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IDMA BULLETIN

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INDIAN PHARMA - GLOBAL HEALTH CARE

INDIAN DRUG MANUFACTURERS' ASSOCIATION

HIGHLIGHTS

IN-DEPTH.
AND WIDE KNOWHOW.
THAT'S OUR BRAND OF
EXPERTISE.

Dear Partner,

Signet is driven by expertise, be that technical or commercial. Nowhere is that more evident than in our partnership with highly reputed companies Dead Sea Periclase, Dead Sea Works Ltd. and Scora, our source of ICL Industrial Products.

Dead Sea Periclase, with its signature 'Aman' process, provides us with the highest quality magnesium oxide, hydroxide and carbonate products. Dead Sea Works Ltd., from whom we source exceptional potassium chloride, is also recognised as the world's top provider. While for all things calcium and magnesium, the specialists at Scora fulfil our every need. So that we can do the same for you.

By associating with expertise, we enhance our own. Making us the foremost name in pharmaceutical excipients.

Signet-ure *expertise*

ICL Specialty Minerals

- MAGNESIUM OXIDE
- MAGNESIUM HYDROXIDE
- MAGNESIUM CARBONATE
- POTASSIUM CHLORIDE, REFINED
- CALCIUM CARBONATE (SCORALITE)
- CALCIUM CARBONATE DC (SCORALITE DC)

Signet

The Complete Excipients Company

A Publication of
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Dr. A.B. Road, Worli, Mumbai - 400 018
Tel : 022-2494 4624 / 2497 4308 **Fax:** 022-2495 0723
e-mail: publications@idmaindia.com/
actadm@idmaindia.com/ website: www.idma-assn.org

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IDMA BULLETIN

Vol. No. 53 **Issue No. 25** **01 to 07 July 2022**

IDMA ACTIVITIES:

DGFT MATTERS:

INDIAN PHARMACOPOEIA COMMISSION:

GOVERNMENT COMMUNICATIONS:

GOVERNMENT NOTIFICATIONS:

GOVERNMENT PRESS RELEASE:

CBIC MATTERS:

NPPA MATTERS:

NATIONAL NEWS:

Dear Member,

APPQM - EXECUTIVE PROGRAM IN PHARMACEUTICAL QUALITY MANAGEMENT

For companies who want to grow their business in Europe & the US.

APPQM+ Series 3 Commences September 2022

Why APPQM in INDIA?

We live in a world of 'Brutal Disruption'. Covid pandemic – what next? **Prosperity awaits those who do the basics to PhD level.**

When launching the first series of the APPQM, we at IDMA along with NSF Health Sciences, UK boldly stated that APPQM, the unique, World-Class education program will just do that and ***Develop Change Agents For Quality Excellence.***

Well, Series One & Two lived up to the expectations of the industry. Over 40 delegates attended Series One & 28 delegates attended Series Two.

Both the series were a resounding success and this is what the delegates thought:

- ✓ Transformative
- ✓ World-class
- ✓ Best business investment we've ever made
- ✓ Worth every penny and more
- ✓ Has helped transform our quality culture
- ✓ Educating oneself while Educating others
- ✓ The course was really pragmatic and foundational in understanding the core Quality Systems framework

'Work Placement Projects' *have been completed by APPQM delegates. These have generated $ millions in savings for their parent companies, improved their operational efficiency (profit), regulatory compliance and reduced risk.*

APPQM+ Series 3

Based on the success of Series 1 & 2, we are pleased to announce the launch of APPQM+ Series 3 that is expected to commence in September 2022 and covers special sessions on Digitization.

Please refer to the brochure and the video link for details of the Program covering:

- ✓ Challenges Facing the Pharmaceutical Industry
- ✓ How APPQM can help
- ✓ Benefits of the Program
- ✓ Course Format
- ✓ Details of Key Topics of the 5 Course Modules and the List of Tutors

Additional Benefits:

This virtual education program offers the following additional benefits.

- ➢ Safety of Individuals during this COVID-19 pandemic.
- ➢ Reduction in Course Fees (from £8000 for Physical Class to £3300 for Virtual Class)
- ➢ Saving of time especially travel time to venue in Bangalore and travel & hotel stay expenses

Please don't get left behind and register for the third series of APPQM to have a competitive edge in the global market and to be future ready.

Registration Fee for APPQM+ Series 3

The Registration Fee for APPQM+ Series 3 is Rs.4,00,000/- (Rupees Four Lakh Only) Plus 18% GST Per Participant.

You can initially block the seats by paying an advance amount of Rs.1,00,000/- (Rupees One Lakh Only) and balance 15 days before commencement of the program.

Registration Procedure :

Please fill the Registration Form and send it to

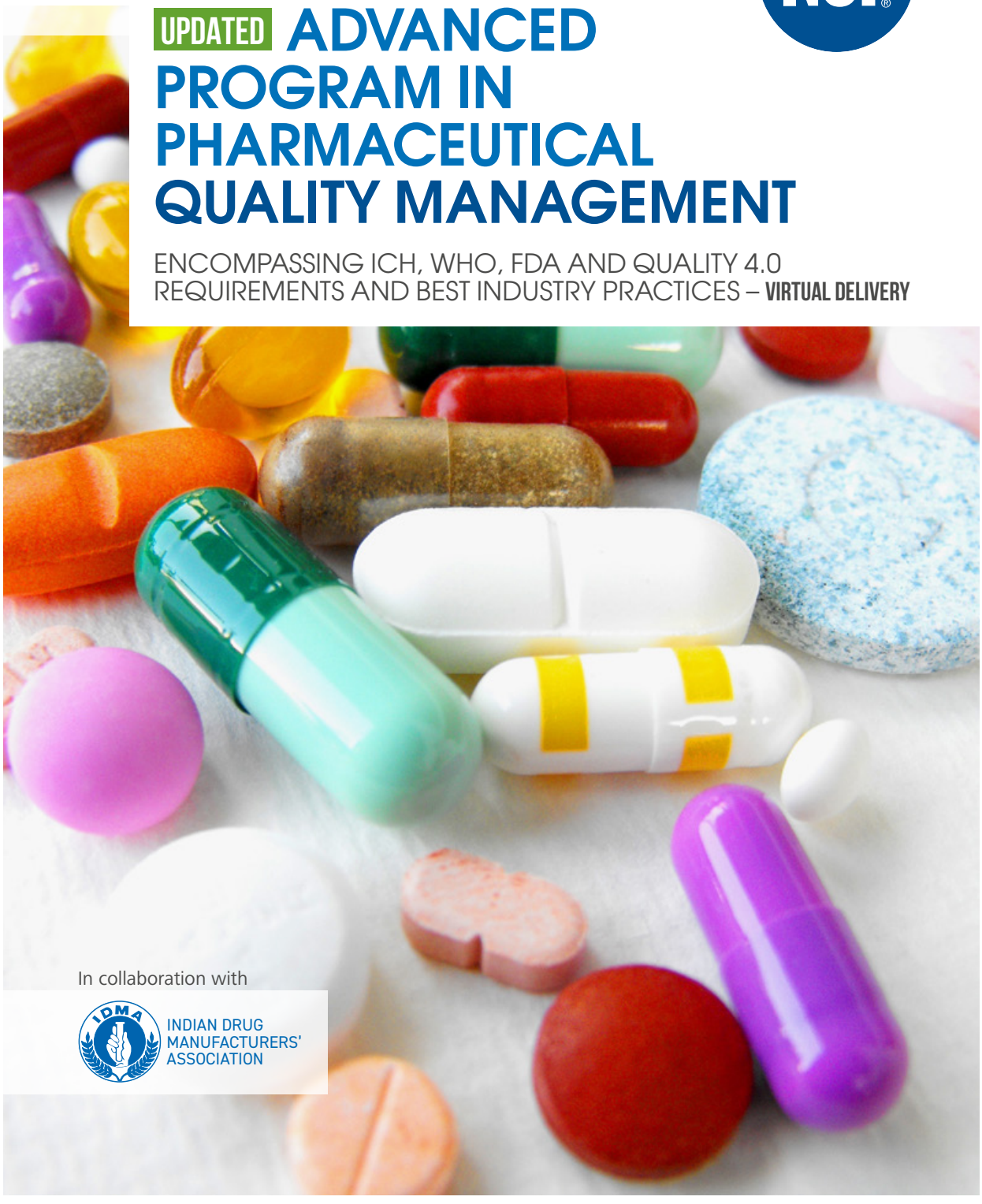
Melvin	**Batul**
actadm@idmaindia.com	technical@idmaindia.com
9821868758	9920045226

For further information / queries :
You may also contact Mr. S. M. Mudda
@ mudda.someshwar@gmail.com / 9972029070

We sincerely hope that you see the benefit of attending this World-Class, MBA style, education program in order that you may reap the same benefits.

Sincerely Yours,

S M Mudda Chairman, Regulatory Affairs Committee, IDMA & Program Director, APPQM	**Dr. Viranchi Shah** National President, IDMA	**Mehul Shah** Hon. General Secretary IDMA	**Daara B Patel** Secretary – General, IDMA


UPDATED ADVANCED PROGRAM IN PHARMACEUTICAL QUALITY MANAGEMENT
ENCOMPASSING ICH, WHO, FDA AND QUALITY 4.0 REQUIREMENTS AND BEST INDUSTRY PRACTICES – VIRTUAL DELIVERY
In collaboration with
INDIAN DRUG MANUFACTURERS' ASSOCIATION

FOR COMPANIES WHO WANT TO GROW THEIR BUSINESS IN EUROPE AND THE U.S.

For companies who want to grow their business in Europe and the U.S.

CHALLENGES FACING THE PHARMACEUTICAL INDUSTRY

India is the world's third largest pharmaceutical generics producer with the highest number of FDA and MHRA GMP-approved manufacturing plants outside the U.S. and Europe. The challenge of remaining in GMP compliance continues to be the main concern. India has seen a resurgence of breach of data integrity and quality issues. Regulatory requirements continue to become more stringent and rigorous.

Technical and QA professionals in India are trained in GMP compliance mainly through experience and need a formal education in pharmaceutical quality management of international standards.

- Sixty-four percent of companies say a shortage of skilled staff is curtailing their growth (Deloitte).
- 'There is an urgent need for more effective training, coaching and mentoring to remove fear and empower.' (Dr. Azaj Hussain, former U.S. FDA Deputy Director of the Office of Pharmaceutical Science)
- We live in a world of 'brutal disruption'. The pandemic – what next? The regulatory landscape will continue to change, and prosperity awaits those who can do the basics to Ph.D. level.

HOW THIS TRAINING CAN HELP

This unique, world-class program will provide the training needed to comply with GMP regulations. Course modules are very interactive and led by world-class, international experts. You will learn best-in-class practices and apply them in practical problem-solving and real-life case studies. You will learn by doing.

In addition to module-specific content, you will be provided with a deep understanding of simplification, risk-based decision making and advanced problem-solving skills. You will receive practical instruction on the leadership and communication skills required to add value to your organisation and to successfully interact with regulatory agencies in the U.S. and EU and other key stakeholders.

WHY CHOOSE NSF?

NSF's Advanced Program in Pharmaceutical Quality Management is taught by world leaders in PQM. Based in the UK, NSF have a global reputation for excellence in PQM. Our course tutors have a minimum of 30 years' global, hands-on industry experience. Many are former MHRA inspectors. All have profound knowledge of PQM and some have authored ICH and WHO guidance documents.

NSF has trained regulators from eight regulatory agencies including those in the EU and USA. Respected by regulatory agency and industry associations, NSF has excellent relationships with IDMA, ISPE, PDA organisations and U.S. FDA, WHO and EU regulatory authorities.

With offices in Delhi, NSF has an excellent understanding of Indian culture and the Indian pharma industry, gained over the last 30 years.

BENEFITS OF THIS TRAINING

From attending this program, you will gain the skills and knowledge to help your company improve business performance and regulatory compliance. Clients who have attended NSF programs have generated $ millions in savings.

For example by:

- Reducing repeat deviations by 78 percent
- Reducing 'human error' deviations by 67 percent
- Achieving 99 percent 'right first time' at product release
- Using risk-based decision making to simplify processes and systems, and to focus resources
- Achieving zero regulatory observations following an audit

Attendees will also:

- Change how they think. NSF courses are designed to change behaviours, not just provide knowledge. Participants will be able to transfer the learning into their workplace
- Learn best industry practices in PQM so that their companies can compete with the best
- Gain an in-depth understanding of the critical aspects of PQM (see Course Modules)
- Leave with the knowledge required to help protect their company's legacy, reputation and future

COURSE FORMAT

The program is presented in five modules, each comprising four days, over a 10-month period. Training takes place using virtual instructor led training via Zoom. Attendees at the second series which was delivered virtually were impressed with how easy it was to interact with other participants and how the course was specifically developed with virtual breakout rooms and information using the NSF Learning Management System. You will receive:

- A minimum of two tutors per module, to ensure a good tutor-to-delegate ratio
- An intensive, distraction-free and highly interactive learning environment using real-life case studies and problem solving exercises
- A work-based project to complete

▶▶

COURSE MODULES

Some of the key topics covered in each module are provided below.

MODULE ONE: Pharmaceutical Quality Management Systems – Best Industry Practices

Tutors: **Mr Rob Hughes and Mr S. Mudda**

- How to ensure your PQS is regulatory compliant, improves your competitive edge and drives business improvements
- Integration of quality systems across the product lifecycle (quality systems approach for cGMP implementation, from philosophy to practice)
- Making use of risk information to drive improvements (risk-based decision making)
- Senior management roles and responsibilities for the PQS – who must do what
- The essentials of data integrity
- Best practices in designing an electronic PQS
- Integration of Industry 4.0 into the design of the PQS
- The art and science of simplification
- Batch release system: How to achieve 100 percent 'right first time'
- How to become stronger and better following complaints and recalls
- Product quality reviews: How to use data and knowledge to drive improvement
- Management review of quality systems and the use of quality metrics (measuring only what matters)
- Continuous quality improvement and the cost of poor quality

MODULE TWO: Managing Change; Change Control and Deviations

Tutors: **Mr Rob Hughes, Mr S. Mudda and Ms R. Carmichael**

- Change control: How to use your system to:
  - Stop unnecessary change to ensure resources are focused on changes that only add value
  - Approve changes in minutes, not hours or days
  - Improve successful implementation of approved changes
  - Make change control fast and efficient
- CAPA management
- Investigation and report writing skills
- Deviation management: How to ensure your system:
  - Prevents repeat deviation incidents
  - Is simple, fast and effective
- Data Integrity:
  - Data Integrity principles and how to implement them effectively
  - Understanding data lifecycle

MODULE THREE: Human Factors – Getting People to Follow the Rules

Tutors: **Mr Rob Hughes and Mr S. Mudda**

- Human error: Causes and prevention
- Behavioural GMP: How to improve behaviours in the workplace
- How to get the best from your people and keep them
- Train vs. educate: How to build second-level leadership for quality management
- Making your quality organisation fit for purpose, whether centralised, decentralised or site managed
- How to overcome pitfalls in remediation programs and integrate them within the PQS
- Fostering a culture of quality (how to identify the relationship between company quality performance and prevailing quality culture and make quality normal, easy and rewarding)

▶▶

MODULE FOUR: Data Analysis for Business Improvement

Tutors: **Dr P. Gough and Dr D. Young**

- Summarising and visualising data (histograms, probability curves and box plots)
- Confidence in your means and proportions
- Statistical process control
  - Control charts
  - Fishbone diagrams and Pareto charts
  - Process capability
  - Six Sigma
  - Statistical testing
  - T-test
  - ANOVA
  - Outliers
- Regression analysis
- Design of experiments
- Multivariate analysis

MODULE FIVE: Quality by Design, Process Validation and Technology Transfer

Tutors: **Mrs Emma Ewins and Mr Richard Kettlewell**

- Quality by Design (QbD): ICH Q 8, 9, 10 and 11
- Modern approach to process validation
- Process design
- Application of quality risk management to process validation
- Tools for process validation implementation
- Equipment and utilities qualification
- Applying statistics for process validation
- Process performance qualification (PPQ) – How many batches?
- Process validation strategy and planning
- Ongoing/continued process verification
- Packaging validation
- Technology transfer
- Laboratory electronic data management
- Computer systems validation

NEXT STEPS YOUR CALL TO ACTION

If you would like more information on this unique opportunity, please:

- View a video of past participants on this course, click here
- Contact IDMA at: **actadm@idmaindia.com** or **technical@idmaindia.com**
- Contact NSF at: **pharmamail@nsf.org**

- **S. M. Mudda**
  Chairman, Regulatory Affairs Committee, IDMA & Program Director, APPQM
- **Dr Viranchi Shah**
  National President, IDMA
- **LynneByers**
  Global Managing Director, Pharmaceutical Consulting, NSF Health Sciences

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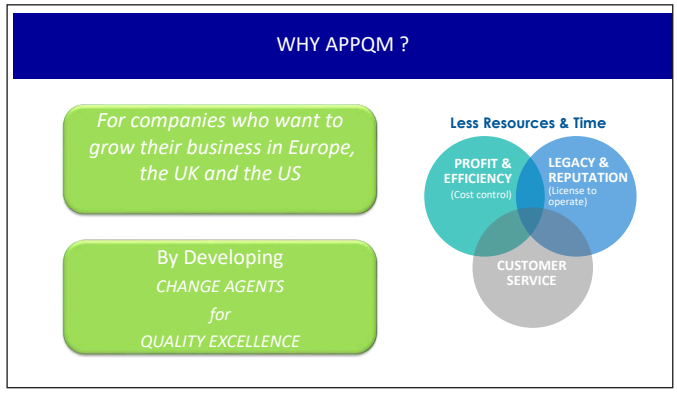
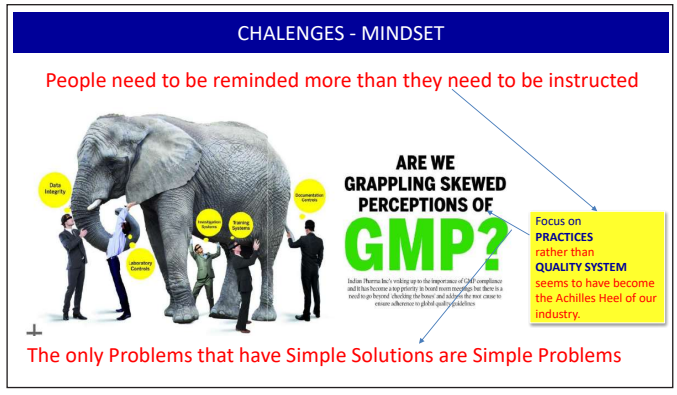
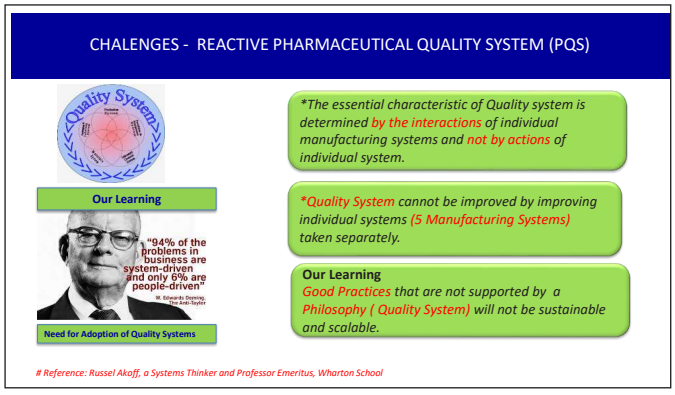
PRESENTATION

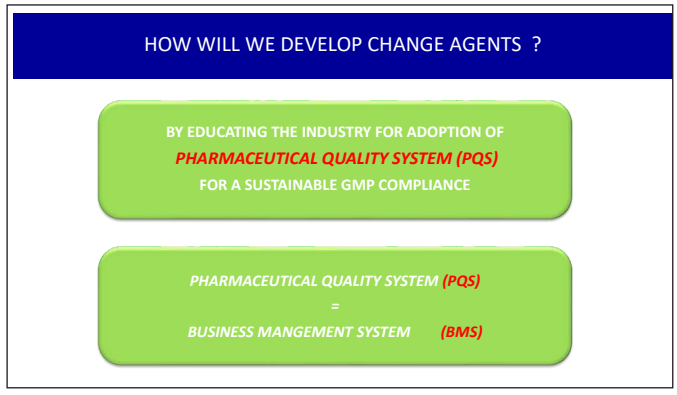
Launch of APPQM Series 3

Mr S M Mudda, Program Director & Chairman Regulatory Affairs Committee, IDMA









APPQM IS DESIGNED FOR INDIAN COMPANIES

APPQM is adopted from highly successful Quality Management Program of NSF UK.

The contents are selected by experts keeping in mind challenges faced by India Pharma*

- *NSF is the global leader in providing 'Qualified Person'(QP) training across the EU.The expert faculty include ex-regulators (MHRA) and*
- *Seasoned professionals with 35 years plus hands on experience .*

Mr. S.M.Mudda
Chairman, Regulatory Affairs, IDMA and a strong Proponent of Quality Systems

Mr. Martin Lush
Ex- Global VP, NSF International, UK and a leading consultant & tutor

Dr. Ajaz Hussain
Ex-Deputy Director US FDA , Educationist, Advisor and Mentor

HOW APPQM IS DIFFERENT FROM OTHER TRAINING PROGRAMS ?

APPQM is
Not a TRAINING PROGRAM
but
An EDUCATION PROGRAM in PQS
Focussed on 21st century Leadership Development of QA , QC, Manufacturing and R&D professionals

APPQM- Program Modules

- Pharmaceutical Quality Management Systems – Best Industry Practices *(How to ensure your QMS drives business improvements)*
- Managing Change; Change Control and Deviations *(Advanced problem solving, deviation management, report writing and change management)*
- Human Factors–Getting people to follow the rules *(How to improve performance, reduce human error, embed a quality mind-set & keep your people)*
- Transforming Data into Information – the Practical Application of Statistics to Transform your Business *(The practical application of statistics to transform your business)*
- Quality by Design, Process Validation and Technology Transfer *(Building a foundation for Product Quality and Knowledge Management)*

APPQM SERIES 1 & 2 DELEGATES SURVEY FEEDBACK

APPQM SERIES 1 & 2 DELEGATES SURVEY FEEDBACK

OUR DAY AT THE PLACE OF WORK WILL NEVER BE THE SAME

This is what they thought after a year of implmenatation of APPQM Learnings:

Transformative and Life Changing.

It is highly recommended for anyone who wants to challenge the status quo (at work) but doesn't know how.

Decision making has become more efficient and so the inter-personal relationship.

Educating Oneself while Educating Others

Has helped transform our quality culture.

Best business investment we've ever made.

Worth every penny and more.

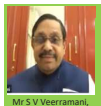
APPQM SERIES 2 VALEDICTORY – APPRECIATION FROM DIGNITARIES

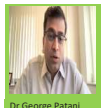

APPQM will help build the quality culture in Indian Pharma Industry
Dr V G Somani, DCGI


APPQM will help develop future quality leaders
Dr. B Suresh, Pro-Chancellor, JSS University

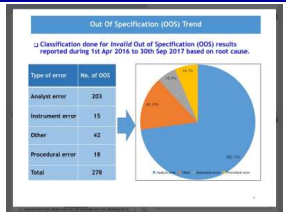

Virtual APPQM Program will be a boon for saving Time, Travel & Cost and yet deliver the same quality education
Dr. Viranchi Shah- National President -IDMA


Inclusion of Digitization topics will enhance the next series of APPQM
Mr Mehul Shah MD, Encube Ethicals &Hon. General Secretary, IDMA


IDMA should aim at developing 1000 Change Agents for quality excellence in coming years
Mr S V Veerramani, MD, Fourrts India


APPQM will help to remain competitive even while complying with the regulations
Dr George Patani ,VP (Western Region), IDMA

Benefits of APPQM –ROI



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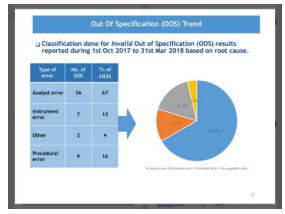

AFTER

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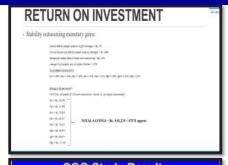
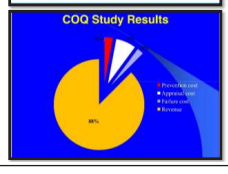
Benefits of APPQM -ROI





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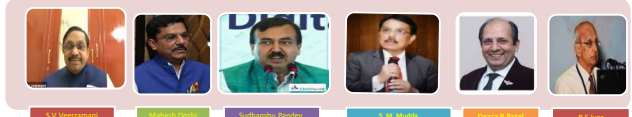


S.V. Veerramani — Past National President, IDMA for mentoring this program & providing his unstinted support.

Mahesh Doshi — Immediate Past National President, IDMA for his continued support

Sudhanshu Pandey, — Joint Secretary, Department of Commerce, Ministry of Commerce & Industry, Govt. of India, for his support

S. M. Mudda — Chairman, Regulatory Affairs, IDMA and Program Director, APPQM for his Vision & Innovation and for his unstinted support & active participation in conducting this World Class program

Dsara B Patel — Secretory General IDMA for his continual support, active participation and coordination success of APPQM

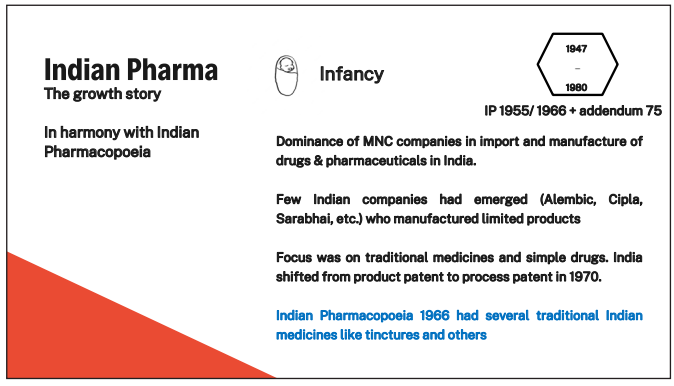
R.S.Iyer — Renowned Quality Guru and our Inspiration "Quality of Work Determines The Quality Of Products"

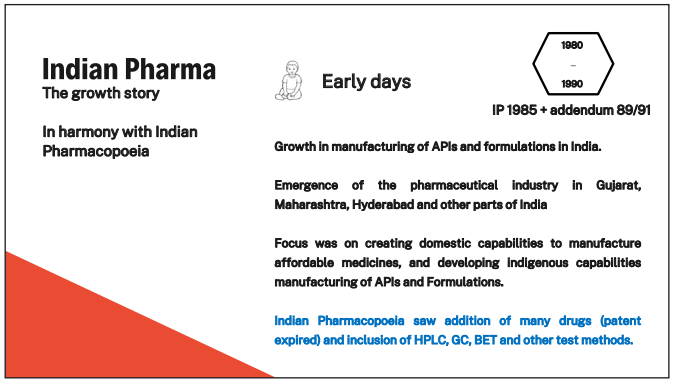
THANK YOU FOR YOUR ATTENTION

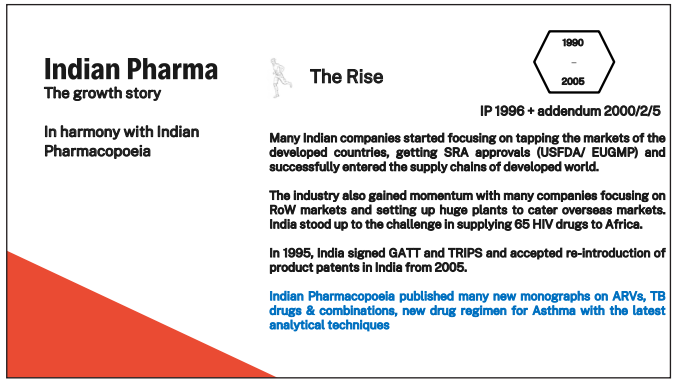
PRESENTATION

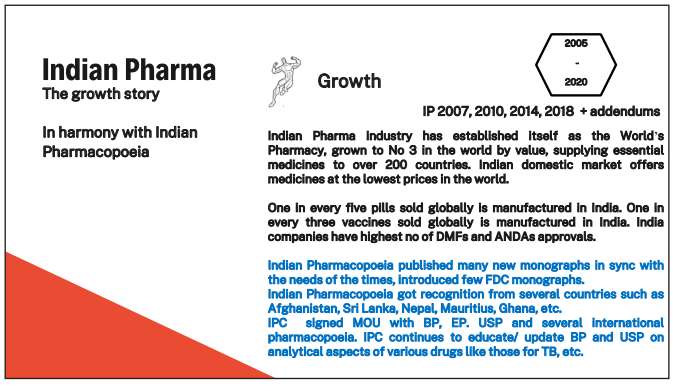
Indian Pharmacopoeia - The Indian Identity

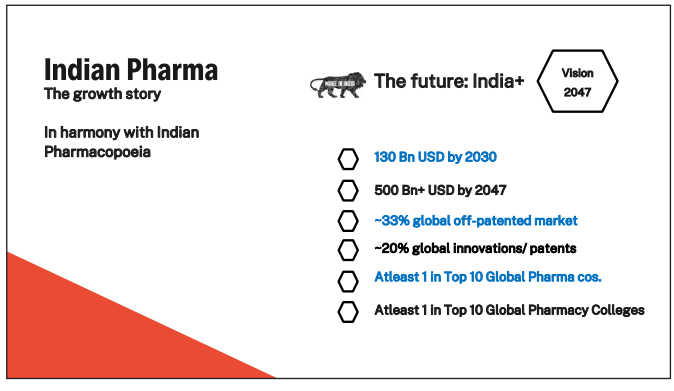
Dr Viranchi Shah, National President, IDMA at IPC Conference held on 1st July 2022











Indian Pharma
The growth story

In harmony with Indian Pharmacopoeia

The future: India+ Vision 2047

- Ayushman Bharat Jan Aushadhi Pariyojna
- Exports Global demand
- Increase in household incomes
- Illness to Wellness
- Products going off-patent
- Technology- Increased access
- API Industry Fermentation, Synthetic, Large Molecules, biologics
- R&D NDDS, NCE, F&D

Indian Pharma
The growth story

In harmony with Indian Pharmacopoeia

The future: India+ Vision 2047

IP 2022 and beyond

The way forward

1. IPC and Industry shall have to play a collaborative role in order to achieve Vision 2047, and to continue to reinforce the Indian identity. Industry and IPC have to continue to work cohesively.
2. Organizing Industry-IPC workshops and conventions like PAC of IDMA to exchange knowledge & expertise on technical subjects
3. Organizing interactive meetings in each Pharma hub across India, facilitated by IDMA, bringing together the IPC team, Industry players, Experts, state regulators. This will close gaps, help boost confidence of stake holders and improve the quality of monographs

Indian Pharma
The growth story

In harmony with Indian Pharmacopoeia

The future: India+ Vision 2047

IP 2022 and beyond

The way forward

4. To create IPC-IDMA workgroups with a goal of working closely for the upkeep of quality and implementing latest and state-of-the art techniques and technologies for tomorrow.
5. Collaborative approach in evaluating suggestions from IDMA/ Industry (Softgel / Ferrous Ascorbate / Amoxy-Clav to cite a few)
6. IDMA can contribute/ support to provide reliable source of candidate materials for the preparation of IPRS and impurities. IDMA can also contribute on various technical committees of the IPC.

Indian Pharma
The growth story

In harmony with Indian Pharmacopoeia

The future: India+ Vision 2047

IP 2022 and beyond

The way forward

7. Inclusion of atleast top 25 FDCs (by volume in the Indian market) in IP, it would enhance the confidence between manufacturers and regulatory mechanism.
8. Since volumes are likely to go three to four folds, QC labs in the industry will have to shift to automated, IT driven, high throughput and faster analytical techniques. This would also help reduce manual errors and bring transparency & reliability in Lab practices. IDMA-IPC can work jointly on this approach. (a recent example: Rapid Microbiology incl. in IP22)
9. In order to push Herbal products to mainstream, we should reconsider our current approach, and work on bringing more Herb based monographs to IP

Indian Pharmacopoeia

The Indian Identity

Harmonized with the National Goals

The future: India+ Vision 2047

Indian Pharmacopoeia can emerge as the Asian Pharmacopoeia or as the Pharmacopoeia of the developing world.

Indian Pharmacopoeia has played a significant role in the growth of the Indian Pharma industry as the Global Pharmacy, by keeping in pace with National goals and harmonizing with the Industry's curve.

There are big opportunities ahead for India, and Indian Pharmacopoeia will be a great enabler.

Let us work together to make Indian Pharma – bigger and better, in the interest of reinforcing growth through promoting affordability, accessibility and availability of quality medicines.

Thank you!

Feel free to approach me
if you have any questions.

Dr. Viranchi Shah
National President - IDMA
president@idmaindia.com

Opinions expressed in this presentation are my personal opinions and not attributed to the organizations or the companies that I represent

While care has been taken to verify the authenticity and accuracy of data presented, I do not claim them to be absolute facts.

INDIAN DRUG MANUFACTURERS' ASSOCIATION
(Tamil Nadu, Puducherry & Kerala State Board)

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5th Edition PHARMAC SOUTH 08 09 JULY 2022 CHENNAI TRADE CENTRE, NANDAMBAKKAM, CHENNAI

DAY - 1
08th July (Friday), 2022

INAUGURATION
10.00 a.m. to 11.30 a.m.

Chief Guest
Shri. P. Senthil Kumar, IAS.,
Principal Secretary to Government,
Health, Medical Education and Family Welfare,
Govt. of Tamil Nadu

Guest of Honour
Shri. V. Arun Roy, IAS.,
Secretary to Government,
MSME Department,
Govt. of Tamil Nadu

J. Jayaseelan Chairman – IDMA (TNPKSB) Chairman – IPD, IPA-Mumbai	**S. V Veerramani** Past National President - IDMA	**T. Sathish** Vice Chairman - IDMA (TNPKSB) Chairman - Pharmac South Hony. Secretary – IPD, IPA - Mumbai
S. Sivanandhan Hon. Secretary - IDMA (TNPKSB)	**R. Sabapathy** Treasurer – IDMA (TNPKSB)	**S. Sridharan** Vice Chairman - Pharmac South

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5th Edition PHARMAC SOUTH 08 09 JULY 2022 CHENNAI TRADE CENTRE, NANDAMBAKKAM, CHENNAI

DAY - 1
08th July (Friday), 2022

INAUGURAL SESSION
10.00 a.m. to 11.30 a.m.

Welcome Address : **Shri. J. Jayaseelan,** Chairman- IDMA (TNPKSB)

Overview of Pharma Industry : **Shri. S. V. Veerramani,** Vice Chairman- Pharmexcil

Inauguration of Conference by Lighting of Kuthuvilakku

Address by Special Guests : **Shri. Mehul M. Shah,** Hon. General Secretary, IDMA
Shri. T. V. Narayana, National President, IPA
Shri. Daara B. Patel, Secretary General, IDMA
Tmt. P. V. Vijayalakshmi, Director of Drugs Control (I/C)
Shri. B. Kumar, Deputy Director, CDSCO, South Zone

Guest of Honour Address : **Shri. V. Arun Roy, IAS.,**

Chief Guest Address : **Shri. P. Senthil Kumar, IAS.,**

Vote of Thanks : **Shri. T. Sathish,** Vice Chairman, IDMA (TNPKSB)

12.00 Noon - 12.30 p.m : **Press Meet**

PROGRAM

02.00 p.m. to 03.00 p.m. **CEO Talk – Success story of Encube Ethicals**
Shri. Mehul M. Shah
Managing Director, Encube Ethicals
Chairperson :
Shri. T. Ravichandran, Vice President, IDMA - Southern Region

03.00 p.m. - 04.00 p.m. **Growth: A 360 degree perspective**
(Secrets to 10x Business Growth for Pharma MSME)
Shri. Prakash Seshadri
Founder and Management Consultant: See Change Consulting
Chairperson :
Shri. S. Sridharan, Vice Chairman, Pharmac South

5th Edition PHARMAC SOUTH 08 09 JULY 2022 CHENNAI TRADE CENTRE, NANDAMBAKKAM, CHENNAI

DAY - 2
09th July (Saturday), 2022

PROGRAM

10.00 a.m to 11.00 p.m. : **CEO Talk – Scaling of Business Strategics for Startups**
Shri. C. K. Kumaravel, Co-Founder & CEO– M/s Naturals Salon & Spa
Chairperson :
Shri. T. Sathish, Vice Chairman, IDMA (TNPKSB)

11.00 a.m to 12.00 Noon. : ***Marketing Conclave***
Pharma Market Insights & Opportunities
Dr. Hari Natarajan, Founder & Managing Director, Pronto Consult
Emotional Intelligence @ work – Pharma Marketing
Shri. Sivakumar Bellan,
Director – Marketing, Simple and Smart Solutions
Chairperson :
Shri. Rajarathinam, (IDMA TNPKSB)

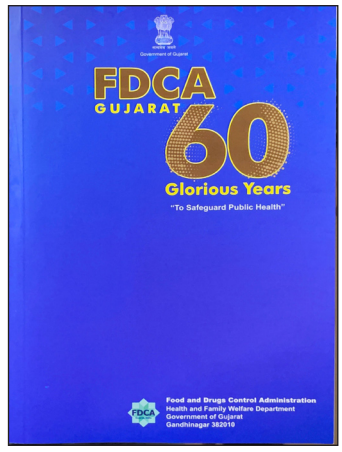
02.00 p.m to 03.00 p.m. : ***Export Conclave***
Export Opportunities for Pharma MSME
Shri. Udaya Bhasker, Director General, Pharmexcil
Chairperson :
Shri. S. V. Veerramani, Vice Chairman – Pharmexcil

03.00 p.m to 03.15 p.m. : **Requirements for Clean Room Garments & Accessories**
Shri. M. Raja, Lindstrom India, Chennai

03.15 p.m to 03.30 p.m. : **SAP for MSMEs - End to end & Easy to use**
Shri. Shravan Kumar Pothu & Shri. Madhu Mukku,
Vestrics Solutions Pvt Ltd., Hyderabad

03.30 p.m to 04.00 p.m. : **Valedictory Function**
Closing Remarks & Vote of Thanks
Shri. S. Sivanandhan, Hon. Secretary – IDMA (TNPKSB)

Dr H. G. Koshia, Commissioner, FDCA, Gujarat presented a book - FDCA Gujarat 60 Glorious years to IDMA



Dr. H. G. Koshia
Commissioner

Office of The Commissioner
Food and Drugs Control Administration,
Block-8, 1st Floor, Dr. Jivraj Mehta Bhavan, Gandhinagar, Gujarat, INDIA.

Date: 06/07/2022

To,
Dr. Viranchi Shah
President, IDMA.

Respected, Dr. Viranchi Shah

Gujarat is a leader in the pharmaceuticals and medical devices industry in India. It commands a major share of our national pharmaceutical market. Many of the drugs consumed globally, are manufactured in the State of Gujarat.

Ever since it came into existence on the 1st May 1960, the Food and Drug Control Administration, Govt. of Gujarat, has been working relentlessly alongside our pharmaceutical entrepreneurs to support their growth. Its efforts have helped Gujarat based pharma entrepreneurs to claim globally acclaimed positions.

To commemorate this incredible journey of 60 glorious years of existence in service to humankind and safeguarding public health, the FDCA Gujarat has launched a book "Six Decades of FDCA & Pharma Industry Gujarat". The book tries to capture the growth of the pharmaceutical industry in Gujarat and the FDCA in the words of prominent Gujarat based business leaders.

This is the first such book to be launched by any State Drug Controlling Authority in India. Further, it gives us immense pleasure to share that our book "Six Decades of FDCA & Pharma Industry Gujarat" was formally launched by **Shri Bhupendra Patel**, Hon'ble Chief Minister of Gujarat, during Vibrant Gujarat Pre-Event Summit "Holistic Healthcare: Focus on Pharmaceuticals and Medical Devices", on 18th December 2021, at Pandit Deendayal Energy University, Gandhinagar, Gujarat.

We are pleased to present to you a copy of this book and hope that you will be able to appreciate the successes and contributions made by FDCA Gujarat.

With Regards

Yours Sincerely,

(Dr. H. G. Koshia)

Mobile-9978405054, e-mail: hkoshia@yahoo.co.in, comfdca@gujarat.gov.in, Phone- 07923253399

Extension in deadlines for submission of applications under MEIS for exports made in the 4 months period, Sept 2020 to Dec 2020

Notification No. 15/2015-2020, dated 1st July 2022

In exercise of the powers conferred by Section 5 of the Foreign Trade (Development and Regulation) Act, 1992 read with Para 1.02 of the Foreign Trade Policy, 2015-20, the Central Government hereby makes the following amendments in para 3.13 A of the Foreign Trade Policy 2015-20 as notified vide Notification No. 58 dated 07.03.2022, with immediate effect, as below:

<table>
<tr><th>Existing Para 3.13A as per Notification no. 58 dated 07.03.2022</th><th>Amended Para 3.13 A</th></tr>
<tr><td>With effect from 07.03.2022, the last date for submission of online applications for certain scrip based Schemes and applicable late cut on such applications would be :
<table>
<tr><th>Scheme</th><th>Last date of submission of Application</th><th>Late Cut if submitted till the Last date as in column 2 (as % age of Entitlement under the scheme)</th></tr>
<tr><td>(1)</td><td>(2)</td><td>(3)</td></tr>
<tr><td>(i) MEIS (for exports made in the period 01.04.2020 to 31.12.2020)</td><td>30.04.2022</td><td>Nil</td></tr>
<tr><td>(ii) 2 % additional ad hoc incentive (under para 3.25 of the FTP — for exports made in the period 01.01.2020 to 31.03.2020 only)</td><td>30.04.2022</td><td>Nil</td></tr>
</table></td><td>The last date for submission of online applications under MEIS for exports made in the period 01.09.2020 to 31.12.2020 , and applicable late cut as in Para 9.02 of HBP would he as below:
<table>
<tr><th>Scheme</th><th>Last date of submission of Application</th><th>Late Cut if submitted till the Last date as in column 2 (as % age of Entitlement under the scheme)</th></tr>
<tr><td>(1)</td><td>(2)</td><td>(3)</td></tr>
<tr><td>MEIS (for exports in the period 01.09.2020 to 31.12.2020)</td><td>31.08.2022</td><td>Nil</td></tr>
</table>
No further MEIS applications would be allowed to be submitted after the prescribed last date (as above) and such applications would become time-barred. Late cut provisions shall also not be available for submitting claims at a later date.</td></tr>
</table>

(iii) ROSCTL (for exports made in the period 07.03.2019 to 31 12.2020)	15.03.2022	Nil
(iv) ROSL (for exports made upto 06.03.2019 for which claims have not yet been disbursed under scrip mechanism)	15.03.2022	Nil

No further applications would be allowed to be submitted after the prescribed last date (as above) as they would become time-barred. Late cut provisions shall also not be available for submitting claims thereafter.

Effect of this Notification: The last date of submitting applications under MEIS , for exports made in the period 01.09.2020 to 31.12.2020, has been extended upto 31.08.2022.

File No. 01/61/180/288/AM20/PC3 (Part-1)1

Santosh Kumar Sarangi, Director General of Foreign Trade Ex-officio Additional Secretary, Government of India, Ministry of Commerce & Industry, Department of Commerce, Udyog Bhawan, New Delhi.

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IP 2022 Salient Features

Indian Pharmacopoeia 2022

Published By

INDIAN PHARMACOPOEIA COMMISSION
Ministry of Health and Family Welfare
Government of India
Sector 23, Raj Nagar, Ghaziabad 201 002, India
Website: www.ipc.gov.in; **Email:** lab.ipc@gov.in

Effective Date

1ST DECEMBER 2022 (Tentative)

Salient Features

- New Monographs: 92
- APIs: 27
- Dosage Forms (Chemicals): 33
- Vitamins, Minerals, Amino acids, Fatty Acids etc.: 21
- Herbs & Herbal Products: 02
- Vaccines and Immunosera for human use: 04
- Biotechnology Derived Therapeutic products: 03
- Blood & Blood Related Products: 02
- General Chapters: 12

NOTE: *For more details, Interested member are requested to visit IPC webiste: www.ipc.gov.in*

Seminar On "Reinvigorating India's Pharma Exports: Awareness Workshop on Export Incentives" - 12th July 2022, Chandigarh

PXL/HO/Cir-026/2022-23, dated 24th June 2022

We have pleasure in informing our member companies that Pharmexcil is organizing an interactive session on **Reinvigorating India's Pharma Exports: Awareness Workshop on Export Incentives" on 12th July 2022.**

The one day Seminar is focused to highlight and bring forth recent amendments in the policies of trade, taxation and regulations for the benefit of small and medium scale enterprises. The key areas of discussion during the proposed program would be as follows:

- Foreign Trade Policy (New) & Incentives for Pharma Industry.
- Tax Regime for pharmaceuticals.
- Collaborative Support of CDSCO & FDA to Manufacturers/Exporters for Regulatory Compliance to International Standards
- Export Opportunities for SMEs
- Market Access Initiative Scheme (MAI)

The program details are as below:

Reinvigorating India's Pharma Exports: Awareness workshop on export incentives	
Date	12th July, 2022
Time	10: 00 AM – 05 PM
Venue	Hotel Lalit, Rajiv Gandhi IT Park, Chandigarh - 160101
Registration Link	**https://forms.gle/GC5XtZeEJft49XHr7**

Kindly note that there is no participation fee for Pharmexcil members and a Max of 2 persons are allowed per each member company. In case you are unable to access the google form, kindly send us the duly filled enclosed form to **rodelhi@pharmexcil.com), rodelhi@pharmexcil.com.**

Name Of The Organization	
Name Of Participant	
Designation	
Email	
Mobile Number	
Are You A Member of Pharmexcil	
Any Questions/Issues Related To Dgft	
Any Questions/Issues Related To Taxation	
Any Questions/Issues Related To Customs	
Any Questions/Issues Related To Cdsco	
Any Questions/Issues Related To State Drugs Control Department	

You are requested to actively participate in this full day Seminar and make it a grand success. We are sure that the topics by eminent speakers in the technical session would greatly benefit all participants in terms of updating their knowledge and skills. For any further queries, you may please write to rodelhi@pharmexcil.com .

With regards,

Udaya Bhaskar
Director General

Revised Dates for Stall reservation of India Pavilion at CPhI Worldwide 2022

PXL/HO/Cir-028/2022-23, date 29th June 2022

With reference to our Circulars regarding CPhI Worldwide vide No. PXL/HO/Cir-027/2022-23 Dt: 28.06.2022 and Circular No. PXL/Cir-020/2022-23 Dt: 20.06.2022, members are aware that Online Reservation for Stalls in Indian Pavilion at CPhI WW got deferred due to technical glitches. We were able to resolve the technical issues and the Stall Reservation Link is going to be live on 01st July 2022, Friday at 3:00 pm onwards.

Interested members to book the stalls may please click on the following link and reserve the stall as per their choice.

ONLINE RESERVATION

(Link will open at 3.00pm on 01st July 2022, Friday)

For further information about the event, members may contact us at events@pharmexcil.com');" >events@pharmexcil.com or contact on 040 23735462/64/66

With regards,

Udaya Bhaskar

Director General

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Digital Labeling of Medicines and Medical Devices by the Republic of Uzbekistan'' w.e.f 1st Sep 2022

PXL/HO/Cir-030/2022-23, date 04th July 2022

Pharmexcil is in receipt of the communication from the Indian embassy, Uzbekistan regarding Mandated digital labeling of Medicines and Medical Devices by the Republic of Uzbekistan. As per the resolution of the Cabinet of Ministers of the Republic of Uzbekistan "On the introduction of a mandatory system of digital labeling of Medicines and Medical Devices" (NO. 149 Dtd.: 02.04.2022), In short, a Phased introduction of a mandatory digital labeling system in the Republic of Uzbekistan in 2022-25 is imposed and Decree 149 is annexed herewith.

According to the decree, starting from September 1, 2022, medicines and medical devices of foreign origin can be imported into the territory of the Republic of Uzbekistan only with the presence of mandatory digital labeling (in secondary packaging). A similar requirement comes into force on November 1, 2022 for medicines in primary packaging. At the same time, the possibility of labeling by sticking stickers has been created in addition to the technology of direct application.

Also, a norm has been established according to which, after 12 months from the date of the introduction of mandatory digital labeling, a foreign manufacturer is obliged to open an official representative office in the territory of the Republic of Uzbekistan or sign an agreement with a local (Uzbek) company on the representation of interests and obligations in the field of the introduction of digital labeling in the territory of the Republic of Uzbekistan.

For these purposes, foreign manufacturers must register in the National Information System for Monitoring Labeling and Traceability of Products "Asl belgisi" by July 1, 2022, using an electronic digital signature (EDS). EDS is provided by diplomatic missions and consular offices of the Republic of Uzbekistan with the registration of a personal identification number of an individual (PINI) to representatives of foreign organizations-manufacturers of medicines who have received a taxpayer identification number (TIN) from the state tax service. The Procedure for procuring the TIN, PINI and EDS is assisted by the responsible officials of the State Tax Committee. The contact details of the officials of the Sales Tax Committee for procuring TIN, PINI and EDS is enclosed as Annexure for your reference.

Members may kindly make a note of these important requirements of the Republic of Uzbekistan.

With Regards,

Udaya Bhaskar

Director General

Note: *Annexures are not reproduced. For more details, interested member can contact IDMA Secretariat*

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Drugs Rules, 1945 amended (Fifth Amendment of 2022)

Drugs & Cosmetics Notification G.S.R.502(E), dated 30th June 2022

(Published in the Gazette of India on 1st July, 2022)

Whereas a draft of certain rules further to amend the Drugs Rules, 1945, 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.383(E), dated the 23rd May, 2022, 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 seven 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 23rd May, 2022;

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 Drugs and Cosmetics Act, 1940 (23 of 1940), the Central Government, after consultation with the Drugs Technical Advisory Board, hereby makes the following rules further to amend the Drugs Rules, 1945, namely:-

1. (1) These rules may be called the **Drugs (Fifth Amendment) Rules, 2022.**

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

2. In the Drugs Rules, 1945, in Schedule K, in the serial number 39, in the column under the heading "Extent and Conditions of Exemptions", at the end, the following proviso shall be inserted, namely:-

"Provided that the condition specified in clause (d) shall not be applicable for the drugs manufactured on or before the 30th November, 2022.".

Rajiv Wadhawan, Advisor, Ministry of Health and Family Welfare, Department of Health and Family Welfare, New Delhi.

Note: *The principal rules were published in the Gazette of India vide notification number F.28-10/45-H (1), dated the 21st December, 1945 and last amended vide notification number G.S.R.357(E), dated the 18th May, 2022.*

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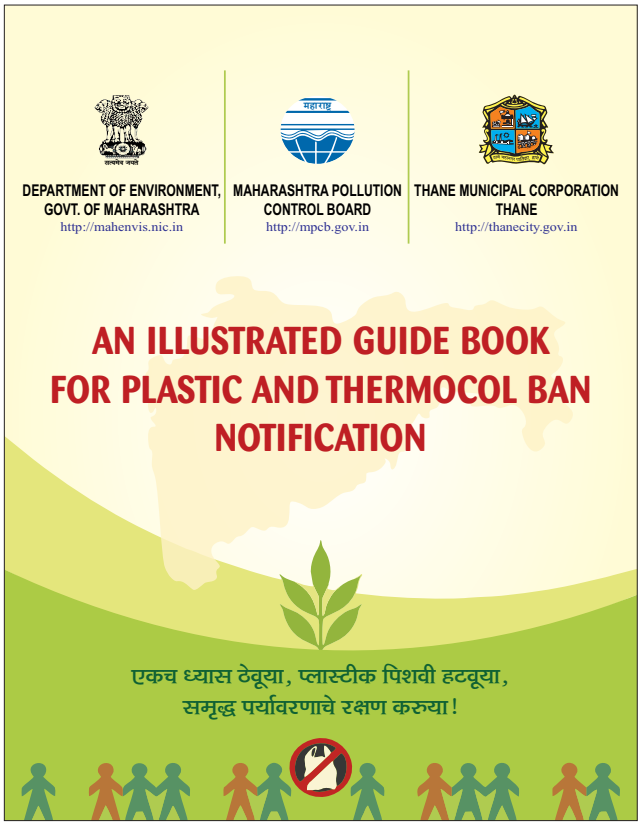
An illustrated Guide Book for Plastic and Thermocol Ban Notification



Allowed

Manufacture of plastic and plastic bags for export purpose in special economic zone & export oriented units.

Allowed

Plastic material madeup of minimum 20 % recyclable plastic material & having a thickness more than 50 micron, used for wrapping the material at the manufacturing stage or integral part of manufacturing. Thermocol used for wrapping the material at manufacturing stage. (printed with manufacturer's details, type of plastic with code number and buy-back price under EPR)

DEPARTMENT OF ENVIRONMENT, GOVT. OF MAHARASHTRA | MAHARASHTRA POLLUTION CONTROL BOARD

Allowed

Plastic packaging material more than 50 micron thickness with minimum two grams weight used toseal groceries & grain products for wholesale& retail. (printed with manufacturer's details, type of plastic with code number and buy-back price under EPR)

DEPARTMENT OF ENVIRONMENT, GOVT. OF MAHARASHTRA | MAHARASHTRA POLLUTION CONTROL BOARD

Banned

Any Compostable Plastic Bags except for Plant nurseries, horticulture , agriculture & handling of solid waste.

Allowed

Compostable Plastic Bags used for Plant nurseries, horticulture, agriculture & handling of solid waste.

DEPARTMENT OF ENVIRONMENT, GOVT. OF MAHARASHTRA | MAHARASHTRA POLLUTION CONTROL BOARD

Allowed

Paper based carton packaging using one or more layer of plastic

Allowed

Virgin Plastic bagsused for milkhaving thickness not less than 50 Micron & printed with a buy back price.

DEPARTMENT OF ENVIRONMENT, GOVT. OF MAHARASHTRA | MAHARASHTRA POLLUTION CONTROL BOARD


Allowed
Recyclable multilayered plastic
Chips packet, Shampoo sachet, Oil packet, Chocolate packet etc.
Allowed
Plastic items used for domestic purpose.
DEPARTMENT OF ENVIRONMENT, GOVT. OF MAHARASHTRA
MAHARASHTRA POLLUTION CONTROL BOARD


Allowed
Use of Plastic for packaging of medicine, medical equipments & medical products.
Banned
Use of Plastic & Thermocol for decoration purpose.
Allowed
Use of Thermocol Boxes to preserve fish in fishery business
DEPARTMENT OF ENVIRONMENT, GOVT. OF MAHARASHTRA
MAHARASHTRA POLLUTION CONTROL BOARD


Allowed
Recyclable plastic stationery products used for office & educations.
Allowed
Other plastic products
DEPARTMENT OF ENVIRONMENT, GOVT. OF MAHARASHTRA
MAHARASHTRA POLLUTION CONTROL BOARD


Penalties under plastic & Thermocol Notification
First offence Rs. 5000/- Fine
Second Offence Rs.10,000/- Fine.
Third Offence Rs. 25,000/- Fine + 3 months imprisonment

Dr Mansukh Mandaviya chairs Indian Pharmacopoeia Commission conference 2022 and releases 9th edition of Indian Pharmacopoeia

"India is world's largest supplier of generic medication and accounts for 20% of the worldwide supply of generic medicines by volume"

We need to prepare a roadmap for pharmacopoeia sector focussing on international trade, indigenous industries and global market: Dr Mansukh Mandaviya

"Pharmacopoeia is important to develop a Swasthya and Samrudh Bharat by maintaining standard quality of medical products"

Posted On 01st July 2022

Union Minister for Health and Family Welfare and Chemicals and Fertilisers, Dr. Mansukh Mandaviya chaired IPC Conference 2022 and released 9th edition of Indian Pharmacopoeia today at Vigyan Bhawan, New Delhi today in the august presence of. Dr Bharati Pravin Pawar, Union Minister of State.

The theme of this year's conference was 'Addressing Medicine Quality for Future'.

Speaking on the occasion, Dr. Mansukh Mandaviya expressed his desire of getting India's pharmacopoeia acknowledged and appreciated worldwide. He said, "We have become "Pharmacy of the World" by specialising in generic medicine formulation and manufacturing, and by supplying affordable medicine to the world. But we still need to strengthen research in pharmaceuticals sector. Till today, four countries – Afghanistan, Ghana, Nepal and Mauritius- have accepted IP as a book of standards. We should make a roadmap and move forward so that more countries accept our pharmacopoeia," he noted.

Highlighting the role of government at international level, Dr Mansukh Mandaviya said, "As a result of the vision of our Hon'ble Prime Minister Narendra Modi ji and our work in that direction, the world has started recognising us and giving importance to our work and accepting it. We should focus on how our pharmacopoeia can take advantage of this focussing on international trade and industries based on our strength in indigenous medicines. Pharmacopoeia is important to develop a Swasthya and Samrudh Bharat, to maintain standard quality of our medical products- vaccines, medicines, equipment etc. and to keep an eye on the effect of these medicines on patients."

Pointing out that India is world's largest supplier of generic medication and accounts for 20% of the worldwide supply of generics by volume, he further said that during Covid pandemic, India has delivered accessible and affordable vaccines to 150 countries. "While delivering vaccines and other generic medicines to so many countries, we have never compromised with the quality and standards or delivered sub-standard or spurious drugs. India has earned global accolades as a result of this", he added.

About Indian Pharmacopoeia

The Indian Pharmacopoeia (IP) is published by the Indian Pharmacopoeia Commission (IPC) on behalf of Ministry of Health & Family Welfare, Government of India to fulfil the requirements of the Drugs and Cosmetics Act 1940. IP prescribes the official standards for drugs produced and/or marketed in India and thus contributes in the control and assurance of the quality of the medicines. The standards of the IP are authoritative and legally enforceable. It intends to help in the licensing of manufacturing, inspection and distribution of medicines in our country.

IP 2022 contains a total of 92 new monographs including **60 Chemical, 21 Vitamins, Minerals, Amino acids, Fatty acids etc., 3 Biotechnology-derived Therapeutic Products, 4 Human Vaccines, 2 Blood and Blood Related Products, 2 Herbs and Herbal Related Products,** and 7 Phytopharmaceutical Ingredient Category monographs. This has led to the total number of 3152 monographs in the current edition of IP. In additions, 12 new general chapters have also been introduced. Several monographs and general chapters have also been revised to update them as per current global requirements and to harmonize with other pharmacopoeias like USP, BP, EP, etc. The harmonization of standards with global standards is expected to help IP getting recognized and accepted in foreign countries.

To mark the occasion of release of the IP, IPC organized IPC Conference 2022 with more than 350 registered participants from top pharma industries, State and Central Drug Regulatory bodies, International Pharmacopoeia bodies (BP, USP), industry bodies like IDMA, BDMA, IPA, etc., and academia. During the conference, presentations were made by subject experts on topics related to pharmacopoeia standards, regulatory and quality expectations, and Indian pharma industry followed by panel discussion.

Shri Rajesh Bhushan, Union Health Secretary, Dr. Atul Goel, Director General of Health Services, Dr. V. G. Somani, Drugs Controller General India, Dr Rajeev Singh Raghuvanshi, Secretary-cum-Scientific Director, IPC and other top industry leaders were also present in the meeting.

Source: PIB Delhi, 01.07.2022

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CBIC MATTERS

Prescribing manner of re-credit in electronic credit ledger using FORM GST PMT- 03A – reg.

Circular No. 174/06/2022-GST, dated 6th July, 2022

To,

The Principal Chief Commissioners / Chief Commissioners / Principal Commissioners / Commissioners of Central Tax (All),

The Principal Directors General / Directors General (All).

1. Difficulties were being faced by the taxpayers in taking re-credit of the amount in the electronic credit ledger in cases where any excess or erroneous refund sanctioned to them had been paid back by them either on their own or on being pointed by the tax officer. In order to resolve this issue, GSTN has recently developed a new functionality of **FORM GST PMT-03A** which allows proper officer to re-credit the amount in the electronic credit ledger of the taxpayer. Further, sub-rule (4B) in rule 86 of the Central Goods and Services Tax Rules, 2017 (hereinafter referred to as "CGST Rules") has been inserted vide Notification No. 14/2022-CT dated 05.07.2022 to provide for re-credit in the electronic credit ledger where the taxpayer deposits the erroneous refund sanctioned to him.

2. In order to ensure uniformity in the implementation of the above provisions of the law across field formations, the Board, in exercise of its powers conferred by section 168(1) of the Central Goods and Services Tax Act, 2017 (hereinafter referred to as "CGST Act"), hereby clarifies the following:

3. Categories of refunds where re-credit can be done using FORM GST PMT-03 A:

3.1 Reference is invited to sub-rule (4B) of rule 86 of the CGST Rules, which is reproduced as under:

(4B) Where a registered person deposits the amount of erroneous refund sanctioned to him –

a. under sub-section (3) of section 54 of the Act, or

b. under sub-rule (3) of rule 96, in contravention of sub-rule (10) of rule 96, along with interest and penalty, wherever applicable, through FORM GST DRC-03, in cash, on his own or on being pointed out, an amount equivalent to the amount of erroneous refund deposited by the registered person shall be re-credited to the electronic credit ledger by the proper officer by an order made in **FORM GST PMT-03A.**

3.2 From the above, it can be stated that in respect of the following categories of refund sanctioned erroneously, re-credit of amount in the electronic credit ledger can be done through **FORM GST PMT-03A,** on deposit of such erroneous refund along with interest and penalty, wherever applicable, by the taxpayer:

a. Refund of IGST obtained in contravention of sub-rule (10) of rule 96.

b. Refund of unutilised ITC on account of export of goods/services without payment of tax.

c. Refund of unutilised ITC on account of zero-rated supply of goods/services to SEZ developer/Unit without payment of tax.

d. Refund of unutilised ITC due to inverted tax structure.

4. Procedure for re-credit of amount in electronic credit ledger:

4.1 The taxpayer shall deposit the amount of erroneous refund along with applicable interest and penalty, wherever applicable, through **FORM GST DRC-03** by debit of amount from electronic cash ledger. While making the payment through **FORM GST DRC-03**, the taxpayer shall clearly mention the reason for making payment in the text box as the deposit of erroneous refund of unutilised ITC, or the deposit of erroneous refund of IGST obtained in contravention of sub-rule (10) of rule 96 of the CGST Rules.

4.2 Till the time an automated functionality for handling such cases is developed on the portal, the taxpayer shall make a written request, in format enclosed as **Annexure-A**, to jurisdictional proper officer to re-credit the amount equivalent to the amount of refund thus paid back through **FORM GST DRC-03,** to electronic credit ledger.

4.3 The proper officer, on being satisfied that the full amount of erroneous refund along with applicable interest, as per the provisions of section 50 of the CGST Act, and penalty, wherever applicable, has been paid by the said registered person in **FORM GST DRC-03** by way of debit in electronic cash ledger, he shall re-credit an amount in electronic credit ledger, equivalent to the amount of erroneous refund so deposited by the registered person, by passing an order in **FORM GST PMT-03A**, **preferably within a period of 30 days** from the date of receipt of request for re-credit of erroneous refund amount so deposited or from the date of payment of full amount of erroneous refund along with applicable interest, and penalty, wherever applicable, whichever is later.

5. It is requested that suitable trade notices may be issued to publicize the contents of this Circular.

6. Difficulty, if any, in the implementation of this Circular may be brought to the notice of the Board.

F. No. CBIC-20001/2/2022-GST

Sanjay Mangal,
Principal Commissioner (GST),
Ministry of Finance,
Department of Revenue,
Central Board of Indirect Taxes and Customs,
GST Policy Wing,
New Delhi.

Annexure-A

From,

GSTIN - _____

Legal Name- _____

Trade Name- _____

To,

Jurisdictional Proper officer,

Address _____

Subject: Request for re-credit of amount in Electronic Credit Ledger

I/We have been granted refund under the following category (please tick the relevant category):

a. Refund of IGST, obtained in contravention of sub-rule (10) of rule 96 of the CGST Rules, 2017.

b. Refund of unutilised ITC on account of export of goods/services without payment of tax.

c. Refund of unutilised ITC on account of zero-rated supply of goods/services to SEZ developer/Unit without payment of tax.

d. Refund of unutilised ITC due to inverted tax structure.

2. The details of refund sanction order are as under:

(a) In case of refund of IGST, obtained in contravention of sub-rule (10) of rule 96 of the CGST Rules, 2017:

1. Shipping Bill/ Bill of Export No. & Date _____
2. Amount of IGST paid on export of goods _____
3. Details of Exemption/Concessional Rate Notification used for procuring inputs _____
4. Amount of refund sanctioned _____
5. Date of credit of refund in Bank Account _____

(b) In other cases of refund:

1. Category of refund & relevant period of refund_____
2. GST RFD-01/01A ARN & Date _____
3. GST RFD-06 Order No. & Date _____
4. Amount of refund claimed _____
5. Amount of refund sanctioned _____
6. Date of credit of refund in Bank Account _____

3. I/We have deposited the erroneous refund amount of Rs. _____ along with interest of Rs. _____ and penalty of Rs. _____ (wherever applicable) vide FORM GST DRC -03 Ref/ARN _____ dated_____ voluntarily on my own ascertainment/ against a notice/order/letter No. _____ dated _____ issued by (details of the tax authority). It is now requested to re-credit an amount equivalent to the amount of erroneous refund, so deposited, in the Electronic Credit Ledger.

4. I hereby solemnly affirm and declare that the information given hereinabove is true and correct to the best of my knowledge and belief and nothing has been concealed therefrom.

Date:

Signature of Authorized Signatory

Name

Designation / Status

● ● ●

NPPA changed the Prices of 84 Formulations

ORDER S. O. 2981(E), 30th June, 2022

In exercise of the powers conferred by paragraphs 5, 11 and 15 of the Drugs (Prices Control) Order, 2013, read with S.O. 1394(E) dated the 30th May, 2013 and S. O. 701(E) dated 10th March, 2016 issued by the Government of India in the Ministry of Chemicals and Fertilizers, the National Pharmaceutical Pricing Authority (hereinafter referred as NPPA), hereby fixes, the price as specified in column (6) of the table herein below as the retail price, exclusive of Goods and Services Tax, if any, in relation to the formulation specified in the corresponding entry in column (2) of the said Table with the strength, unit and name of manufacturer & marketing company, as specified in the corresponding entries in columns (3), (4) and (5) thereof;

Table

Sl. No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
1.	Voglibose and (SR) Metformin Hydrochloride Tablet	**Each uncoated bilayered tablet contains:** Voglibose IP 0.3mg Metformin Hydrochloride IP 500mg (As Sustained Release Form)	1 Tablet	M/s Akums Drugs & Pharmaceuticals Ltd. / M/s German Remedies Pharmaceuticals Private Limited	10.47
2.	Olmesartan Medoxomil, Amlodipine & Hydrochlorothiazide Tablet	**Each film coated tablet contains:** Olmesartan Medoxomil 20mg Amlodipine Besilate IP eq. to Amlodipine 5mg Hydrochlorothiazide IP 12.5mg	1 Tablet	M/s Akums Drugs & Pharmaceuticals Ltd. / M/s German Remedies Pharmaceuticals Private Limited	12.91
3.	Hydroxychloroquine Sulphate Tablet	**Each film coated tablet contains:** Hydroxychloroquine Sulphate IP 300 mg	1 Tablet	M/s Hetero Healthcare Ltd.	11.74
4.	Linezolid for Oral Suspension (combipack with Steril Water)	**Each Combi pack Contains:** (A) Linezolid for oral Suspension Each 5 ml of Constituted Suspension Contains : Linezolid IP 100 mg (B) 1 vial of Sterile water for Injection IP Each Vial Contains : Sterile water for Injection IP 30 ml	Per Combi Pack	M/s Pure & Cure Healthcare Pvt. Ltd. / M/s Eris Healthcare Pvt. limited	102.00
5.	Paracetamol and Caffeine Tablets	**Each uncoated tablet contains:** Paracetamol IP 650mg Caffeine Anhydrous IP 50mg	1 Tablet	M/s Rivpra Formulation Pvt. Ltd. / M/s Dabur India Ltd.	2.88
6.	Paracetamol &	**Each 5ml contain**s:	1 ML	M/s Bioconic	0.33

	Ibuprofen Suspension	Paracetamol IP 162.50mg Ibuprofen IP 100mg		Remedies. / M/s Dales Laboratories Pvt. Ltd.	
7.	Metformin Hydrochloride (SR), Glimepiride and Voglibose Tablets	**Each uncoated bilayered tablet contains:** Metformin Hydrochloride IP 1000mg (in Sustained Release form), Glimepiride IP 1mg Voglibose IP 0.2mg Tablets	1 Tablet	M/s Swiss Garnier Genexiaa Sciences / M/s Sun Pharmaceutical Industries Limited	11.43
8.	Metformin Hydrochloride (SR), Glimepiride and Voglibose Tablets	**Each uncoated bilayered tablet contains:** Metformin Hydrochloride IP 1000mg (in Sustained Release form), Glimepiride IP 2mg Voglibose IP 0.2mg Tablets	1 Tablet	M/s Swiss Garnier Genexiaa Sciences / M/s Sun Pharmaceutical Industries Limited	13.30
9.	Metformin Hydrochloride (SR), Glimepiride and Voglibose Tablets	**Each uncoated bilayered tablet contains:** Metformin Hydrochloride IP 1000mg (in Sustained Release form), Glimepiride IP 1mg Voglibose IP 0.2mg Tablets	1 Tablet	M/s Swiss Garnier Genexiaa Sciences / M/s Sun Pharma Laboratories Limited	11.43
10.	Metformin Hydrochloride (SR), Glimepiride and Voglibose Tablets	**Each uncoated bilayered tablet contains:** Metformin Hydrochloride IP 1000mg (in Sustained Release form), Glimepiride IP 2mg Voglibose IP 0.2mg Tablets	1 Tablet	M/s Swiss Garnier Genexiaa Sciences / M/s Sun Pharma Laboratories Limited	13.30
11.	Sucralfate & Oxetacaine Oral Suspension	**Each 10ml contains:** Sucralfate IP 1gm Oxetacaine BP 20mg	1 ML	M/s Pure and Cure Healthcare Pvt. Ltd. / M/s German Remedies Pharmaceuticals Private Limited	1.76
12.	Rosuvastatin, Aspirin & Clopidogrel Capsule	**Each Hard Gelatin Capsule contains:** Rosuvastatin Calcium IP eq. to Rosuvastatin 10mg (as film coated tablet) Aspirin IP 75mg (as Gastro-resistant tablet) Clopidogrel Bisulphate IP eq. to Clopidogrel 75mg (as film coated tablet)	1 Capsule	M/s Akums Drugs & Pharmaceuticals Ltd. / M/s German Remedies Pharmaceuticals Private Limited	13.91
13.	Rosuvastatin, Aspirin & Clopidogrel Capsule	**Each Hard Gelatin Capsule contains:** Rosuvastatin Calcium IP eq. to Rosuvastatin 20mg (as film coated tablet) Aspirin IP 75mg (as Gastro-resistant tablet) Clopidogrel Bisulphate IP eq. to Clopidogrel 75mg (as film	1 Capsule	M/s Akums Drugs & Pharmaceuticals Ltd. / M/s German Remedies Pharmaceuticals Private Limited	20.27

		coated tablet)			
14.	Glimepiride, Pioglitazone Hydrochloride & Metformin Hydrochloride (SR) Tablet	**Each uncoated bilayered tablet contains:** Glimepiride IP 1 mg Pioglitazone Hydrochloride IP eq. to Pioglitazone 15 mg Metformin Hydrochloride IP 500 mg (In Sustained Release Form)	1 Tablet	M/s Akum Drugs & Pharmaceuticals Limited/M/s German Remedies Pharmaceuticals Pvt. Ltd.	8.03
15.	Glimepiride, Pioglitazone Hydrochloride & Metformin Hydrochloride (SR) Tablet	**Each uncoated bilayered tablet contains:** Glimepiride IP 2 mg Pioglitazone Hydrochloride IP eq. to Pioglitazone 15 mg Metformin Hydrochloride IP 500 mg (In Sustained Release Form)	1 Tablet	M/s Akum Drugs & Pharmaceuticals Limited/M/s German Remedies Pharmaceuticals Pvt. Ltd.	11.10
16.	Amoxycillin & Potassium Clavulanate Tablets IP	**Each film coated tablet contains:** Amoxycillin Trihydrate eq. to Amoxycillin IP 875mg Potassium Clavulanate Diluted eq. to Clavulanic Acid IP 125mg	1 Tablet	M/s Medicef Pharma /M/s Themis Medicare Limited	34.03
17.	Amoxycillin & Potassium Clavulanate Oral Suspension	**Each 5ml of reconstituted suspension contains:** Amoxycillin Trihydrate eq. to Amoxycillin IP 400mg Potassium Clavulanate Diluted eq. to Clavulanic Acid IP 57mg Steril water for injection 30ml	1 ML	M/s Medicef Pharma M/s Themis Medicare Limited	3.90
18.	Paracetamol & Thiocolchicoside Tablet	**Each uncoated tablet contains:** Paracetamol IP 500 mg Thiocolchicoside IP 8 mg	1 Tablet	M/s Micro Labs Limited	27.90
19.	Ferrous Ascorbate and Folic Acid Oral Drops	**Each ml contains:** Ferrous Ascorbate IP eq. to Elemental Iron 10mg Folic Acid IP 100mcg	1 ML	M/s Akums Drugs & Pharmaceuticals Ltd. / M/s German Remedies Pharmaceuticals Private Limited	5.06
20.	Ferrous Ascorbate and Folic Acid Suspension IP	**Each 5 ml contains:** Ferrous Ascorbate IP eq. to Elemental Iron 30mg Folic Acid IP 500mcg	1 ML	M/s Akums Drugs & Pharmaceuticals Ltd. / M/s German Remedies Pharmaceuticals Private Limited	0.87
21.	Amlodipine and Telmisartan tablets	**Each uncoated bilayered tablet contains**: Amlodipine Besilate IP eq. to Amlodipine 5mg Telmisartan IP 80mg	1 Tablet	M/s Akums Drugs & Pharmaceuticals Pvt. Ltd. / M/s German Remedies Pharmaceuticals Private Limited	17.33
22.	Amlodipine and Telmisartan tablets	**Each uncoated bilayered tablet contains**: Amlodipine Besilate IP eq. to Amlodipine 5mg Telmisartan IP 40mg	1 Tablet	M/s Akums Drugs & Pharmaceuticals Pvt. Ltd. / M/s German Remedies Pharmaceuticals	9.76

				Private Limited	
23.	Clopidogrel & Aspirin Tablets	**Each uncoated / film coated bilayered tablet contains:** Clopidogrel Bisulphate IP eq. to Clopidogrel 75mg Aspirin IP 150mg	1 Tablet	M/s Skymap Pharmaceuticals Pvt. Ltd.	4.34
24.	Aceclofenac, Paracetamol & Trypsin Chymotrypsin Tablets	**Each enteric coated tablet contains:** Proteolytic enzymes Trypsin & Chymotrypsin In the ratio of Approximately 6:1 and provides enzymatic activity eq. to 150000 Armour Units Aceclofenac IP 100mg Paracetamol IP 325mg	1 Tablet	M/s Akums Drugs & Pharmaceuticals Ltd. / M/s Ipca Laboratories Limited	13.85
25.	Ferrous Ascorbate, Folic Acid & Zinc Tablets	**Each film coated tablet contains:** Ferrous Ascorbate IP eq. to Elemental Iron 100mg Folic Acid IP 1.5mg Zinc Sulphate Monohydrate IP eq. to Elemental Zinc 22.5mg	1 Tablet	M/s Akums Drugs & Pharmaceuticals Ltd. / M/s German Remedies Pharmaceuticals Private Limited	9.65
26.	Calcium Carbonate, Calcitriol & Zinc Capsules	**Each soft Gelatin Capsule contains:** Calcium Carbonate IP 500mg eq. to Elemental Calcium 200mg Calcitriol IP 0.25mcg Zinc Sulphate Monohydrate IP eq. to Elemental Zinc 7.5mg	1 Capsule	M/s Akums Drugs & Pharmaceuticals Ltd. / M/s German Remedies Pharmaceuticals Private Limited	14.07
27.	Cilnidipine & Telmisartan Tablets	**Each film coated tablet contains** Cilnidipine IP 10 mg Telmisartan IP 40 mg	1 Tablet	M/s Ravenbhel Healthcare Pvt. Ltd. / M/s Troikaa Pharmaceuticals Limited	9.92
28.	Cilnidipine, Telmisartan & Metoprolol (ER) Tablets	**Each film coated bilayered tablet contains** Telmisartan IP 40 mg Cilnidipine IP 10 mg Metoprolol SuccinateIP 23.75mg eq. to Metoprolol Tartrate 25mg (as extended release)	1 Tablet	M/s Ravenbhel Healthcare Pvt. Ltd. / M/s Troikaa Pharmaceuticals Limited	10.24
29.	Cilnidipine, Telmisartan & Metoprolol (ER) Tablets	**Each film coated bilayered tablet contains** Telmisartan IP 40 mg Cilnidipine IP 10 mg Metoprolol SuccinateIP 47.50mg eq. to Metoprolol Tartrate 50mg (as extended release)	1 Tablet	M/s Ravenbhel Healthcare Pvt. Ltd. / M/s Troikaa Pharmaceuticals Limited	12.77
30.	Ceftriaxone & Tazobactam for Injection	**Each vial contains:** Sterile Ceftriaxone Sodium IP eq. to Ceftriaxone 1000mg Sterile Tazobactam Sodium IP eq. to Tazobactam 125mg	Per Vial	M/s Theon Pharmaceuticals Ltd. / M/s Cadila Pharmaceuticals Ltd.	168.43
31.	Ceftriaxone &	**Each vial contains:**	Per Vial	M/s Skymap	168.43

	Tazobactam Injection	Ceftriaxone Sodium IP (Sterile) eq. to anhydrous Ceftriaxone 1000mg Tazobactam Sodium IP (Sterile) eq. to Anhydrous Tazobactam 125mg		Healthcare Pvt. Ltd.	
32.	Diclofenac Injection IP	**Each ml contains:** Diclofenac Sodium IP 75mg water for Injection	1 ML	M/s Nichepharm Lifesciences Pvt. Ltd. / M/s Cipla Ltd.	20.72
33.	Atorvastatin and Fenofibrate Tablets	**Each film coated tablet contains:** Atorvastatin Calcium IP eq. to Atorvastatin 10mg Fenofibrate IP (Micronized) 160mg	1 Tablet	M/s Pure and Cure Healthcare Pvt. Ltd. / M/s Cipla Ltd.	13.87
34.	Budesonide & Formoterol Fumarate Respirator Suspension	**Each 2ml contains:** Budesonide IP 0.5mg Formoterol Fumarate Dihydrate IP eq. to Formoterol Fumaret 20mcg	1 ML	M/s Aishwarya Healthcare / M/s Torrent Pharmaceuticals Ltd.	22.75
35.	Ceftriaxone & Sulbactam water for injection	**Each vial contains :** Sterile Ceftriaxone Sodium IP eq. to Ceftriaxone 1000mg, Sterile Sulbactam Sodium IP eq. to Sulbactam 500mg Each ampoule contains: Sterile water for injection IP 10ml	Per Pack	M/s Inject Care Parenterals Pvt. Ltd. / Torrent Pharmaceuticals Ltd.	143.52
36.	Ceftriaxone & Tazobactam for Injection 1125mg	**Each Combipack Contains:** Part-I Each vial contains : Ceftriaxone Sodium IP (Sterile) eq. to Ceftriaxone 1gm, Tazobactam Sodium Sterile eq. to Tazobactam (Sterile) 125mg Part-II (For Reconstitution) Each FFS Ampoule contains: Sterile Water for Injection IP 10ml	Per Pack	M/s Nitin Lifesciences Limited / M/s Softdeal Pharmaceutical Private Limited	168.43
37.	Metformin Hydrochloride (SR), Glimepiride and Voglibose Tablets	**Each uncoated bilayered tablet contains:** Metformin Hydrochloride IP 1000mg (In Sustained Release form) Glimepiride IP 1mg Voglibose IP 0.2mg	1 Tablet	M/s Swiss Garnier Genexiaa Sciences Pvt. Ltd. / M/s Abbott Healthcare Pvt. Ltd.	11.43
38.	Metformin Hydrochloride (SR), Glimepiride and Voglibose Tablets	**Each uncoated bilayered tablet contains:** Metformin Hydrochloride IP 1000mg (In Sustained Release formm) Glimepiride IP 2mg Voglibose IP 0.2mg	1 Tablet	M/s Swiss Garnier Genexiaa Sciences Pvt. Ltd. / M/s Abbott Healthcare Pvt. Ltd.	13.85
39.	Rabeprazole Sodium (gastro-resistant) & Domperidone	**Each hard gelatin capsule contains**: Rabeprazole Sodium IP 40mg (as reddish brown coloured	1 Capsule	M/s Windlas Biotech Limited / M/s Intas Pharmaceuticals Ltd.	10.83

	(SR) Capsules	enteric coated pellets) Domperidone IP 30mg (as orange coloured sustained release pellets)			
40.	Metformin Hydrochloride (SR), Glimepiride and Voglibose Tablets	**Each uncoated bilayered tablet contains:** Metformin Hydrochloride IP 1000mg (In Sustained Release form) Glimepiride IP 2mg Voglibose IP 0.2mg	1 Tablet	M/s Swiss Garnier Genexiaa Sciences Pvt. Ltd. / M/s Intas Pharmaceuticals Ltd.	13.85
41.	Metformin Hydrochloride (SR), Glimepiride and Voglibose Tablets	**Each uncoated bilayered tablet contains:** Metformin Hydrochloride IP 1000mg (In Sustained Release form) Glimepiride IP 1mg Voglibose IP 0.2mg	1 Tablet	M/s Swiss Garnier Genexiaa Sciences Pvt. Ltd. / M/s Intas Pharmaceuticals Ltd.	11.43
42.	Sitagliptin Phosphate & Metformin Hydrochloride Tablets	**Each Film Coated tablet contains:** Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50mg Metformin Hydrochloride IP 500 mg	1 Tablet	M/s Alembic Pharmaceuticals Limited	16.96
43.	Sitagliptin Phosphate & Metformin Hydrochloride Tablets	**Each Film Coated tablet contains:** Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50mg Metformin Hydrochloride IP 1000 mg	1 Tablet	M/s Alembic Pharmaceuticals Limited	18.75
44.	Sitagliptin and Metformin Hydrochloride SR Tablets	**Each film coated tablet contains:** Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50mg Metformin Hydrochloride IP 1000mg (as sustained release form)	1 Tablet	M/s Akums drugs & Pharmaceuticals Limited / M/s Abbott Healthcare Pvt. Ltd.	20.06
45.	Sitagliptin and Metformin Hydrochloride SR Tablets	**Each film coated tablet contains:** Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50mg Metformin Hydrochloride IP 500mg (as sustained release form)	1 Tablet	M/s Akums drugs & Pharmaceuticals Limited / M/s Abbott Healthcare Pvt. Ltd.	18.34
46.	Sitagliptin and Metformin Hydrochloride SR Tablets	**Each film coated tablet contains:** Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 100mg Metformin Hydrochloride IP 1000mg (as sustained release form)	1 Tablet	M/s Akums drugs & Pharmaceuticals Limited / M/s Abbott Healthcare Pvt. Ltd.	19.81

47.	Sitagliptin and Metformin Hydrochloride Tablets	**Each film coated tablet contains:** Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50mg Metformin Hydrochloride IP 500mg	1 Tablet	M/s Torrent Pharmaceuticals Limited	18.34
48.	Sitagliptin and Metformin Hydrochloride Tablets	**Each film coated tablet contains:** Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50mg Metformin Hydrochloride IP 850mg	1 Tablet	M/s Torrent Pharmaceuticals Limited	19.14
49.	Sitagliptin and Metformin Hydrochloride Tablets	**Each film coated tablet contains:** Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50mg Metformin Hydrochloride IP 1000mg	1 Tablet	M/s Torrent Pharmaceuticals Limited	20.02
50.	Sitagliptin Phosphate and Metformin Hydrochloride Tablets	**Each film coated tablet contains:** Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50mg Metformin Hydrochloride IP 500mg	1 Tablet	M/s Skymap Pharmaceuticals Pvt. Ltd.	18.34
51.	Sitagliptin Phosphate and Metformin Hydrochloride Tablets	**Each film coated tablet contains:** Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50mg Metformin Hydrochloride IP 1000mg	1 Tablet	M/s Skymap Pharmaceuticals Pvt. Ltd.	20.02
52.	Sitagliptin Phosphate and Metformin Hydrochloride Tablets	**Each film coated tablet contains:** Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50mg Metformin Hydrochloride IP 500mg	1 Tablet	M/s Skymap Pharmaceuticals Pvt. Ltd. / M/s Glensmith Labs Pvt. Ltd.	18.34
53.	Sitagliptin Phosphate and Metformin Hydrochloride Tablets	**Each film coated tablet contains:** Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50mg Metformin Hydrochloride IP 1000mg	1 Tablet	M/s Skymap Pharmaceuticals Pvt. Ltd. / M/s Glensmith Labs Pvt. Ltd.	20.02
54.	Sitagliptin and Metformin Hydrochloride Tablets	**Each film coated tablet contains:** Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50mg Metformin Hydrochloride IP 500mg	1 Tablet	M/s Micro Labs limited	18.34

55.	Sitagliptin and Metformin Hydrochloride Tablets	**Each film coated tablet contains:** Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50mg Metformin Hydrochloride IP 1000mg	1 Tablet	M/s Micro Labs limited	20.00
56.	Sitagliptin and Metformin Hydrochloride (SR) Tablets	**Each film coated tablet contains:** Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50mg Metformin Hydrochloride IP 1000mg (as sustained release form)	1 Tablet	M/s Akums Drugs & Pharmaceuticals Ltd. / M/s Zydus Healthcare Limited	20.06
57.	Sitagliptin and Metformin Hydrochloride (SR) Tablets	**Each film coated tablet contains:** Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50mg Metformin Hydrochloride IP 500mg (as sustained release form)	1 Tablet	M/s Akums Drugs & Pharmaceuticals Ltd. / M/s Zydus Healthcare Limited	18.67
58.	Sitagliptin and Metformin Hydrochloride (extended release) Tablets	**Each film coated bilayered tablet contains:** Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 100mg Metformin Hydrochloride IP (In extended release form) 500mg	1 Tablet	M/s Zydus Healthcare Limited	20.17
59.	Sitagliptin and Metformin Hydrochloride (extended release) Tablets	**Each film coated bilayered tablet contains:** Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 100mg Metformin Hydrochloride IP (In extended release form) 1000mg	1 Tablet	M/s Zydus Healthcare Limited	21.56
60.	Sitagliptin and Metformin Hydrochloride (as extended release) Tablets	**Each film coated bilayered tablet contains:** Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 100mg Metformin Hydrochloride IP (as extended release form) 500mg	1 Tablet	M/s Exemed Pharmaceuticals / M/s Glenmark Pharmaceuticals Limited	20.17
61.	Sitagliptin and Metformin Hydrochloride (as extended release) Tablets	**Each film coated bilayered tablet contains:** Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 100mg Metformin Hydrochloride IP (as extended release form) 1000mg	1 Tablet	M/s Exemed Pharmaceuticals / M/s Glenmark Pharmaceuticals Limited	21.56
62.	Sitagliptin and Metformin Hydrochloride (as extended release) Tablets	**Each film coated bilayered tablet contains:** Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 100mg	1 Tablet	M/s Exemed Pharmaceuticals / M/s Emcure Pharmaceuticals Limited	21.56

		Metformin Hydrochloride IP (as extended release form) 1000mg			
63.	Sitagliptin and Metformin Hydrochloride Tablets	**Each film coated tablet contains:** Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50mg Metformin Hydrochloride IP 1000mg	1 Tablet	M/s Synokem Pharmaceuticals Limited / M/s FDC Limited	10.41
64.	Sitagliptin and Metformin Hydrochloride Tablets	**Each film coated tablet contains:** Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50mg Metformin Hydrochloride IP 500mg	1 Tablet	M/s Synokem Pharmaceuticals Limited / M/s FDC Limited	8.92
65.	Sitagliptin and Metformin Hydrochloride (as extended release) Tablets	**Each film coated bilayered tablet contains:** Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 100mg Metformin Hydrochloride IP (as extended release form) 500mg	1 Tablet	M/s Exemed Pharmaceuticals / M/s Emcure Pharmaceuticals Limited	20.17
66.	Sitagliptin Phosphate and Metformin Hydrochloride Tablets	**Each film coated tablet contains:** Sitagliptin Phosphate Monohydrate IP 64.25 eq. to Sitagliptin 50mg Metformin Hydrochloride IP 500mg	1 Tablet	M/s Unison Pharmaceuticals Pvt. Limited	18.34
67.	Sitagliptin and Metformin Hydrochloride (extended release) Tablets	**Each film coated bilayered tablet contains:** Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50mg Metformin Hydrochloride IP (As Extended Release form) 500mg	1 Tablet	M/s Exemed Pharmaceuticals / M/s Eris Life Sciences Limited	18.67
68.	Sitagliptin and Metformin Hydrochloride (extended release) Tablets	**Each film coated bilayered tablet contains:** Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50mg Metformin Hydrochloride IP (As Extended Release form) 1000mg	1 Tablet	M/s Exemed Pharmaceuticals / M/s Eris Life Sciences Limited	20.06
69.	Sitagliptin and Metformin Hydrochloride (extended release) Tablets	**Each film coated bilayered tablet contains:** Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 100mg Metformin Hydrochloride (As Extended Release) IP 500mg	1 Tablet	M/s Exemed Pharmaceuticals / M/s Eris Life Sciences Limited	20.17
70.	Sitagliptin and Metformin Hydrochloride (extended	**Each film coated bilayered tablet contains:** Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin	1 Tablet	M/s Exemed Pharmaceuticals / M/s Eris Life Sciences Limited	21.56

	release) Tablets	100mg Metformin Hydrochloride IP (As Extended Release form) 1000mg			
71.	Sitagliptin Phosphate and Metformin Hydrochloride Tablets	**Each film coated tablet contains:** Sitagliptin Phosphate Monohydrate IP 64.25 eq. to Sitagliptin 50mg Metformin Hydrochloride IP 1000mg	1 Tablet	M/s Unison Pharmaceuticals Pvt. Limited	20.02
72.	Sitagliptin and Metformin Hydrochloride (as extended release) Tablets	**Each film coated bilayered tablet contains:** Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50mg Metformin Hydrochloride IP (As Extended Release form) 500mg	1 Tablet	M/s Exemed Pharmaceuticals / M/s Zydus Healthcare Limited	18.67
73.	Sitagliptin and Metformin Hydrochloride (as extended release) Tablets	**Each film coated bilayered tablet contains:** Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50mg Metformin Hydrochloride IP (As Extended Release form) 1000mg	1 Tablet	M/s Exemed Pharmaceuticals / M/s Zydus Healthcare Limited	20.06
74.	Sitagliptin and Metformin Hydrochloride (as extended release) Tablets	**Each film coated bilayered tablet contains:** Sitagliptin Phosphate IP eq. to Sitagliptin 50mg Metformin Hydrochloride IP (As Extended Release form) 500mg	1 Tablet	M/s Alkem Healthscience (A unit of Alkem Laboratories Ltd.) M/s Alkem Laboratories Ltd.	18.67
75.	Sitagliptin and Metformin Hydrochloride (as extended release) Tablets	**Each film coated bilayered tablet contains:** Sitagliptin Phosphate IP eq. to Sitagliptin 50mg Metformin Hydrochloride IP (As Extended Release form) 1000mg	1 Tablet	M/s Alkem Healthscience (A unit of Alkem Laboratories Ltd.)/ M/s Alkem Laboratories Ltd.	20.06
76.	Medroxyprogesterone Acetate SR Tablets	**Each uncoated sustained release tablet contains:** Medroxyprogesterone Acetate IP 30mg	1 Tablet	M/s Synokem Pharmaceuticals Ltd. / M/s Obsurge Biotech Ltd.	14.04
77.	Cefixime and Potassium Clavulanate Oral Suspension	**Each 5ml of the reconstituted suspension contains:** Cefixime (As Trihydrate) IP eq. to Anhydrous Cefixime 50mg Potassium Clavulanate Diluted IP eq. to Clavulanic Acid 31.25mg	1 ML	M/s Prosperity Drugs Pvt. Ltd. / M/s Intas Pharmaceuticals Ltd.	2.70
78.	Diclofenac, Virgin Linseed Oil, Methyl Salicylate, Menthol & Capsaicin Gel	**Composition**: Diclofenac Diethylamine IP 1.16%w/w (eq. to Diclofenac Sodium 1%w/w), Virgin Linseed Oil BP 3%w/w (Containing Predominantly	1 Gram	M/s Akums Drugs & Pharmaceuticals Ltd. / M/s German Remedies Pharmaceuticals Private Limited	3.12

		Alpha Linolenic Acid), Methyl Salicylate IP 10% w/w Menthol IP 5%w/w Capsaicin USP 0.025% w/w			
79.	Ofloxacin and Metronidazole suspension	**Each 5ml contains:** Ofloxacin IP 50mg Metronidazole Benzoate IP eq. to Metronidazole 100mg	1 ML	M/s Hema Laboratories Pvt. Ltd. / M/s Abbott Healthcare Pvt. Ltd.	0.70
80.	Dapagliflozin and metformin Hydrochloride (IR) Tablets	**Each film coated tablet contains**: Dapagliflozin propanediol monohydrate eq. to Dapagliflozin 5mg Metformin Hydrochloride IP 500mg (as Immediate release form)	1 Tablet	M/s Sun Pharma Laboratories Limited	6.25
81.	Dapagliflozin & Metformin Hydrochloride Extended Release Tablets	**Each film coated tablet contains:** Metformin Hydrochloride…500mg (as extended release form) Dapagliflozin Propanediol Monohydrate eq to Dapagliflozin 5mg	1 Tablet	M/s Exemed Pharmaceuticals / M/s Cipla Ltd.	6.25
82.	Dapagliflozin & Metformin Hydrochloride Extended Release Tablets	**Each film coated tablet contains:** Metformin Hydrochloride…1000mg (as extended release form) Dapagliflozin Propanediol Monohydrate eq to Dapagliflozin 5mg	1 Tablet	M/s Exemed Pharmaceuticals / M/s Cipla Ltd.	7.23
83.	Dapagliflozin & Metformin Hydrochloride Extended Release Tablets	**Each film coated tablet contains:** Metformin Hydrochloride…500mg (as extended release form) Dapagliflozin Propanediol Monohydrate eq to Dapagliflozin 10mg	1 Tablet	M/s Exemed Pharmaceuticals / M/s Cipla Ltd.	9.21
84.	Dapagliflozin & Metformin Hydrochloride Extended Release Tablets	**Each film coated tablet contains:** Metformin Hydrochloride…1000mg (as extended release form) Dapagliflozin Propanediol Monohydrate eq to Dapagliflozin 10mg	1 Tablet	M/s Exemed Pharmaceuticals / M/s Cipla Ltd.	10.69

Note:

(a) The manufacturer of above mentioned formulations i.e. "new drug" under paragraph 2(u) of the DPCO, 2013 shall fix the retail price as specified in column (6) of the table hereinabove.

(b) The manufacturer may add Goods and Services Tax only if they have paid actually or it is payable to the Government on the retail price mentioned in column (6) of the above said table.

(c) The retail price for a pack of the aforesaid formulation shall be arrived at by the concerned manufacturer in accordance with the retail price specified in column (6) of the above table as per provisions contained in paragraph 11 of the DPCO, 2013.

The manufacturer shall issue a price list in Form–V from date of Notification as per paragraph 24 of the DPCO, 2013 to NPPA through IPDMS and submit a copy to State Drug Controller and dealers.

(d) *As per para 24(4) of DPCO 2013, every retailer and dealer shall display price list and the supplementary price list, if any, as furnished by the manufacturer, on a conspicuous part of the premises where he carries on business in a manner so as to be easily accessible to any person wishing to consult the same.*

(e) *The above mentioned retail price is applicable only to the individual manufacturer / marketer as mentioned above i.e. who have applied for the same by submitting Form-I for price fixation / revision as stipulated under DPCO, 2013 and subject to fulfilment of all the applicable statutory requirements as laid down by the Govt. under relevant statutes/ rules, including manufacturing license permission from the Competent Authority i.e. the Central/State Licensing Authority, as may be applicable, by the concerned manufacturer/marketing companies.*

(f) *In case the retail price of any of the aforesaid formulations is not complied with, as per instant price notification and notes specified hereinabove, then the concerned manufacturer/marketing company shall be liable to deposit the overcharged amount along with the interest thereon under the provisions of the DPCO, 2013 read with the Essential Commodities Act, 1955.*

(g) *Consequent to the issue of ceiling price of such formulation as specified in column (2) of the above table in this notification, the price order(s) fixing ceiling or retail price, if any, issued prior to the above said date of notification, stand(s) superseded.*

PN/231/99/2022/F
F. No. 8(99)/2022/D.P./NPPA-Div.-II

Prasenjit Das, Deputy Director, Ministry of Chemicals and Fertilizers, Department of Pharmaceuticals, National Pharmaceutical Pricing Authority, New Delhi.

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NATIONAL NEWS

Why India needs an overarching drug regulator like USFDA

Creation of a single regulator could open the way for growth and innovation in the pharma sector in India

Why India needs an overarching drug regulator like USFDA

The future of the Indian pharma industry lies in moving up the value chain and innovating in complex generics, speciality drugs, new biological entities and new chemical entities and the country needs to build regulatory expertise in these domains. Towards this, the CDSCO can have dedicated and specialised teams to provide in-house regulatory guidance to pharma innovators working on these innovative segments. Of course, creation of USFDA like regulatory body will prove to be a big boost to the Indian pharmaceutical industry.

It is an undisputed fact that over the last more than four decades, the Indian pharmaceutical industry has registered an exponential growth, exporting affordable and quality medicines to more than 200 countries in the world, including the developed countries such as the US and the European nations. From a mere Rs10 crore in 1948 to more than Rs2 lakh crore at present, the Indian pharmaceutical industry has, indeed, come a long way to adorn the epithet of 'the pharmacy of the world'. For a sector which was dominated by the multinational drug companies until the 1970's, it is really a great achievement.

And the growth trajectory of the Indian pharmaceutical industry is still continuing as the Indian pharmaceutical industry is likely to reach $130 billion by 2030, growing at a CAGR of 12.3 per cent from $40.8 billion in 2020. The current market size of the pharmaceutical industry in India is estimated to be valued above $50 billion (2020-21) with a growth rate of 10-12 percent. The impressive growth is despite the Covid-19 pandemic and may be attributed to the industry's strong credentials in formulation development capabilities, trained workforce, and reputation in international markets such as the US and Europe. Surprisingly, the pharmaceutical industry in the country achieved the current global status without having an ideal policy and regulatory environment on account of

the fact that the industry is being controlled by different ministries and agencies. While all the administrative and pricing related policies are regulated by the Ministry of Chemicals and Fertilizers, the issues related to quality of the drugs produced and marketed in the country are regulated by the Union Health Ministry. Policies related to investment and IPR as well as that of exports are regulated by the Ministry of Commerce and Industry. This multiple regulatory mechanism very often poses hurdles to the growth of these sectors to its full potential.

Of course, there is an urgent need to strengthen the regulatory framework in the country. The current Indian regulatory framework is traditionally geared towards safety and efficacy. However, it should also differentiate in favour of innovation. The Drug Controller General of India in the Central Drugs Standard Control Organisation (CDSCO) is the licensing authority, but there are multiple agencies with different mandates and expertise that a pharma innovator must navigate.

Creation of a single overarching regulator like the US Food and Drug Administration (USFDA), the drug regulator having dedicated specialised teams to provide in-house regulatory guidance to pharma innovators and strengthening exchange of regulator best practices with international regulatory bodies could pave way for a conducive regulatory landscape to pave way for growth and innovation in the pharmaceutical sector in the country. At present, the regulatory approvals for innovative pharmaceutical products take about 18-24 months and from an industry viewpoint, the current regulatory structure appears complicated with a web of entities at the central and state levels having the responsibility of monitoring the sector. The Sugam portal, which is currently operational, has certain limitations such as there is no provision of adding multiple files greater than 10 MB and no automated document management workflows.

Under this background, a report released recently by FICCI and KPMG titled 'Impact of the pharma industry on the Indian economy in the post-Covid era', is of great significance. The report suggested that there should be a central overarching regulatory body such as the US FDA. A collaborative approach followed by different regulators will reduce overlaps and establish predictable timelines for requisite approvals. Faster approval and response time (bring down the current time taken for regulatory approvals for innovative products by at least 50 per cent); a single end-to-end digital platform connecting different departments/regulators and offering a single interface between a pharma innovator and regulator ; automated transfer of data across multiple departments and agencies for facilitating clearance by reducing time and efforts; building regulatory expertise in emerging areas such as NCEs, NBEs, biosimilars etc. to build a strong reputation of the quality of Indian products in the international markets; and collaborations with relevant international regulatory agencies to build expertise of Indian regulators on new drug approvals are some of the other suggestions in the report.

The future of the Indian pharma industry lies in moving up the value chain and innovating in complex generics, speciality drugs, new biological entities and new chemical entities and the country needs to build regulatory expertise in these domains. Towards this, the CDSCO can have dedicated and specialised teams to provide in-house regulatory guidance to pharma innovators working on these innovative segments. Of course, creation of US FDA like regulatory body will prove to be a big boost to the Indian pharmaceutical industry. (The author is freelance journalist with varied experience in different fields)

Source: Sreeja Ramesh, Bizz Buzz, 30.06.2022

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Where Quality Meets Humanity

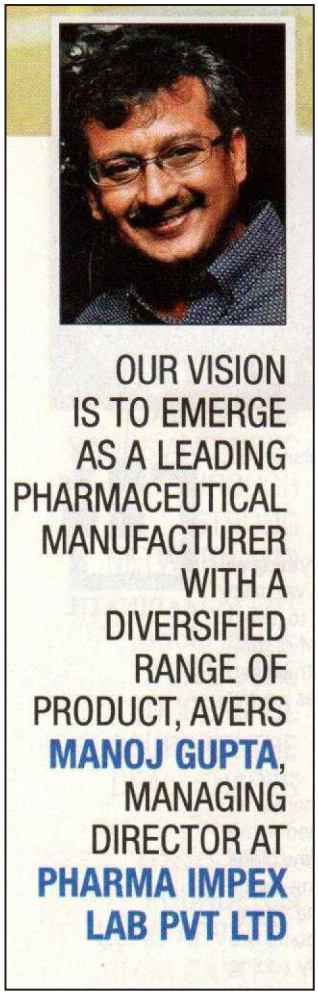
With state-of-the-art manufacturing facilities, Pharma Impex Laboratories Pvt Ltd. is a leading, robust manufacturer and institutional supplier of IV fluids, critical-care products and mostly generics that meet the highest quality standards, yet are cost-effective. "We are serving our country efficiently for the last 45 years and are endeavouring in the export market with our proficiency," shares Manoj Gupta, MD.

- **VENTURING OUT**

Pharma Impex Lab Pvt Ltd was incorporated in 1977 and I am the second generation entrepreneur in our family business of pharmaceuticals. After a short stint as a product manager at a reputed pharma company, I decided to work for our own company and as they say to build a strong foundation, one needs to master the basics. I was initially a junior chemist, got my training on the job and learned a lot about production, sales and distribution channels," he shares.

- **OUTSTANDING ACHIEVEMENTS**

The Pharma industry is growing exponentially. "We are the 3rd highest supplier in volume across the world. Over the years, we have scaled up in terms of our production and serviceability. We are the only company in Eastern India with three WHO-certified manufacturing units in Bengal (Behala, Baruipur and Barakashiara respectively). Our plants are highly automated with sophisticated IV units and injectable units that are EU compliant. We are currently, in the process of being EU GMP certified," states Gupta.



- **CSR ACTIVITIES**

"My wife and I have been actively associated and chaired responsibilities at Round Table India - an organisation aimed at promoting service, fellowship, and goodwill in national and international affairs. We have distributed 500 blankets to the 300workers, labours and their families built a school in Sundarban in association with Round Table India and also organises a health camp. We aim to serve the larger needs of the community and our long-term project is "Freedom Through Education", where we focus on building infrastructure for the education of underprivileged children," he informs.

- **THE USP**

"In addition to our supremely good quality products and their affordability - we take immense pride in delivering the best service, in this healthcare industry," avers Gupta.

- **VISION AND MISSION**

The organisation's mission is to impose self-zero defects in the manufacturing of excellent quality products with strict adherence to the norms and its vision is to emerge as a leading pharmaceutical company with

manufacturing capabilities having a diversified product assortment.

- **ADVANCED TECHNOLOGIES**

Pharma Impex Laboratories Pvt Ltd has the modern age techniques in its all units. "Our products are manufactured in highly sophisticated facilities ensuring the highest level of quality at the people without any compromise. PHARMA IMPEX LABORATORIES PVT. LTD. is equipped with modern, sophisticated and automated FFS Technology," he claims.

- **A FAMILY MAN**

"I believe in prioritising my moments of unwinding after work hours, with my family. Often, work takes precedence over everything else in our lives and this desire to succeed professionally can push us to set aside our own well-being. Creating a harmonious work-life balance is important for our physical, emotional and mental well-being," believes Gupta.

- **INTERNATIONAL PRESENCE**

"Pharma Impex Lab has started the venture in export in ROW, Latam, African, ASEAN regions, Asian, South East Asian and successfully delivered the assignment to Yemen, Uzbekistan, and got PFDA, Phillippines for registration of our products under PICs. Our future prospect is to penetrate the semi-regulated markets, CIS, GCC regions also," he adds.

- **FUTURE AHEAD**

"We have been dedicatedly working on biological products and very soon, we are going to have a set-up of vaccine plant, in eastern India. We also preach and practice- contribution to the society through best-quality products at reasonable prices," claims Gupta.

Source: The Economic Times, Business Beacons, July 2022

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