitasertib could be used to improve the immune system's ability to identify cancerous tumours when they were nascent.

To be sure, silmitasertib (CX-4945) is currently in several clinical trials to treat multiple myeloma, kidney cancer, medulloblastoma, and advanced solid tumours. In January 2017, the US Food and Drug Administration granted it orphan drug status for advanced cholangiocarcinoma.

However, the novelty of Google's effort was not in (re)discovering the drug but that it had scanned the vast cancer biology literature to suggest a novel

use for a drug candidate. Pharmaceutical companies in their usual course spend billions of dollars and employ highly trained personnel to reveal similar insights.

"It's a nice result and was a well-chosen problem to test the capabilities of an LLM [large language model]," Sunil Laxman, systems biologist at the Institute for Stem Cell Science and Regenerative Medicine, Bengaluru, told *The Hindu*. "This would, in the usual course, have taken a focussed team of dedicated researchers several months to suggest such a use of the drug."

'It's very good'

Dr. Laxman however underlined that the model hadn't suggested something that couldn't have occurred to a trained biologist nor had discovered something new about cancer biology.

"It's very good. Not great. The average laboratory in India will not have access to a vast library of chemical compounds where they can be tested. This one had, and while it has certainly shortened the time [in this case] for a potential discovery, it isn't a path-breaking discovery."

LLMs are at the core of AI and are trained on human-annotated data to understand human language and solve problems.

Drs. Azizi and Perozzi have contended that their results demonstrate that it's possible to create LLMs that don't have to be trained on the rules of biological systems. Instead, they wrote, the models can be encouraged to figure the rules out just by having their successes 'rewarded' and failures 'punished'. This is how some of the most powerful chess-playing LLMs were trained.

Good reasoning

Indian Institute of Science, Bengaluru, mathematics professor Siddhartha Gadgil interpreted the findings as significant and reckoned that the best AI models in mathematics were today at the level of a "skilled mathematician but not at genius-human levels".

He said there were "no reasons" to suppose that AI development would one day not be able to solve the most challenging maths problems.

"We can't say when an AI model will solve the Riemann Hypothesis but there's no reason to suppose it never can. Already there are several initiatives and even companies that are tackling unsolved mathematical problems and they do come up with novel hypotheses."

Dr. Gadgil cited the International Mathematical Olympiad 2025, where OpenAI, the maker of ChatGPT, said an "experimental reasoning model" had figured out answers to the questions, which, if it were a human, would have won it a gold medal. The model followed the same time limits as human participants.

Significantly, this model wasn't trained for the Olympiad but was a general-purpose reasoning model with sufficiently good reasoning powers.

This said, the Olympiad's problems aren't representative examples of the problems professional mathematicians work on; they're intended for talented high-schoolers and constitute a gold standard test of mathematical talent.

The Riemann hypothesis on the other hand is a problem many mathematicians are working on. It's a statement about the nature of prime numbers whose proof has eluded mathematicians for over a century. The Clay Mathematical Institute in the US has promised to reward its solver with $1 million.

'Still divided'

Given the vast literature to which these LLM are exposed, they're expected to come up with novel and useful ideas about how to approach a mathematical problem an equivalent human expert wouldn't always immediately see, he added.

Prof. Gadgil, who embraces LLM tools in his own research, added that his field is “still divided” on incorporating them. According to him, there were several good models that “showed no signs of plateauing and had a lot of latent capabilities that still weren't fully explored”, and therefore ought to be encouraged as tools that a working researcher ought to be incorporating.

Source: *The Hindu,* 25th October 2025

Codeine Cough Syrup Worth Rs 2cr Seized from Warehouse

Joint team of food safety and drug administration, police and ANTF recovered a stock of 93,750 bottles of codeine-based syrup worth Rs 1.96 crore from a warehouse in Bhadwar area under Rohania police station on Wednesday. Caretaker of the warehouse was taken into custody by police for interrogation following seizure of codeine cough syrup, which is used as an intoxicant in countries like Bangladesh.

Joint team of FSDA officials from different districts, police and anti-narcotic task force, led by DCP Varuna Pramod Kumar and SIT in charge T Sarvanan, raided a building opposite a private medical college campus in Bhadwar area. The building, owned by husband of Bhadar village head, runs a gym on first floor, while the ground floor was rented out for warehousing. When police raided the place, the caretaker, identified as Azad Jaiswal, tried to escape, but his attempt was foiled and the joint team entered the warehouse, where a huge stock of the syrup was detected. Providing details of the stock of Schedule H1 and Schedule G drug codeine cough syrup recovered from the warehouse, drug inspector Junab Ali said 75,150 bottles were of EsKuf, while 18,600 bottles were of Phensedyl, which expired in Aug. Ali said, "A bill from RS Pharma Ghaziabad issued in favour of Singh Medico Chandauli was also recovered from the warehouse.”

Based on MRP printed on each bottle, total cost of the stock recovered was calculated as Rs 1,96,87,500, said the DCP. Azad Jaiswal said he was in charge of loading and unloading materials for last over one month at the warehouse. Proprietor of RS Pharmaceuticals, Ghaziabad, who sent the consignment, Saurav Tyagi is named in case registered in Ghaziabad following a recent haul of codeine cough syrup stock by police, said the DCP. The consignment was sent in the name of Singh Medicos Chandauli via Bhati Transports, New Delhi. Efforts are now being made to find details of Singh Medico.

Following busting of a codeine-based cough syrup smuggling racket headed by Varanasi-based kingpin Shubham Jaiswal, during a joint operation of FSDA and police, the investigation of 102 firms began. FIR was lodged against 28 individuals, including 26 of those firms and a special investigation team was formed under ADCP Kashi zone T Sarvanan. In the past week, first major action against the drug syndicate became evident on Wednesday afternoon.

Source: *The Times of India,* 20th November 2025

A Simple Daily Habit May Quietly Reduce Hypertension Risk: New Research Hints at A Surprising Tool Against High Blood Pressure

A simple daily routine could offer meaningful protection against one of the world's most dangerous health threats: high blood pressure. A new study published in the American Journal of Hypertension suggests that long-term multivitamin use may help reduce hypertension risk in older adults who have lower quality diets.

High blood pressure, or hypertension, remains the leading global risk factor for death, responsible for nearly half of all heart disease and stroke-related fatalities, according to the World Heart Federation. With lifestyle diseases rising and long-term medication adherence often difficult, researchers are increasingly exploring accessible prevention strategies.

Why Scientists Looked at a Daily Multivitamin

The findings come from secondary analysis of data from the large-scale Cocoa and Multivitamin Outcomes Study (COSMOS), which included about 8,900 adults. Participants were women aged 65 and above and men aged 60 and above.

Speaking to Medical News Today, the study's corresponding author, Dr Rikuta Hamaya of Mass General Brigham, explained the motivation behind the research.

"Since vitamins and minerals play a known biological role in regulating blood pressure, identifying a simple, accessible strategy like supplementation could provide an important tool for prevention," he said in the report.

While earlier studies examining single nutrients such as vitamin D or vitamin E delivered inconsistent results, researchers chose multivitamins due to the possibility of synergistic benefits across multiple micronutrients.

What the Study Found

Overall, the study did not show a major difference in blood pressure for the entire participant group. However, the story changed for adults who began the study with poor diet quality, assessed using the Alternative Healthy Eating Index and the Alternate Mediterranean Diet score. The researchers discovered small but meaningful improvements in this subgroup, particularly among those with normal baseline blood pressure.

Dr Hamaya told Medical News Today: "Individuals with lower diet quality have insufficient baseline levels of key micronutrients such as antioxidants, potassium, and magnesium that are essential for regulating blood pressure and vessel functions. For these individuals, the multivitamin likely restores these levels."

The improvements, he added, suggest that multivitamin use may be most effective as an early preventive measure, rather than after hypertension has already developed.

Expert Response and Why It Matters

Although the findings are promising, cardiology experts emphasize the need for further study. Interventional cardiologist Dr Cheng Han Chen, who was not part of the research team, told Medical News Today: "This study found that daily multivitamin intake over a course of over 3 years did not significantly influence blood pressure control, except in a group of study participants deemed to have lower dietary quality."

He added that more research is needed to understand how diet quality interacts with supplementation and whether younger or more diverse populations experience the same benefits.

A Small Habit with Big Potential

While genetics and ethnicity cannot be controlled, several modifiable lifestyle habits are proven to reduce hypertension risk, including:

Eating a heart-healthy diet
Staying physically active
Maintaining a healthy weight
Managing stress
Avoiding smoking

This study suggests that adding a daily multivitamin could support these efforts, especially for individuals whose diets may lack key nutrients. As Dr Hamaya noted, the aim is to provide practical, accessible tools for prevention while larger solutions to dietary and healthcare access improve. High blood pressure is silent, widespread and deadly, yet small and consistent choices may reduce its impact. For millions at risk, a daily multivitamin alongside healthy lifestyle habits might offer a simple step toward improved heart health and long-term protection.

Source: *The Economic Times,* 9th December 2025

Patients Welcome Introduction of the National Blood Transfusion Bill, 2025

Thalassaemia patients have welcomed the introduction of the National Blood Transfusion Bill, 2025, in Parliament on Friday (December 12, 2025). The proposed legislation seeks to create a dedicated National Blood Transfusion Authority, set uniform national standards for the collection, testing, processing, storage, distribution, issuance and transfusion of blood and blood components, mandate registration of all blood centres, promote voluntary blood donation, and introduce strict penalties for unsafe or non-compliant practices.

"These provisions directly address long standing concerns faced by patients, caregivers, and clinicians due to fragmented regulation and inconsistent quality," the Thalassemia Patients Advocacy Group (TPAG) said. It added that the reform offers hope for a safer, more accountable and more efficient blood ecosystem.

N.K. Ganguly, former Director General of the Indian Council of Medical Research, said, "Strengthening the governance of blood transfusion services is essential for ensuring safety and public trust. The proposed Bill provides a science-based framework to streamline standards and improve patient outcomes."

Anubha Taneja Mukherjee, member secretary, TPAG, said, "For thousands of thalassaemia patients, blood is not a treatment. It is a lifeline. The Bill recognise the urgency of building a strong and unified national framework to ensure safe and equitable access to quality blood."

Source: *The Hindu,* 13th December 2025

Not GMP Compliant, Over 60% of Pharma SMEs Stare at Shutdown

More than 60% of the 8,500 registered small and medium pharmaceutical units in India may be forced to shut shop by the end of this month for failing to comply with the guidelines on good manufacturing practices (GMP).

These manufacturers must upgrade their facilities by December 31 as per the extended deadline to comply with the revised Schedule M rules, which deal with good manufacturing practices under the Drugs and Cosmetic Act. But most of them, which operate single facilities, are unlikely to meet the deadline, said industry executives. Closing down these units many cause a shortage of commonly used drugs, affect thousands of jobs and impact the medicine security of low- and middle income countries that depend on imports from India, they warned.

India is estimated to have about 12,000 drug manufacturing units. The units that risk being shut down account for about ₹75,000 crore of India's ₹2.5 lakh crore domestic drug market, the executives said. This may result in shortages of antibiotics, anti-hypertensives, anti-inflammatory medicines, analgesic, anti-cough and cold tablets, diabetes drugs and general medicines, among others, said a pharma industry expert, speaking on the condition of anonymity. "The shortages of medicines will be seen across the country. Many of these units also cater to government supplies along with supplies to tier-II and tier-III cities and exports."

As reported earlier, more than 20 pharma associations had asked the government to extend the deadline. The government has not yet changed its stance.

"Ironically, there are companies which have been in the industry for over 2-3 decades. They are already overburdened with the existing cash credit and cannot infuse any further capital," said Rajesh Gupta, who heads the pharma committee of the RSS-affiliated Laghu Udyog Bharati and is president of the Himachal Drug Manufacturers Association, Baddi.

According to the drug regulator's November 7 order, drug makers will face stricter enforcement if they are found to be non-compliant with the guidelines. State drug regulators have been asked to submit monthly reports to the Central Drugs Standard Control Organisation, containing details of inspections.

Source: *ET Pharma,* 16th December 2025

Novartis Bets Big on India; Looks to Grow Beyond Cost Arbitrage to High-Value Innovation

Novartis is deepening its presence in India, positioning the country as one of its most important global centres for biomedical research and **drug development** outside its headquarters in Basel, Switzerland.

India is among the few markets where the Swiss drugmaker has established biomedical research alongside a full-spectrum development and operations footprint.

The company, which operates the largest pharma Global Capacity Centre (GCC) in India, has ramped up its workforce over the last couple of years to strengthen early-stage research. The India team now has over 9,000 employees,

accounting for about 11% of its global workforce, a top company official said.

India-based teams now contribute to nearly every Novartis molecule that reaches late-stage development, spanning clinical operations, biostatistics, regulatory a airs and advanced analytics. The company's expanding India hub underscores a shift beyond cost arbitrage to high-value, science- and data-led innovation.

The Novartis Corporate Centre (NOCC) in Hyderabad has evolved since the company became one of the first multinational pharmaceutical firms to set up a GCC in India over two decades ago. What began as a support hub has grown into Novartis's largest global corporate centre, housing biomedical research, drug development, finance and HR, commercial (US and International), strategy and growth, data, digital and technology, manufacturing and supply operations, besides other corporate functions.

"NOCC Hyderabad is no longer about simply cost efficiency – it is where Novartis integrates science, digital, finance, technology platforms, and global services to drive transformation," said Dr. Sadhna Joglekar, Senior Vice President and Head, Development India Hub, Novartis. With nearly 9,000 associates, the centre represents all business units and global functions, efectively making it a microcosm of the company's worldwide operations. Around 2,800 employees work in development across Hyderabad and Mumbai, alongside large teams in operations, commercial analytics and finance.

A Novartis spokesperson said the company's commitment to India continues to strengthen through the expanding footprint of Novartis Healthcare Private Limited (NHPL), even as Novartis AG conducts a strategic review of its stake in the listed **Novartis India** Limited (NIL).

"Today, the Novartis Corporate Centre in Hyderabad is one of the important and largest of the six centres in the global organization, supporting our purpose of reimagining medicine," the spokesperson said, adding that the GCC's annual operating cost in India is around $400 million. The spokesperson also clarified that the GCC remains unaffected by the strategic review of NIL.

India is now deeply embedded in Novartis's **global drug development** model. Rather than running India-only programmes, the company integrates Indian teams across global assets, contributing to chemistry, analytics, biostatistics, data science and clinical operations. According to Dr. Joglekar, nearly every molecule that reaches late-stage development at Novartis has some contribution from India, whether through technical development at Genome Valley, global clinical trial support, or regulatory documentation.

Several high-profile medicines illustrate this role. India-based teams have supported clinical development, biostatistics, data management and regulatory documentation for inclisiran, the company's siRNA therapy for lowering LDL cholesterol.

Scientists in Genome Valley contribute to radioligand therapy precursors and analytical testing for lutetium-177 vipivotide tetraxetan, a treatment for metastatic castration-resistant prostate cancer. India has also supported clinical operations and biostatistics for remibrutinib, recently approved in the US for chronic spontaneous urticaria.

The rationale for building a large India GCC has also shifted over time. A decade ago, Novartis was drawn by Hyderabad's scientific talent and the emerging Genome Valley ecosystem. Today, the strategic logic is broader. India combines deep scientific expertise with advanced digital, data and AI capabilities, enabling Novartis to handle complex, high-value work across the entire development pipeline.

The hub now supports cutting-edge platforms including radioligand therapy, xRNA, and cell and gene therapies, alongside advanced analytics, AI-driven protocol design and digital and hybrid trials. “India is critical because it offers a combination of scale, capability and ecosystem advantages that are hard to replicate elsewhere,”

“India is not about doing work cheaper. It is about doing more complex, higher-value work that underpins Novartis' strategy across our four priority therapeutic areas: cardiovascular, renal and metabolic (CRM), oncology, immunology and neuroscience, leveraging ve cutting-edge technology platforms: Chemistry, Biotherapeutics, Cell and Gene Therapy, Radioligand Therapy and xRNA,” said Joglekar.

Source: *The Economic Times,* 19th December 2025

Pfizer and Cipla Announce Partnership

Pfizer India and Cipla Limited has announced a partnership where Cipla now has the sole right to market, distribute and sell the cough syrup Corex Dx and Corex LS, the non-steroidal anti-inflammatory drug (NSAID) Dolonex, the proton pump inhibitor (PPI) Neksium and the oral antibiotic Dalacin Cin India.

Pfizer will continue to manufacture, source and supply these medicines to Cipla for India.

Meenakshi Nevatia, country president, Pfizer India, said: “At Pfizer, expanding the reach of our medicines for patients is paramount and we are partnering with Cipla to achieve this common mission.'' Added Achin Gupta, global chief operating officer, Cipla Ltd.: “This association with Pfizer aligns with our focus on building a formidable presence across key therapy areas and enhancing access to high quality treatments guided by our purpose of 'Caring for Life'. Our distribution capabilities will support wider reach for such trusted therapies to patients who need them the most.”

Dalacin C is a part of Pfizer Products India Pvt. Ltd

Source: *The Hindu,* 20th December 2025

Tamil Nadu Medical Services Corporation Blacklists Over 50 Products for Failing Quality Checks

The Tamil Nadu Medical Services Corporation (TNMSC) has blacklisted over 50 products — drugs and injections — for failing to meet quality control norms since 2023.

According to data from TNMSC, an organisation that was set up to streamline the procurement, storage and distribution of essential drugs for government hospitals, 22 products were blacklisted for quality failures during 2023-2024. During 2024-2025, 26 products were blacklisted, of which 22 were quality-related and four for non-

execution of purchase orders. A total of 14 products were blacklisted so far in 2025, all related to quality failures.

Firm-wise, TNMSC blacklisted five firms during 2023-2024 (two for non-execution of purchase orders and three on quality grounds. While two firms were blacklisted during 2024-2025, one was blacklisted so far this year on quality grounds.

Year	Number of blacklisted firms	Reasons	Number of products blacklisted	Reasons
2023 -2024	5	2 for non -execution of purchase orders; 3 on quality grounds	22	All related to quality failures
2024 -2025	2	On quality grounds	26	22 quality related 4 non execution of purchase orders
2025 (till date)	1	On quality grounds	14	All related to quality failures

How quality checks are performed

Officials of TNMSC said that quality checks on medicines are conducted as per the relevant pharmacopoeia (such as Indian Pharmacopoeia, British Pharmacopoeia, United States Pharmacopoeia) at their entry level at warehouses through NABL (National Accreditation Board for Testing and Calibration Laboratories) accredited empanelled laboratories. In case of any adverse reports from empanelled laboratories, the same drugs are re-tested at government laboratories in the State - laboratories at Teynampet and Guindy. Presently, TNMSC has contracts with 12 laboratories situated all over the country.

The top reason for blacklisting products is failure to meet quality standards, an official said. Blacklisting is done for products due to quality failure/non supply and for companies as a whole, for quality failures.

According to blacklisting details on TNMSC's website, “not of standard quality” is the major reason cited for blacklisting a particular drug. “Purchase orders not executed” and “substandard quality” are other reasons. In fact, one drug has been blacklisted for the “presence of an iron piece inside the tablet”. For firms blacklisted from 2024, misbranded drugs is the main reason.

Monitoring of warehouses

TNMSC's warehouses are monitored through the centralised portal - Drug Distribution Management System - for stock receipt, sampling process, receipt of lab reports, distribution to medical institutions and its fund management. The shelf life expired drugs are disposed through biomedical waste management agencies approved by the T.N. Pollution Control Board once in a year, officials added.

As far as equipment is concerned, TNMSC procures only equipment with standardisation certificates such as European CE/US FDA/equivalent Indian standards, they said.

Source: *The Hindu,* 27th July 2025

medopharm

With best compliments from:

medopharm

We Value... Life

Corporate Office : "MEDO HOUSE" No. 25, Puliyur 2nd Main Road, Trustpuram, Kodambakkam, Chennai - 600 024, India
Phone: +91 44 40149999 Visit: www.medopharm.com

Factory : 50, Kayarambedu Village, Guduvanchery - 603 202, INDIA.