PRICE
PER COPY
₹25/-

LICENSED TO POST WITHOUT PREPAYMENT
LICENCE NO. MR/TECH/WPP-337/WEST/2021-23
RNI REGN. NO. 18921/1970
REGN NO. MCW/95/2021-23

IDMA BULLETIN

VOL. NO. 53 | ISSUE NO. 40 (PAGES: 20) | 22 TO 30 OCTOBER 2022 | ISSN 0970-6054 | WEEKLY PUBLICATION

INDIAN PHARMA - GLOBAL HEALTH CARE

INDIAN DRUG MANUFACTURERS' ASSOCIATION

HIGHLIGHTS

- ★ **IDMA – GSB jointly with BCIL and SNL, USA Organizing Two day training programme on "Know-Your-Customer (KYC) best practices" for Indian Pharmaceutical industry at Hotel Courtyard by Marriott, Ahmedabad on November 14-15, 2022** *(Page No. 6)*
- ★ **Trade facilitation by DGFT through Video Conference with DGFT RAs on all working days from 10.30 am to 11.30 am (effective from 02.Oct.2022)** *(Page No. 10)*
- ★ **Extension of last date for filing statutory forms prescribed under DPCO, 2013** *(Page No. 11)*

UNWAVERING ATTENTION TO DETAIL. FOR ABSOLUTE **PRECISION.**

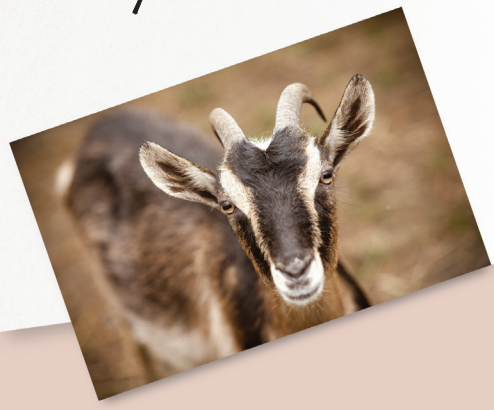
Dear Partner,

We are firm believers in partnering with those who make us stronger and add value to our customers. Partners such as Tereos and Biogrund who allow us to provide for even the most highly technical and specialised needs, with perfect precision.

Tereos is one of the world's leading sucrose producers, with expert products that allow for a wide variety of pharmaceutical applications. Over the last two decades, Biogrund has built itself as the specialists in top-quality solutions for oral dosage forms, such as film coating, tableting and colouration.

Together, we ensure that customers get exactly what they want, when they want it.

Signet-ure *Precision*



Tereos

COMPRESSUC (Directly Compressible Sucrose)
ICING SUGAR (Milled Sucrose)
CASTER SUGAR (Screened Sucrose)
ALVEOSUCRE (Agglomerated Sucrose)

BIOGRUND

AQUAPOLISH (Film Coating Systems)
HME CLEANER PLUS (Cleaning Agent for Hot Melt Extrusion)
BONUWAX (Ready-to-use Waxes)
ISUPOLISH (Sugar & Sugar-free Coating Systems)

Signet

The Complete Excipients Company

IDMA BULLETIN

Vol. No. 53 **Issue No. 40** **22 to 30 October 2022**

IDMA ACTIVITIES:

GOVERNMENT COMMUNICATIONS:

NPPA MATTERS:

NATIONAL NEWS:

INDIAN DRUG MANUFACTURERS' ASSOCIATION (IDMA)

102, Poonam Chambers, A Wing, 1st Floor, Dr. Annie Besant Road, Worli, Mumbai - 400 018. Maharashtra, India. Tel: +91-22-24974308 / 24944624 Email: actadm@idmaindia.com Website: www.idma-assn.org

Postponement of IDMA "Symposium on Nasal and Pulmonary Drug Delivery" till further notice.

Dear Members,

We, IDMA, were extremely keen about this **"Symposium on Nasal and Pulmonary Drug Delivery"** scheduled on Thursday, 10th & Friday, 11th November 2022 at Hotel Sofitel, BKC, Mumbai as many eminent international dignitaries / speakers / sponsors as well as participants who had confirmed their presence for this symposium.

However, due to certain unavoidable circumstances few of our International Dignitaries including our Chief Guest / Keynote Speaker and our Sponsors are unable to attend the event due to personal reasons as well as visa issues, the IDMA Management has decided to postpone the symposium till further notice.

This is an appalling moment for all of us as our International Dignitaries are unable to secure visas to India and hence, our symposium is being postponed.

Please be rest assured that this **Symposium on Nasal and Pulmonary Drug Delivery** would be organized at a later date during 2023. We will ensure that you would receive the information at least 30-45 days prior to the new date.

The inconvenience caused to you is sincerely regretted.

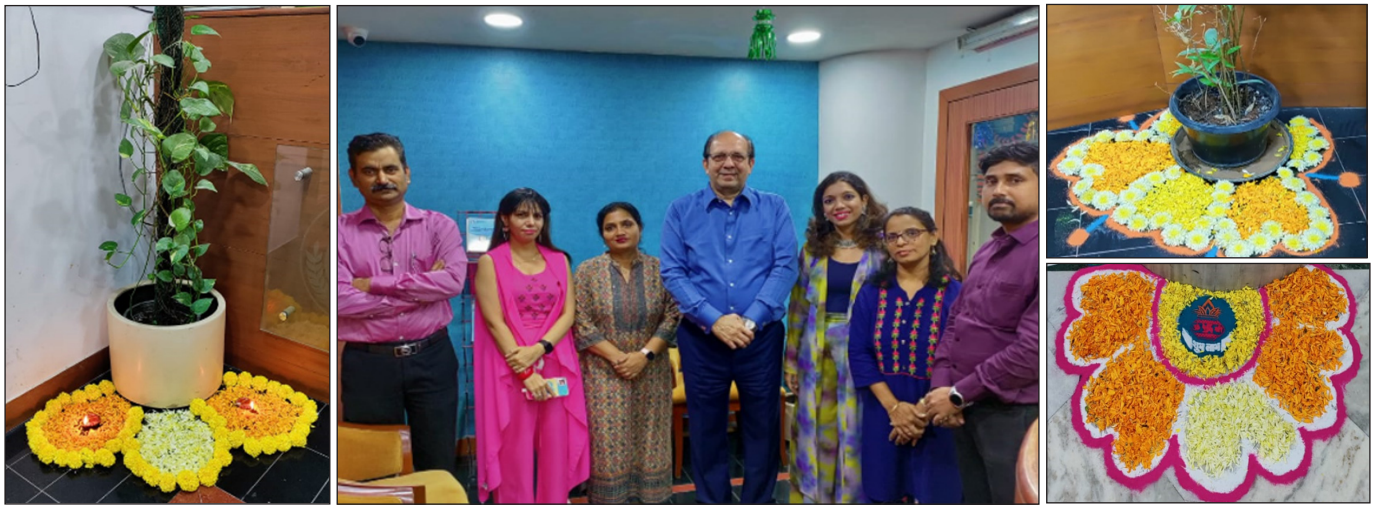
We sincerely thank all our Dignitaries, speakers, invitees and participants for their support, co-operation and understanding during these tough and trying times.

Wishing you, your family and all at your esteemed organization a Happy and Prosperous New Year.

Thanks & regards,

Daara B Patel
Secretary – General

IDMA Secretariat (Mumbai) Celebrates Diwali



IDMA Secretariat Mumbai office celebrate Diwali with lighting of lamps/diyas, rangolis and distribution of sweets on 21st October 2022

● ● ●

NOW AVAILABLE ! IDMA-APA GUIDELINES / TECHNICAL MONOGRAPHS

TECHNICAL MONOGRAPH NO. 1
STABILITY TESTING OF EXISTING DRUGS SUBSTANCES AND PRODUCTS

TECHNICAL MONOGRAPH NO. 2
PRIMARY & SECONDARYCHEMICAL REFERENCE SUBSTANCES

TECHNICAL MONOGRAPH NO. 3
INVESTIGATION OF OUT OF SPECIFICATION (OOS) TEST RESULTS

TECHNICAL MONOGRAPH NO. 4
PHARMACEUTICAL PREFORMULATION ANALYTICAL STUDIES

TECHNICAL MONOGRAPH NO. 5
ENVIRONMENTAL MONITORING IN CLEANROOMS

TECHNICAL MONOGRAPH NO. 6
CORRECTIVE/PREVENTIVE ACTIONS (CAPA) GUIDELINE

TECHNICAL MONOGRAPH NO. 7
DATA INTEGRITY GOVERNANCE

TECHNICAL DOCUMENT NO. 8
QUALITY 4.0 DIGITAL TECHNOLOGY OF THE FUTURE

Copies are available at IDMA Office, Mumbai. We do not mail any publications against VPP payment. All payments to be made in advance as Cheque/DD/RTGS/NEFT in favour of **"INDIAN DRUG MANUFACTURERS' ASSOCIATION"** at Mumbai.

For more details please contact: ***PUBLICATIONS DEPARTMENT*** *Tel.: 022 - 2494 4624 / 2497 4308 Fax: 022 - 2495 0723*
E-mail: **publications@idmaindia.com/actadm@idmaindia.com**,
Website: ***www.idma-assn.org/www.indiandrugsonline.org***

IDMA – GSB jointly with BCIL and SNL, USA Organizing Two day training programme on "Know-Your-Customer (KYC) best practices" for Indian Pharmaceutical industry at Hotel Courtyard by Marriott, Ahmedabad on November 14-15, 2022

Dear Member,

Greetings of the day!!!!!

We are pleased to inform you that Indian Drug Manufacturers' Association – Gujarat State Board (IDMA – GSB), jointly with Biotech Consortium India Limited (BCIL), New Delhi and Sandia National Laboratories (SNL), USA is organizing a 02 -day training programme on "**Know-Your-Customer (KYC) best practices"** for Indian Pharmaceutical industry at **Hotel Courtyard by Marriott, Ramdev Nagar Cross Road, Satellite Road, Ahmedabad on November 14-15, 2022.**

The objective of the training programme is to raise awareness of chemical weapons proliferation potential and to provide Know-your-customer best practices in the pharmaceutical industry. Details are in attached pamphlet. This training is appropriate for all pharmaceutical companies producing and using potentially lethal (e.g., fentanyl) and other incapacitating and/or dissociative agents (e.g., benzodiazepines). It is designed for **pharma industry managers, security officers, regulators, and transportation logistics company managers.** There are a total 20 slots and participants will be selected based on the activities undertaken by their organization in reference to the topic of the programme and the usefulness to the participant's organization thereby achieving the objective of the training.

Kindly note that expenses towards travel by Air (economy) / Train (2nd AC fare) / Taxi and boarding & lodging (accommodation at Hotel Courtyard by Marriott and meals) of participants will be borne by SNL/BCIL. More details and registration link are given in the attached pamphlet.

We request you to nominate concerned officials from your organization for the training programme.

There is No registration fee, however, the REGISTRATION IS MANDATORY for consideration in the training programme.

With kind regards,

Sumit J. Agrawal
Hon. Secretary
IDMA - GSB

Brief about organizing partners:

a) Biotech Consortium India Limited (BCIL), New Delhi

BCIL is a company set up in 1990 as an initiative of the Department of Biotechnology (DBT), Ministry of Science & Technology, Government of India and All India Financial Institutions. As part of our activities, we are engaged in capacity building related to biosafety and chemical security issues. Such activities are undertaken in collaboration with national and international agencies.

b) Sandia National Laboratories (SNL), USA

SNL undertakes capacity building programmes, with support from US Department of State's Chemical Security Program (CSP).

Know-Your-Customer (KYC) Workshop for Indian Pharmaceutical Industry

14-15 November 2022, 09:00-17:00 IST

Announcement: Biotech Consortium India Limited (BCIL), Indian Drug Manufacturers' Association (IDMA) and Sandia National Laboratories (SNL) on behalf of the United States Department of State's Chemical Security Program (CSP) are organizing an in-person workshop to raise awareness of the chemical weapons (CW) proliferation potential of key pharmaceuticals and to provide Know-Your-Customer (KYC) best practices for the Indian Pharmaceutical industry. During this workshop participants will learn how to recognize suspicious purchase requests, develop customer vetting strategies, and understand regulations regarding the sale of 'dual use' chemicals that may be misused as chemical weapons. Additional topics will also include chemical security threats and chemicals of concern. The overarching focus of this event is to develop strategies that deny access to weaponizable pharmaceuticals. This workshop is appropriate for all pharmaceutical companies producing and using potentially lethal (e.g., fentanyl) and other incapacitating and/or dissociative agents (e.g., benzodiazepines).

Audience:

- Up to 20 Indian Pharma industry managers, security officers, regulators, and transportation logistics company managers.

Goal:

- Provide participants with the awareness of the chemical weapons proliferation potential of key pharmaceuticals, an understanding of KYC, and the knowledge and resources to implement KYC best practices and policies at their institutions to ensure their products are not acquired for illicit purposes.

Agenda:

14 November 2022	15 November 2022
• Welcome, Introduction, Goals • Industry Case Study • Chemical Security Threats • Pharmaceuticals of Concern with exercise • Illicit Procurement Tactics with Case Studies	• Overview of KYC Principles and Practices • Interactive Scenario-Based Activities on KYC Indicators • KYC Implementation • Next Steps • Valedictory

Registration Site:
https://gcbs-events.sandia.gov/chemical-security-program/remote-know-your-customer-kyc-training-for-indian-pharmaceutical-industry

Points of Contact:

Dr. Cecelia Williams, Ph.D.
Sandia National Laboratories
cvwilli@sandia.gov

Dr. Andrew W. Nelson
Sandia National Laboratories
awnelso@sandia.gov

Dr. Vibha Ahuja, Ph.D.
Biotech Consortium India Limited
vibhaahuja@biotech.co.in
Phone no. 98912 44434

Registrations open for ET MSME Awards 2022. Apply Now!

Dear Member,

Greetings from The Economic Times Digital and IDMA.

IDMA is pleased to inform its members that IDMA is the Associate Partner for the ET MSME AWARDS 2022 and is herewith sharing The Economic Times Digital launch of the third edition of ET MSMEs Awards.

Over the years, organizations like: IMC Chamber of Commerce, Indian Textile Accessories & Machinery Manufacturers Association, Plastics export promotion council, Association of Diagnostic Manufactures of India, Sports Goods Foundation of India, Synthetic and Rayon textiles export promotion council and many others have associated with The Economic Times Digital.

For your reference please find the attached MSME Awards mailer.

About the programme:

ET MSMEs Awards was introduced to identify the top MSMEs in the country and highlight the good work the sector is doing. The first and second editions of ET Rise MSMEs Ranking saw a participation of over **8,000 and 10,000 businesses respectively,** out of which the top-ranked MSMEs were identified through a rigorous evaluation process. In both the previous editions the top-ranked businesses were felicitated in a digital event that witnessed the leading voices of the MSME ecosystem.

This year the **Final Felicitation Day** will be an on-ground event which will serve as an agenda-setting forum for industry leaders, policymakers, and the entrepreneurial ecosystem to define actionable strategies and solutions to boost the global competitiveness of MSMEs and strengthen the industry, shaping the new India growth story.

This year Economic Times Digital will award and recognize MSMEs in **26 different categories**.

1. **Overall industry awards (6 Awards)**
   a. Indian MSME of the Year Award **(1 for services; 1 for manufacturing)**
   b. Global Indian MSME of the Year Award **(1 for services; 1 for manufacturing)**
   c. India's Top Exporter of the Year Award **(1 for services; 1 for manufacturing)**
2. **Awards by each MSME category (9 awards)**
   a. India's Top-Performing MSME of the Year Award (1 for Micro, 1 for Small, 1 for Medium)
   b. India's Fastest-growing MSME Award (1 for Micro, 1 for Small, 1 for Medium)
   c. India's Top Innovative MSME of the Year Award (1 for Micro, 1 for Small, 1 for Medium)
3. **MSME Enabler Awards (2 Awards)**
   a. Indian MSME Enabler Award for Tech & Innovation
   b. Indian MSME Enabler Award for Banking & Financing
4. **Special Award Categories (5 awards)**
   a. Top-performing Listed SME (1 for Listed SMEs)
   b. Indian MSME Women Entrepreneur of the Year Award (1 for Micro; 1 for Small; 1 for Medium)
   c. Best CSR Initiative by an SME (1 for Medium)

5. Industry Focussed Award Categories (4 awards) - These are all manufacturing sector focused

a. Automobile & OEM MSME of the Year

b. Pharmaceutical & Healthcare MSME of the Year

c. Electrical & Electronics MSME of the Year

d. Clothing & Apparel MSME of the Year

Key KPI of the Event:

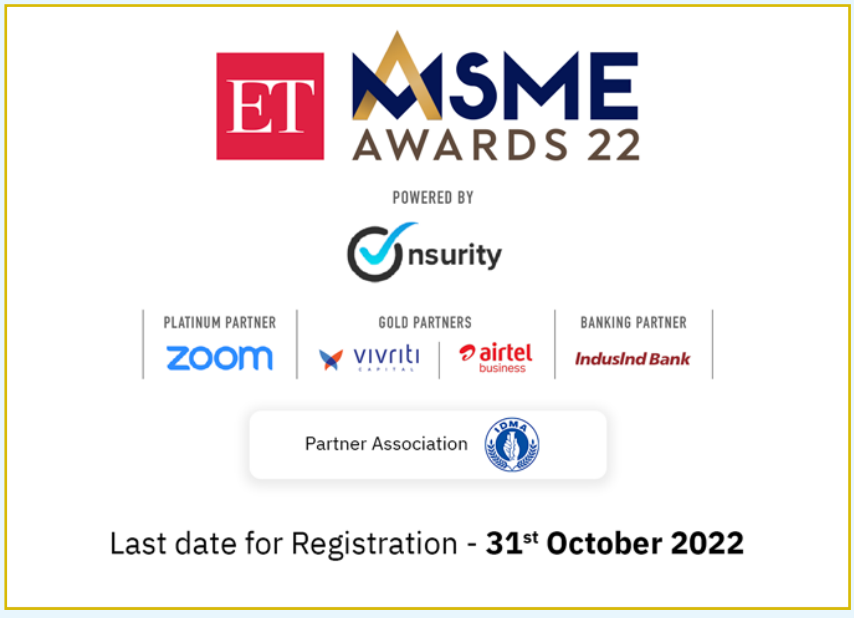
- 10000+ Registrations
- 15Mn+ Reach
- 10Mn+ Impressions
- 1Mn+ Video Views
- 300+ Minutes of content
- 30+ speakers
- 10+ sessions

Kindly, use the UTM tracker embedded URL for the registration purpose.
https://economictimes.indiatimes.com/engage/et_msmeawards2022.cms?utm_source=Ext7&utm_medium=PromoMailer1&utm_campaign=ETMSMEAwards

We sincerely request our MSMEs members to actively support and participate in this **Economic Times MSME Awards 2022.**

Thanks & regards,

Daara B Patel
Secretary – General



Trade facilitation by DGFT through Video Conference with DGFT RAs on all working days from 10.30 am to 11.30 am (effective from 02.Oct.2022) – reg.

PXL/HO/Cir-054/2022-23, 22nd October, 2022

IDMA have received communication from Mr Uday Bhaskar, Director General, Pharmexcil, Hyderabad (Set Up by Ministry of Commerce & Industry, Government of India) dated 22nd October 2022 as reproduced below on the above subject.

We would like to inform member companies that the Office of DGFT has created an online platform to encourage faceless, effective facilitation of trade & industry and to minimise person-to-person interactions, a Video Conference facility has been set up by DGFT Regional Authorities.

The Video Conferencing facility is available from 10.30 am to 11.30 am on all the working days. Click here to connect and interact with your DGFT RA:

https://www.dgft.gov.in/CP/?opt=ra-vclinks. Link will be operational between 10:30 AM to 11:30 AM.

The objective is to facilitate the exporters' interaction with their DGFT Regional Authority officials on various trade issues and to address the grievances and member companies are therefore requested to take advantage of this opportunity.

● ● ●

Constitution of a Committee for preparation of "National Drugs Database" - reg.

File No. ED/Misc.-365/2022, dated 27th October, 2022

A comprehensive database of drug formulations manufactured/marketed in the country providing detailed information on the drug, its dosage form, strength. details of manufacturer/marketer/importer etc. is crucial, for not only empowering consumers but also for improving the monitoring mechanism for quality of drugs in circulation, across the country and uniform administration of regulatory system. etc.

In order to have such a comprehensive 'National Drugs Database", it has been decided to constitute a Committee, comprising following members:

i. Dr. H.G. Koshia. Commissioner, FDCA Gujarat

ii. Sh. A. K. Pradhan, Joint Drugs Controller (India). CDSCO (Convener) (email: akp 1964)@ rediffmail.com, akpradhan@cdsco.nic.in

iii. Dr. Pooja Gupta, Addl. Professor, AIIMS, New Delhi

iv. Dr Jerian Jose, Scientist D, ICMR, New Delhi

v. Shri D.R. Gahane, Joint Commissioner, FDA, Maharashtra

vi. Sh. B.T. Khanapure, State Drugs Controller, Karnataka

vii. Sh. Navneet Marwaha, State Drugs Controller, Himachal Pradesh

The Committee will examine the existing database available with various Authorities like States/U.T.Drug Control Departments, CDSCO, various manufacturers/ marketers/importers. Further, the Committee will give recommendation & prepare a comprehensive **"National Drugs Database"** of drug formulations manufactured/ marketed in the country providing detailed information on the drug, its dosage form, strength, details of manufacturer/ marketer/importer etc. The Committee may co-opt any other expert, as deemed necessary.

The committee shall submit its recommendation including the **"National Drugs Database"** of the drug formulations in three months.

Dr V G Somani, Drugs Controller General (India), Central Drugs Standard Control Organization, Directorate General of Health Services, Ministry of Health & Family Welfare, New Delhi.

● ● ●

NPPA MATTERS

Extension of last date for filing statutory forms prescribed under DPCO, 2013 - reg.

OFFICE MEMORANDUM F. No. 15(109)/2022/Div.III/NPPA, dated 21st October 2022

To
All Manufacturers,
All Industry Associations,
All State Drug Controllers.

1. Several representations requesting for extension of last date for filing statutory Forms- III, V and VI as prescribed under DPCO, 2013 in Integrated Pharmaceutical Database Management System (IPDMS) 2.0 have been received from industry associations/ companies.

2. The matter has been examined and the time limit for filing of Forms- III, V and VI is hereby extended as follows:

Forms	Purpose	Prescribed under	Time limit for filing	Extension in time limit
III	Quarterly production/ sales data for scheduled drugs	Para 21(1)	Within fifteen days from the end of quarter	For the quarter ending Sept.'2022, Form III can be filed up to 31.12.2022
V	Intimation about MRP change of scheduled and non-scheduled drugs	Para 24, 25	Within a period of fifteen days of price revision	For any MRP revision done between 1.08.2022 and 15.12.2022, Form V can be filed up to 31.12.2022.
VI	Intimation about MRP change of medical devices	Para 24, 25	Within a period of fifteen days of price revision	For any MRP revision done between 1.08.2022 and 15.12.2022, Form VI can be filed up to 31.12.2022.

3. This issues with the approval of the Competent Authority.

Saurabh Bansal,
Deputy Director,
Ministry of Chemicals & Fertilizers,
Department of Pharmaceuticals,
National Pharmaceutical Pricing Authority
New Delhi.

● ● ●

Industry urges govt to share IPRS & impurity standards free of cost to MSMEs

Even as the drug regulator of the country has called for the State drug regulators to ensure use of Indian Pharmacopoeia Reference Standards (IPRS) and impurity standards by the pharmaceutical manufacturers and testing laboratories, the industry demanded that the government should share the reference standards free of cost to the micro, small and medium enterprises (MSMEs) as the current prices are not affordable to the units.

The Central Drugs Standard Control Organisation (CDSCO) has issued a letter to all State and Union Territory Drugs Controllers on October 10, to ensure use of IPRS and Impurity Standards by the pharma manufacturers and testing laboratories for quality testing of drugs, as per the Drugs and Cosmetics Act, 1940 and Rules thereunder.

The directive followed an Indian Pharmacopoeia Commission's (IPC) letter seeking the Drugs Controller General (India) to write to the state regulators to support promotion of IPRS and Impurity Standards and update the status of action in the 22nd meeting of the Government Body of IPC scheduled for October 14, 2022.

The Government Body, in its 21st meeting on April 26, 2022, advised the DCGI to communicate to the State regulators regarding the use of the standards and the DCGI in March, requested the same to the State drug regulators.

"For a normal unit to buy reference standards, it would cost a minimum of Rs 10 lakh. It could be more also since many units manufacture 100-200 products or more," said Jagdeep Singh, Secretary General, SME Pharma Industries Confederation (SPIC). "The prices are prohibitive," he added.

Such a burden cannot be borne because there is too much competition. Proliferation of the pharma industry from 2005 to 2010 in Tax Holiday states ushered this cut throat competition between pharma units which is the cause of the malaise. Tax Holiday was given by NDA in 2003 but MRP Excise was levied by the then Finance Minister P Chidambaram in 2005 without consulting the concerned Ministries.

High excise burden caused by anomalies in MRP excise was the reason why industry proliferated in Tax Holiday States which made pharma industry unviable. Cut throat competition is responsible for the ills today.

"There is not a single unit which can afford to keep up with the directives unless the market is cleansed of low priced drugs by the drug department which is not easy because of corruption and extortion prevailing all over the country," he averred.

"The government can supply these standards free of cost or at nominal cost, to ensure quality standards. There is no justification for such exorbitant prices for reference standards. Why should IP cost Rs. 60,000 and one impurity standard cost Rs. 20,000?," asked Singh.

In order to ensure quality, the government should intensely regulate bulk drugs and other raw materials. While there have been regulations and amendments to regulate the formulations industry, there is no control over the quality of bulk drugs.

Another solution is that the lowest priced drugs in the market should be sampled, since they are the ones which are cutting corners on quality, he added.

IPC has recently announced that it has achieved the milestone of developing a total of 1000 IPRs and Impurity Standards, with around 660 IPRS and 345 Impurity Standards listed in the IPC catalogue. It has also come out with the publication of the ninth edition of IP 2022 which will be effective from December 1, 2022.

IPC, in its letter to the DCGI, said that it is also making efforts to promote the use of authentic copies of IP 2022 along with IPRS and Impurity Standards by the Pharmaceutical Manufacturers and Drug Testing Laboratories for which awareness programmes for stakeholders are being organised across the country. It added that IPC is the only supplier of IPRS and Impurity Standards and it has not authorised any other party for their distribution.

"Using unauthorised reference standards is a violation of provisions of the Drugs and Cosmetics Act, 1940," added the IPC.

Source: Pharmabiz, Gireesh Babu, 13.10.2022

● ● ●

Indian pharma sees US FDA competitive generic therapies guidance to expedite development & review of ANDAs

Indian pharma sees the US FDA competitive generic therapies guidance to expedite development and review of ANDAs (Abbreviated New Drug Applications). This would in turn facilitate faster approval processes. It was the FDA Reauthorization Act of 2017 which created a pathway by which it could, at the request of the applicant, designate a drug with 'inadequate generic competition' as a competitive generic therapy (CGT).

The guidance provides information on the actions FDA may take to expedite the development and review of ANDAs for drugs designated as CGTs. It provides information on how the regulatory authority implements the statutory provision for a 180-day exclusivity period for certain first approved applicants that submit ANDAs for CGTs. In fact, it revises the guidance of the same title issued in March 2020. This revision is being issued to incorporate information on the meeting types and performance goals included in the Generic Drug User Fee Amendments (GDUFA), said the regulatory authority.

According to Prema Desai, pharma consultant, the guidance provides information on conducting different types of meetings that cover product development meetings, pre-submission meetings, mid-cycle review meetings (MCRMs), enhanced mid-cycle review meetings (EMCRMs), and post-complete response letter (CRL) scientific meetings) with FDA.

It also helps applicants in generating a meeting request, the associated meeting package for complex products and also to support submission of a high-quality, approvable ANDA, as well as to provide or continue to provide targeted, robust advice as applicants work to meet the standards for ANDA approval, she added.

To facilitate expedited development queries related to an ongoing development program, or to discuss the content and format of an ANDA submission, for a drug designated as a CGT. In determining whether to grant certain requests to facilitate the development of a drug designated as a CGT, FDA will consider, among other factors. These include the complexity of developing an application for the specific drug subject to the request. It also covers the potential public health impact of the product, including the severity of the condition treated and the size of the impacted patient population, as well as the availability of therapeutic alternatives. It also focuses on the impact of FDA resources and other existing workload commitments.

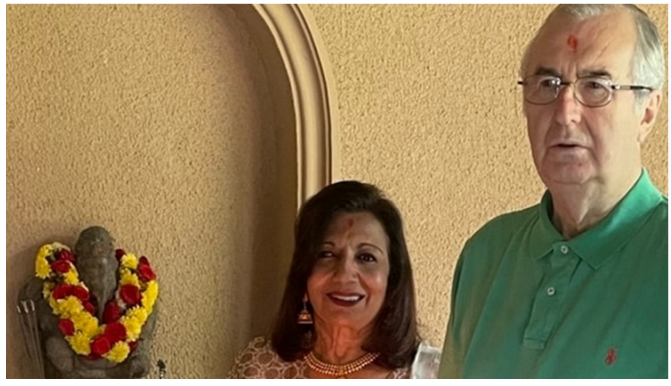
The applicants can request a pre-ANDA meeting. It could be either a product development meeting or a pre-submission meeting) for a CGT using the CDER Direct NextGen Collaboration Portal. The regulatory authority will consider requests for meetings that may expedite the development of a drug designated as a CGT on a case-by-case basis. Such meetings may be granted for both complex and non-complex products, provided a meeting is determined to be appropriate considering factors.

Source: Pharmabiz, Nandita Vijay, 13.10.2022

● ● ●

Biocon founder Kiran Mazumdar Shaw's husband, John Shaw, passes away

Shaw, former vice chairman of Biocon, was being treated in a Bengaluru private hospital, where he passed away on Monday, company officials said.



He was under treatment for cancer for some time(@kiranshaw-Twitter)

John Shaw, the husband of Biocon executive chairperson Kiran Mazumdar Shaw, passed away on Monday at the age of 73.

Shaw, former vice chairman of Biocon, was being treated in a Bengaluru private hospital, where he passed away on Monday, company officials said.

He was under treatment for cancer for some time.

"With profound grief we inform you of the passing away of John Shaw, husband of Kiran Shaw and former vice chairman of Biocon today morning," an official said.

Kiran Shaw lost her mother Yamini Mazumdar, also an entrepreneur, to cancer in June this year.

A Scotsman and Indophile, John Shaw headed textile manufacturer Madhura Coats before joining Biocon in 1999 where he served as the vice chairman and non-executive director for over 22 years, before retiring in July 2021.

It was in 1998 that Kiran Mazumdar married the 1949-born John Shaw.

He also served as foreign promoter and member of the advisory board of various Biocon Group companies. He was also former managing director of Viyella Group.

Shaw had an honorary doctorate from the University of Glasgow, the same institution from where he pursued his masters of arts (MA) in history and political economy.

He contributed majorly to the transformation of Biocon from a small enzymes company to a globally recognised biopharmaceutical firm and played an important role in ensuring the highest levels of corporate governance in the company, as well as, in the financial and strategic development of the group.

Mourning his death, former Infosys director T V Mohandas Pai tweeted, "John Shaw, husband of Kiran Mazumdar-Shaw, passes away. An extraordinary person, a thorough gentleman, warm, compassionate, always positive, always helpful, loved India, helped build India! We will miss you, John! Om Shanthi."

Source: Hindustan Times, 25.10.2022

● ● ●

NPPA extends time limit for submission of production, price data in IPDMS 2.0

The National Pharmaceutical Pricing Authority (NPPA) has extended the last date of filing statutory forms related to details of price list and quarterly returns prescribed under the Drugs (Prices Control) Order, 2013 for drugs and medical devices.

The move comes after the Authority received several representations from the industry requesting for extension of last date for filing the statutory Form III (for submission of quarterly return in respect of production/import and sale data for drugs under the National List of Essential Medicines), Form V (which is an intimation about the Maximum Retail Price change of scheduled and non-scheduled drugs), and Form VI (which is to intimate the Authority regarding the MRP change of medical devices).

"Several representations requesting for extension of last date for filing statutory Forms - III, V and VI as prescribed under DPCO, 2013 in integrated Pharmaceutical Database Management System (IPDMS) 2.0 have been received from industry associations/companies," said the Authority in an Office Memorandum. The authority has examined the matter and the time limit has been extended, said the OM with further details.

While the data under Form III has to be submitted within fifteen days from the end of the quarter, as per the rules, for the quarter ending September, 2022, it can be filed up to December 31, 2022.

Similarly, for any MRP revision done between August 1 to December 15, 2022, the Form V can be filed up to December 31, 2022, as against the previous time limit of fifteen days from the date of price revision.

Under the Form VI, which was inserted by the Department of Pharmaceutical through an order on July 20, 2021, for the intimation about MRP change of medical devices, has to be filed within a period of fifteen days of price revision, according to the price regulation. The NPPA, through the office memorandum, stated that for any MRP revision done between August 1 and December 15, 2022, the Form VI can be filed up to December 31, 2022.

According to reports, the NPPA has in the past also issued orders extending the time limit for submission of the Forms related to the production and sales and price data for drugs and medical devices in response to the requests from the industry.

The IPDMS 2.0 is implemented by the NPPA for online information collection from pharmaceutical manufacturers to monitor and regulate the pharma and medical devices prices, to ensure availability and affordability of drugs and medical devices in the country.

Source: Pharmabiz, 28.10.2022

● ● ●

INDIAN DRUGS ONLINE

PUBLISHED ON 28th OF EVERY MONTH

ADVERTISEMENT BANNER RATES FOR INDIAN DRUGS WEBSITE

(Rates in Rupees per insertion)

Position	Size	RATE	VALIDITY
Right Side Banner	180 X 150 Pixel	25,000	3 MONTHS
Left Side Banner	180 X 150 Pixel	25,000	3 MONTHS

Terms and Conditions

- All payments by DD in advance only to be made in favour of **Indian Drug Manufacturers' Association**, payable at Mumbai
- 25% discount applicable only for IDMA members
- 15% discount is applicable on Annual Contract for Non IDMA Members
- Please provide Banner Artwork as per the size for advertisements before the deadline
- **Advertisement material must reach us 10 days before the date of release**

For more details please contact: **Publications Department**

Indian Drug Manufacturers' Association

102-B, Poonam Chambers, Dr A B Road Worli, Mumbai 400 018. Tel: 24944624/24974308 Fax: 24950723
Email: **publications@idmaindia.com / actadm@idmaindia.com**
Website: **www.idma-assn.org / www.indiandrugsonline.org**

● ● ●

For Advertising in the Classified Columns and also for series advertisements please contact: Geeta Suvarna (+9820161419) Publications Department

IDMA BULLETIN

Tel.: 022 - 2494 4624 / 2497 4308 /
Fax: 022 - 2495 0723/
E-mail: publications@idmaindia.com,
Website: www.idma-assn.org,
www.indiandrugsonline.org
Tel.: 022 - 2494 4624 / 2497 4308 /
Fax: 022 - 2495 0723

Have you renewed your
Membership for the years

2021-2022 & 2022-2023

If not, please do so;
kindly contact IDMA Secretariat at:

Email: actadm@idmaindia.com /
accounts@idmaindia.com

Tel.: 022 - 2494 4624 / 2497 4308 /
Fax: 022 - 2495 0723

₹ 1500/-* only (₹200/- extra towards Courier Charges)

60TH IDMA ANNUAL PUBLICATION 2022

IN THIS ISSUE

- **Success Stories**
- **Export of Bulk Drugs and Intermediates (All Countries) during the year 2020-21 and from April 2021 to December 2021.**
- **Import of Bulk Drugs and Intermediates (All Countries) during the year 2020-21 and from April 2021 to December 2021**
- **Export of Drug Formulations and Biologicals (All Countries) during the year 2020-21 and from April 2021 to December 2021**
- **Import of Drug Formulations and Biologicals (All Countries) during the year 2020-21 and from April 2021 to December 2021**
- **New Drugs Approved for Marketing by Drugs Controller General (I) during the Period January 1961 to 31st December 2021**
- **Approved BA/BE Centres In India**
- **Health Statistics of India**

*SPECIAL RATE FOR IDMA MEMBERS ONLY ₹ 1000/- (₹200/- extra towards Courier Charges)

Payment can be made either by Cheque/Demand Draft in favour of **Indian Drug Manufacturers' Association**, payable at Mumbai OR through NEFT/RTGS to the following Account: Account Name : **Indian Drug Manufacturers' Association**, Bank A/c No.: Current A/c **76080200000242**
Bank : **BANK OF BARODA**, Branch Address : Worli Branch, Mumbai-18,
IFSC Code: **BARB0DBWORL** MICR CODE **: 400012232**

Note: *GST will be charged extra, if applicable

Contact: **Publications Department**

INDIAN DRUG MANUFACTURERS' ASSOCIATION

102, A Wing, Poonam Chambers, Dr. A. B. Road, Worli, Mumbai - 400018, Maharashtra, India.
Tel No. 022 24974308 / 24944624 Fax No. 022 24950723
Email: admin@idmaindia.com/actadm@idmaindia.com
Web: www.idma-ass.org / www.indiandrugsonline.org

IDMA PUBLICATIONS RATE CARD

Sr. No.	Name of Publications	Cost in ₹
1.	**IDMA BULLETIN (Annual Subscription – 48 Issues)** *(Published on 7th, 14th, 21st and 30th of every month)*	
	• Members	1000/- p.a.
	• Government Research / Educational Institutions	2000/- p.a.
	• Non-Members	4000/- p.a.
2.	**INDIAN DRUGS (Annual Subscription – 12 Issues)** *(Published on 28th of every month)*	
	• Members	1000/- p.a
	• Students	1000/- p.a.
	• Government Research / Educational Institutions	2000/- p.a.
	• Non-Members	4000/- p.a.
3.	**IDMA APA Forum**	
	• Annual Membership	500/-
	• Life Membership	5000/-
4.	**TECHNICAL MONOGRAPHS**	
	NO. 1: STABILITY TESTING OF EXISTING DRUG SUBSTANCES AND PRODUCTS	400/-
	NO. 2: PRIMARY & SECONDARY CHEMICAL REFERENCE SUBSTANCES	400/-
	NO. 3: INVESTIGATION OF OUT OF SPECIFICATION (OOS) TEST RESULTS	400/-
	NO. 4: PHARMACEUTICAL PREFORMULATION ANALYTICAL STUDIES	400/-
	NO. 5: ENVIRONMENTAL MONITORING IN CLEANROOMS	400/-
	NO. 6: CORRECTIVE/PREVENTIVE ACTIONS (CAPA) GUIDELINE	400/-
	NO. 7: DATA INTEGRITY GOVERNANCE	400/-
5.	**TECHNICAL DOCUMENT** QUALITY 4.0 DIGITAL TECHNOLOGY OF THE FUTURE	500/-
6.	**IDMA MEMBERSHIP DIRECTORY**	1,500/-
7.	**IDMA ANNUAL PUBLICATION**	1,500/-

KINDLY NOTE:

- *Mailing of IDMA Bulletin and Indian Drugs by Post will commence prospectively only after receipt of payment.*
- *All payments may be made in advance by Cheque / DD / RTGS / NEFT only in favour of:* ***"Indian Drug Manufacturers' Association".***

  For RTGS/NEFT: Name: BANK OF BARODA, **Branch:** Worli, **Name of Account Holder:** INDIAN DRUG MANUFACTURERS' ASSOCIATION, **Account No.** Current A/c 76080200000242, **IFSC :** BARB0DBWORL, **MICR CODE :** 400012232
- Courier charges for Publications under Serial Nos. 4 to 7 will be extra as applicable.
- Please intimate us details through email immediately after making the remittance through RTGS/NEFT, so as to enable us to do the needful promptly.
- GST will be charged extra, as applicable.

INDIAN DRUG MANUFACTURERS' ASSOCIATION

102-B, "A"-Wing, Poonam Chambers, Dr A B Road, Worli, Mumbai 400 018.Tel: 2494 4624 / 2497 4308 Fax: 022- 2495 0723
Email: admin@idmaindia.com/publications@idmaindia.com, Website: www.idma-assn.org / www.indiandrugsonline.org

IDMA BULLETIN

PUBLISHED ON 7th, 14th, 21st and 30th of Every Month

ADVERTISEMENT TARIFF

(Effective from 01.11.2017)

Magazine Size: 21.5 cm x 27.5 cm / Print Area: 18.5 cm x 23.5 cm

Position		Rate per Insertion ₹	
		B/W	Colour
Full Page (18 cm wd x 23.5 cm ht)	:	9,000	12,500
Half Page (18 cm wd x 11.5 cm ht) (Horizontal)		5,000	8,500
Half Page (8.5 cm x 23.5 cm) (Vertical)	:	5,000	8,500
Quarter Page (8.5 cm wd x 11.5 cm ht)	:	2,500	6,000
Strips Advts (4 cm ht x 18 cm wd)	:	2,500	-
Inside Cover Pages	:	-	18,000
Back Cover	:		25,000
Centre Spread (double spread) Print area (40cm wd x 27cm ht)	:	25,000	30,000

Terms and Conditions:

- All payments by **Cheque/ Demand Draft/RTGS** in advance only to be made in favour of **"Indian Drug Manufacturers' Association", Payable at Mumbai**

  The RTGS details are as follows:- BANK: BANK OF BARODA
  Account Name : ***Indian Drug Manufacturers' Association,*** *Bank A/c No. : Current A/c* ***76080200000242***
  Bank : ***BANK OF BARODA,*** *Branch Address : Worli Branch, Mumbai-18,* ***IFSC : BARB0DBWORL***
  MICR CODE : 400012232
- GST will be charged extra, as applicable. *(Current Rate is @5%)*
- SPECIAL DISCOUNTS for Series Advertisements
- For colour advertisements, positives to be supplied otherwise processing charges to be paid.
- **Advertisement material must reach us 7 days before the date of publication.**
- Positioning of the Advt other than Cover Positions will be at our discretion.
- Only Colour Advts will be entertained on Cover Positions.

Classified Advertisements

- Upto 80 words — ₹2,000/-
- 50% extra for Advt Box Number
- 50% extra for indent/layout spacing, bold captions, etc.
- ₹50/- extra for voucher copy
- Series discount not applicable for classifieds

For further details such as series discounts etc, please contact:
Melvin Rodrigues — Cell: +9821868758 (Email: actadm@idmaindia.com)/
Geeta Suvarna — — Cell: +9820161419 (Email: publications@idmaindia.com)

PUBLICATIONS DIVISION

INDIAN DRUG MANUFACTURERS' ASSOCIATION

102-B, Poonam Chambers, Dr. A. B. Road, Worli, Mumbai 400 018. Tel: 022-2494 4624/2497 4308 Fax: 022-2495 0723
Website: **www.idma-assn.org/www.indiandrugsonline.org**

LICENSED TO POST WITHOUT PREPAYMENT
LICENCE NO. MR/Tech/WPP-337/West/2021-23
RNI REGN. NO. 18921/1970, REGN.NO.MCW/95/2021-23
Published and Posted on 7th, 14th, 21st and 30th of every month
This issue posted at Mumbai Patrika Channel Sorting Office on 30.10.2022

Edited, Printed and Published by **Dr.Gopakumar G. Nair** on behalf of **Indian Drug Manufacturers' Association**, Printed at **Ebenezer Printing House**, Unit No. 5 & 11, 2nd Floor, Hind Services Industries, Veer Savarkar Marg, Dadar (West), Mumbai 400 028 and Published from 102-B, Poonam Chambers, "A" Wing, 1st Floor, Dr. A. B. Road, Worli, Mumbai 400 018. Editor: **Dr.Gopakumar G. Nair.**