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IDMA BULLETIN

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INDIAN PHARMA - GLOBAL HEALTH CARE

INDIAN DRUG MANUFACTURERS' ASSOCIATION

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22nd IDMA-APA PHARMACEUTICAL ANALYSTS CONVENTION (PAC) 2023

With EDQM, IPC, USP & US FDA on Friday, 24th February and Saturday, 25th February 2023 at Hotel Four Seasons, Worli, Mumbai

THEME: "Towards Creative Global Compliance"

(Details on Pages 12 - 16)

HIGHLIGHTS

A Publication of
Indian Drug Manufacturers' Association
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IDMA BULLETIN

Vol. No. 54 Issue No. 01 01 to 07 January 2023

IDMA ACTIVITIES:

PRESENTATION:

PARLIAMENT NEWS:

MoEFCC MATTERS:

NATIONAL NEWS:

IDMA BULLETIN

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Geeta Suvarna — — Cell: +9820161419 (Email: publications@idmaindia.com)

PUBLICATIONS DIVISION

INDIAN DRUG MANUFACTURERS' ASSOCIATION

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Website: **www.idma-assn.org/www.indiandrugsonline.org**

IDMA's National President Dr Viranchi Shah along with other Senior Members of IDMA seek the blessings of Lord Ganesha at Siddhivinayak Temple, Mumbai on 16th December 2022

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Glimpses of Inauguration of renovated IDMA J B Mody Conference Room and 12th IDMA National Executive Committee Meeting (Hybrid) on 16th December 2022 at IDMA Mumbai office

Inauguration of Renovated IDMA J B Mody Conference Room

IDMA Executive Committee Members

Executive Committee meeting (hybrid) in progress

Release of IDMA Members Directory 2023

Christmas Celebration

● ● ●

IDMA - An organisation in pursuit of QUALITY Commitment

Dr Viranchi Shah, National President, IDMA

IDMA has always been in the forefront in promoting Excellence in Quality in the pharma industry by organizing various technical seminars and workshops and the Pharmaceutical Analysts Convention in its 22nd Year and APPQM Series in its 3rd Year will surely be considered as IDMA's major Quality Initiatives.

IDMA has conducted various seminars and workshops in collaboration with Department of Pharmaceuticals such as the successfully organized series of Workshops titled 'GMP Workshop for SMEs – Schedule M and Beyond' for upgradation of GMP standards and Seminar series on 'Meeting Quality Challenges and Achieving Global Compliance' all over India. Just before the pandemic, as requested by many Drug Controllers General of India, IDMA had organized a 'Workshop on E-Governance Initiatives of CDSCO' at Mumbai jointly with CDSCO and CDAC.

IDMA has envisaged great plans through its series "Vriddhi" to support its MSME Members in their pharmaceutical success journey & bring them on the rapid growth path by knowledge sharing and hand holding. IDMA is earnest in its endeavours to work with Global Quality, Regulatory and Technology Leaders to educate, train and develop change agents for quality excellence.

The International MBA Styled Executive Program in Pharmaceutical Quality Management - "Advanced Program in Pharmaceutical Quality Management" (APPQM) in collaboration with NSF Health Sciences, UK. The third series would be commencing April 2023 onwards.

The APPQM program covers diverse aspects such as

- Pharmaceutical Quality Management Systems
- Best Industry Practices, Management of Change
- Human Factors- How to get people to follow the rules
- Data Analysis for Business Improvement
- Quality by Design, Process Validation and Technology Transfer
- Digitalization

Many Drugs controllers have addressed the Pharmaceutical industry through IDMA Platform on changes to the Drug rules Schedule M, New Drugs Policy Schedule. IDMA has worked together with stalwarts like Shri RS Iyer, Shri J L Sipahimalani, Dr. Vinay Nayak & Mr. Raghunandan to contribute in the Monographs & General chapters of Indian Pharmacopoeia for 20 long years. IDMA has been auditing member companies and selecting the best in class with awards for GMP for 30 years.

IDMA has awarded eminent scientists & industry experts for almost 40 years. IDMA expert groups have regularly hosted good seminars with USFDA, USP & IPA to promote new knowledge & practices. IDMA has also brought out various technical monographs on below subjects :

- Stability Testing of Existing Drug substances & Products
- Primary & Secondary Chemical Reference Substances
- Investigation of OOS Test Results
- Pharmaceutical Performulation Analytical Studies
- Environmental Monitoring in cleanrooms
- Corrective/Preventive Actions (CAPA) guidelines
- Data Integrity Governance

Our publication department has a Lion's share in publishing all Goverment Notifications in IDMA bulletin on weekly basis to 1000+ members to be made aware of changes & upgrades. And other changes to pharma regulations.

IDMA has been a great platform encouraging professionals to rise in career goals. IDMA is committed to be the torch bearer in enhancing & raising commitment to manufacture Quality medicines of sustainable Quality at affordable prices for patients in India and Globally.

Our Goal Atmanirbhar India, sustainable pharma Industry.

Jai Hind!

● ● ●

Oral Rehydration Therapy

Dr. Nagaraj N. Rao
Associate Editor, Indian Drugs

Dear Reader,

Cholera epidemics have wiped out clans, communities and large chunks of populations whenever they have raged across the globe. Of the seven large epidemics over the last two hundred years, lasting from seven to twenty-four years, Bengal has borne the brunt of its fury four times. Cholera, caused by *Vibrio cholerae* bacteria, is characterised by mild to potentially fatal acute watery diarrhoea. Prompt rehydration therapy is the cornerstone of management, since the body's ability to absorb salts, water and fluids is lost faster than it is replaced, causing dehydration via stool, urine, vomit and sweat. Repeated attacks of diarrhoea are a major cause of malnutrition, stunted growth and low body weight.

That a simple mixture of salt and sugar could rehydrate cholera patients suffering from mild to moderate dehydration was first observed in Kolkata by the physician Dr. Hemendra Nath Chatterjee, whose results of treating 186 patients with an oral glucose-sodium electrolyte solution were published in November 1953 in the *Lancet.* The article did not stir much interest, perhaps also because it was not "scientific enough" as it did not provide information on controls and net fluid balance sheets. The Iraqi physician Dr. Qais Al-Awqati confirmed the effect of the oral rehydration therapy (ORT) when he used it in 1966 to combat an outbreak of cholera in Baghdad and published it in the *Lancet* subsequently.

The prejudice against ORT in the medical fraternity those days was very strong. Doctors were used to giving intravenous fluids ("saline") packed in glass bottles and regarded ORT as a second-class treatment. To convince patients, who were made to believe that intravenous saline was the best treatment, the term "oral saline" was coined in order to convince patients and their relatives that ORT was a better option and could be administered even by relatives at home.

Dr. Nagaraj Narayan Rao *obtained Bachelor's degrees in Science (Chemistry) and in the Technology of Pharmaceuticals and Fine Chemicals from the University of Mumbai. After working with Colgate-Palmolive (India) for two years as a laboratory chemist, he obtained his doctorate in science with magna cum laude from the University of Tuebingen, Germany, under the guidance of Prof. Dr. H. J. Roth. He carried out post-doctoral research at the Institute of Biotechnology of the Research Center Juelich, Germany. He was a member of the Editorial Board for the first official German-language version of the European Pharmacopoeia. He was a visiting scientist at Juelich and a visiting faculty at the Institute of Chemical Technology Mumbai from 1993 to 2007 in the field of bioprocess technology. He has authored several original research articles, a patent, review articles and book chapters in the fields of pharmaceuticals, biotechnology, brewery and surface coatings. He was Chief Editor of the "Transactions of the MFAI" for a few years. He contributes a monthly 'Report from India' to a leading German technical journal since fourteen years and is a distinguished alumnus of the Research Center Juelich.*

Dr. Rao is co-founder of the RRR group of small and medium enterprises, manufacturing organic fine chemicals, formulations for surface coating technologies and fertilizers, process sensors and process units for life sciences, brewery and chemical process industries, as well as representing select overseas companies for cell culture media, bulk drugs and used chemical equipment and plants.

The term “oral saline” was coined by another physician, Dr. Dilip Mahalanabis, who was born in today’s Bangladesh and was working with the John Hopkins International Center for Medical Research and Training in Kolkata. When there was an outbreak of cholera among refugees of the Bangladesh Liberation War in 1971 in overflowing camps, Dr. Mahalanabis instructed his staff to prepare and distribute an oral rehydration fluid prepared from individual ingredients (and kept in drums!) to family members and caregivers. Over 3000 cholera patients were thus treated and the mortality rate was found to be 30% (with intravenous therapy) but only 3.6% with ORT. These findings were finally published in the John Hopkins Medical Journal in 1973, attracting the attention of WHO officials in Geneva, in particular, the attention of the trained physician Dr. Dhiman Barua, a medical officer working on cholera and other diarrhoeal diseases. Dr. Barua was born to a family of doctors and traditional medicine practitioners in Rangoon, Burma (now Nay Pyi Taw in Myanmar). At the WHO office in Geneva, the normally introvert Dr. Barua ran one day accidentally into Dr. Halfdan Mahler in the parking garage and made successfully an impassioned plea to include ORT in the WHO global programme. The rest, as they say, is history.

Originally, WHO and UNICEF approved, recommended and distributed oral rehydration salts (ORS). In 1984, another mixture containing trisodium citrate instead of sodium bicarbonate was developed with the aim of improving the stability of ORS in hot and humid climates. This product provided a solution containing 90 mEq L^{-1} of sodium with a total osmolarity of 311 mOsm L^{-1}, and proved effective and without apparent adverse effects in use worldwide. The efficacy of ORS solution for treatment of children with acute non-cholera diarrhoea was improved by reducing its sodium concentration to 75 mEq L^{-1}, its glucose concentration to 75 mmol L^{-1}, and its total osmolarity to 245 mOsm L^{-1}. The particular advantage of citrate containing ORS (over bicarbonate containing ORS) is its stability in tropical countries, where - up to temperatures of 60°C - no discoloration occurs over 2-3 years. Another key reason for the success of the ORS was the discovery by a Swiss company at the end of 1970 that packaging of the ingredients of ORS in aluminum foil bags prevented absorption of moisture, caking and discoloration of the powder. Thanks to this discovery, the shelf life increased dramatically and transportation became very cheap. To this day, aluminum foil is an inherent part of ORT-packaging, though different types of laminates have been developed.

ORS is a drug under Class 27 of Schedule K of Drugs and Cosmetics Rules 1945 and it is being widely manufactured, distributed and sold in the Indian market by small and big pharmaceutical companies in various flavours and colours. The global ORS market was valued at $ 660 million in 2021 and is projected to reach $ 906 million by the end of 2027. In India also, the packaging industry has played a significant role in making ORS a success. The brand leader holds about 72% share in the Indian market. World ORS Day is observed every year on 29th of July to raise awareness about using ORS. The *Lancet* has reportedly called ORS as “the most important medical discovery of the 20th century.” The Poshan Abhiyaan programme of the Indian Government promotes strongly the use on child immunisation, antenatal care check-ops and ORS for treating diarrhoea.

Not much is known about the later life of Dr. Hemendra Nath Chatterjee. Dr. Dhiman Barua died in 2020 at the ripe old age of almost 100 in Geneva. Dr. Dilip Mahalanabis was conferred with the Pollin Prize for paediatric research in 2002 in the USA, and in 2006 he became the first Indian to be awarded the Prince Mahidol Award of Thailand. In 1994, he was elected as a foreign member of the Royal Swedish Academy of Sciences. He died in October 2022 in Kolkata due to age-related complications at the age of 88, largely unnoticed by the media. Although Bengal has suffered the most due to cholera, it has gracefully gifted to the world three brilliant physicians who discovered one of the most affordable medicines of all times and carved out a place for it in medical history.

Happy reading!

Courtesy: Indian Drugs, Editorial, 59 (12), December 2022

IDMA representation to Dr Ms Vinod Kotwal, Member Secretary, NPPA regarding Stakeholders Meeting on IPDMS 2.0 - 12.12.2022

IDMA have submitted following representation to Dr Ms Vinod Kotwal, Member Secretary, National Pharmaceutical Pricing Authority, Ministry of Chemicals and Fertilizers with a copy to Shri Kamlesh Kumar Pant, Chairman, National Pharmaceuticals Pricing Authority, Department of Pharmaceuticals on 13th December 2022 as reproduced below on the above subject:

Dear Madam,

We appreciate the swift initiatives taken to address the teething problems faced by the Industry in migrating to IPDMS 2.0, through regular interactions with all the stakeholders. We at IDMA are grateful for the opportunity given to us to highlight the few operational issues that adversely affect the industry, at the said Meeting.

As advised by you, we give below the discussions held highlighting the queries raised by us and response provided by NPPA.

We would earnestly request you to resolve the pending issues at the earliest.

Thanking you,

Yours sincerely,
For Indian Drug Manufacturers' Association,

Dr Viranchi Shah
National President

	IDMA Query	**NPPA Reply**
1	Data migration of old forms from IPDMS 1.0 to 2.0 still pending.	NPPA will implement the same in Jan. 23. There will be a facility to view earlier submitted data.
2	The product label has data in MMYY format but data in Form II and Form V is to be entered in DDMMYYYY format which is inconvenient. Kindly allow entry in MMYY format only. In Form III MMYY entry is allowed but not in other forms.	This is under consideration, we have understood the issue.
3	In IPDMS 1.0 on submission of data in form V, a unique Reference Number was allotted for each form and was displayed on the form. In IPDMS 2.0 a reference number appears for each entry only in the index page (**Exhibit I below**) but is not displayed on the Form V when it is printed or saved as PDF(**Exhibit II below**). Request to display the reference number on every Form generated for ease of access and retrieval.	The reference number appears on the index page and list page (**Our request is for display of the reference number on the Form that is saved or printed which please allow)**
4	PTS (Price to Stockist) is not a part of DPCO 2013 but its entry is made mandatory in IPDMS 2.0. We checked DPCO Para 2x, 24,25,26 on which Form V is based as well as all the 10 amendments in DPCO 2013 since its enactment.	It is not in DPCO 2013 and your suggestion is under review.

5	OTP code generated before printing any Form is alpha-numeric and 8 digit long. Also the last digit merges with the 'Regards' in the text message. This complicated OTP leads to confusion. Request to send a numeric only 4 digit OTP code for ease of use.	Noted.

Exhibit I

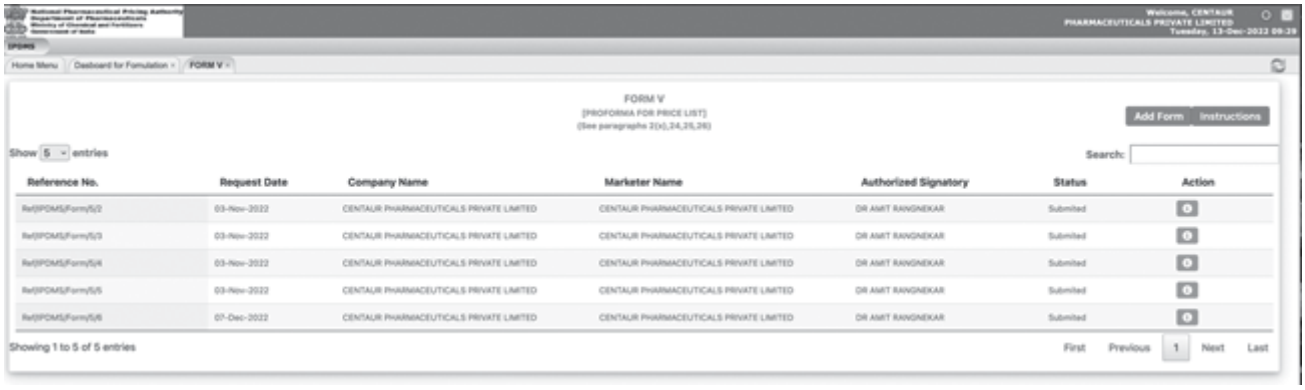

Exhibit II

SCHEDULE - II
FORM - V
PROFORMA FOR PRICE LIST
(See paragraphs 2(x),24,25,26)

1. **Name and address of the manufacturer / importer / distributor :** CENTAUR PHARMACEUTICALS PRIVATE LIMITED, Add :CENTAUR HOUSE, NEAR GRAND HYATT, VAKOLA, SANTACRUZ (E)

2. **Name and address of the marketing company, if any :** CENTAUR PHARMACEUTICALS PRIVATE LIMITED, Add :CENTAUR HOUSE, NEAR GRAND HYATT, VAKOLA, SANTACRUZ (E)

TABLE-A

Sl. No.	Name of the Product(Formulation and its dosage forms)	Composition Approved By Drug Control Authorities	Pack Size	Price to Stockist (inclusive of GST) (Rs.)	Price to Retailer (inclusive of GST) (Rs.)	Maximum Retail Price (inclusive of GST) (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)	(7)
	Scheduled formulation					
	Own Manufactured Formulation					
	Purchased/Imported Formulation					

TABLE-B

Sl. No.	Name of the Product(Formulation and its dosage forms)	Composition Approved By Drug Control Authorities	Pack Size	Price to Stockist (inclusive of GST) (Rs.)	Price to Retailer (inclusive of GST) (Rs.)	Maximum Retail Price (inclusive of GST) (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)	(7)
	Non-Scheduled formulation					
	Purchased/Imported Formulation					
1	Nepacent 0.1 % Eye Drops 5 Ml(5.00 Ml) (Nepafenac EYE DROPS)	Nepafenac 0.1 % EYE DROPS	5	130.26	144.73	202.62
2	Sinarest Ccf New 5/2/10 Mg Capsule 10(10.00 Capsule) (Phenylephrine + Cpm + Dextromethorphan CAPSULE)	Phenylephrine + Cpm + Dextromethorphan 5/2/10 MG CAPSULE	10	44.88	49.86	69.81

Notes:-In case of purchased/imported formulation, Name of the manufacturer shall be indicated.

The information furnished above is correct and true to the best of my knowledge and belief.

Place : Mumbai

Date : 03-Nov-2022

Authorized Signatory : DR AMIT RANGNEKAR
Name : DR AMIT RANGNEKAR
Designation : VP SCM

● ● ●

INDIAN DRUG MANUFACTURERS' ASSOCIATION

102-B, POONAM CHAMBERS, 'A' WING, DR. A.B. ROAD, WORLI, MUMBAI 400 018, INDIA

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actadm@idmaindia.com
Website : www.idma-assn.org

PARTNER IN GLOBAL HEALTHCARE

REGISTER NOW

22nd IDMA-APA PHARMACEUTICAL ANALYSTS CONVENTION (PAC) 2023

With EDQM, IPC, USP & US FDA on Friday, 24th February and Saturday, 25th February 2023 at Hotel Four Seasons, Worli, Mumbai

THEME: "Towards Creative Global Compliance"

We have lined up for you:

Eminent Speakers + Relevant Interesting Topics on Current Scenario + Exhilarating Panel Discussions + Excellent Venue

We need enthusiastic participation from you to make this Convention Successful

We are committed to make PAC an important milestone for Quality, Technical, Production & Regulatory Affairs Personnel every year, since 1997. Indian Drug Manufacturers' Association (IDMA) and Association of Pharmaceutical Analysts (APA) have pleasure in announcing the 22nd IDMA-APA Pharmaceutical Analysts' Convention 2023 **on Friday, 24th February and Saturday, 25th February 2023 at Hotel Four Seasons, Worli, Mumbai.**

THE THEME FOR THIS YEAR: "Towards Creative Global Compliance"

We have also invited illustrious luminaries and Industry Captains along with other senior CDSCO and FDA officials to grace the occasion along with Regulatory Authorities from Europe, USA and India. ***As you will all appreciate, the PAC has a unique tradition of the Eminent Guests interacting with the participants and exhibitors.***

CHIEF GUEST AND KEYNOTE SPEAKER:

PADMA SHRI PROF. (DR.) G. D. YADAV

National Science Chair (SERB/DST/GoI), Emeritus Professor of Eminence, Former Vice Chancellor & R T Mody Distinguished Professor, TATA Chemicals Darbari Seth Distinguished Professor of Leadership and Innovation, Institute of Chemical Technology, Mumbai

SPECIAL GUEST OF HONOUR :

DR. RAJEEV SINGH RAGHUVANSHI, Ph.D.

Secretary-Cum-Scientific Director

Indian Pharmacopoeia Commission

At this prestigious Convention, Eminent technical personnel from EDQM, IPC, US FDA, USP and the Indian Pharmaceutical Industry, Research, Academic and Regulatory Affairs will converge and get-together to interact on various recent developments and on the various issues and challenges faced by the Industry.

CONVENTION TOPICS / FACULTY (TENTATIVE TOPICS):

- ❖ Recent updates on Certificate of Suitability
- ❖ EDQM Inspection & Certifications, Changes after Brexit
- ❖ Recent updates in EP and New chapters included in the Pharmacopoeia
- ❖ Industry participation in Regulatory Implementations
- ❖ Educational booklets from EDQM
- ❖ Current trends in Harmonization of Pharmacopoeial Monographs

OBJECTIVE

This Convention will allow the delegates to receive hands-on information regarding the global requirements in the field of Quality Management and Regulatory Compliance, various recent developments and on the various issues and challenges faced by the Industry

➲ WHO SHOULD ATTEND

This Convention is designed to attract all those involved in:

Pharmaceutical Industry	Microbiological Industry	Business Consulting Companies	API, Excipients & Intermediates Manufacturers
Biopharmaceutical Industry	Government Laboratories	Contract Manufacturing Organizations	R & D Equipment Manufacturers
Biotechnology Industry	Research Institutions	Contract Research Organizations	R & D Machine Manufacturers
Nutraceutical Industry	Academic Institutions	Quality Control	Quality Assurance

➲ EXCELLENT OPPORTUNITIES FOR:

CEOs, Directors, VPs, GMs, Chemists, Microbiologists and Heads of:

Strategy and Business Development	Regulatory Affairs	Analytical Development Laboratory	Pharmacology / Toxicology
R & D	Production / Packaging	Quality Control / Assurance	Medical Affairs
Pharma Product Development		Clinical Research	

➲ GREAT REASONS TO ATTEND:

➢ **Interact with National & International Regulators**	➢ **Partnership Strategies**
➢ **Updates on Current ICH Guidelines**	➢ **Technology and Platforms**
➢ **New/Current Trends and Technologies**	➢ **Driving Innovations**
➢ **Opportunities for Business Development**	➢ **Branding Opportunities**
➢ **Showcase your Products & Services**	➢ **Networking Opportunities**
➢ **Hours of Facilitated Networking and Benchmarking**	➢ **Q and A Sessions**
➢ **Explore New Products, Solutions and Services**	
➢ **Market Development**	

➲ TABLE SPACE AREA:

IDMA strives harder and harder to organize inspiring & innovative conventions wherein we have bigger participation from the pharma industry and wherein various types of Equipment manufacturers and allied industries to get a platform to display their products and also, to interact with the eminent guests and participants.

➲ DELEGATE FEES:

IDMA & NON-IDMA MEMBERS	STUDENTS
Rs.8,000/- + GST @ 18%	**Rs.6,000/-** + GST @ 18%

➢ ***Early bird discounts (IDMA / Non-IDMA Members)***
Before 31st January 2023 : 10% discount

➢ ***Group registration benefits (cannot be combined with discounts):***
For every 4 Delegates registered from an organisation, the fifth (5) delegate will be complimentary

➲ SPONSORSHIP OPPORTUNITIES:

➲ Event Sponsor:–

PLATINUM SPONSOR	GOLD SPONSOR	SILVER SPONSOR
Rs.5 Lakhs	**Rs.3 Lakhs**	**Rs.2 Lakhs**
20 Minutes speaker slot	20 Minutes speaker slot	N.A.
The Speaker & Sr. Most Official of the company will be invited to the Dinner with the Speakers and Organizers	The Speaker & Sr. Most Official of the company will be invited to the Dinner with the Speakers and Organizers	Sr. Most Official of the company will be invited to the Dinner with the Speakers and Organizers

Sponsor's 4-5 minute film or an AV presentation to be played during the breaks	N.A.	N.A.
Logo Visibility on all banners at the venue	Logo Visibility on all banners at the venue	Logo Visibility on all banners at the venue
Full Page Colour Advertisement in Souvenir	Full Page Colour Advertisement in Souvenir	Full Page Colour Advertisement in Souvenir
Full Page Colour Advertisement in IDMA Bulletin publishing the Report of the Event	Full Page Colour Advertisement in IDMA Bulletin publishing the Report of the Event	N.A.
Company Brochures to be distributed at the venue to all participants	Company Brochures to be distributed at the venue to all participants	N.A.
Table Space inside the Convention Hall with power connection – 1 Tables for both the days **(at a prominent position)**	Table Space inside the Convention Hall with power connection – 1 Table for both the days	Table Space inside the Convention Hall with power connection – 1 Table for both the days
Complimentary Registrations – 4 nos.	Complimentary Registrations – 2 nos.	Complimentary Registrations – 2 nos.

➲ Kit Bags – Rs. 1,50,000/- + GST

(**IDMA Offers**: One Table Space, Two Delegates Complimentary, the sponsor name to be printed inside the kit bag and Advt. in Souvenir & IDMA Bulletin)

➲ Badges and Lanyards Sponsor - Rs. 1,00,000/- + GST

(**IDMA Offers**: Your Company Name and Logo to be printed on the Badges Lanyards & Two Delegates Complimentary, One Full Page Colour Advertisement in Souvenir)

➲ Lunch – Rs. 50,000/- + GST per session (2 Days)

(**IDMA Offers**: Company Banner would be placed around the lunch area & Two Delegates Complimentary)

➲ Tea / Coffee - Rs. 30,000/- + GST per session (2 Days)

(**IDMA Offers**: Banner would be placed around the tea/coffee area & One Delegate Complimentary)

➲ Spiral Bound Note Books and Pens - Rs.1,00,000/- + GST

(**IDMA Offers**: A full page colour advertisement in the spiral bound note book, Company name to be printed on the Pens & Two Delegates Complimentary.)

➲ Distribution of Company Brochures – Rs. 25,000/- + GST

(**IDMA Offers**: Company Brochures would be distributed to all the participants at the convention and One Delegate Complimentary)

➲ EXHIBITION OPPORTUNITIES

➲ Pre-function Area

Table Space – Rs.50,000/- + GST per table for 2 days (**IDMA Offers**: Table Size: 6ft. x 2ft. with a power connection, Lunch for Two delegates only & One Complimentary advt. in souvenir. Your Name & Logo will appear on the standee at the entrance.

➲ **ADVERTISING OPPORTUNITIES IN SOUVENIR**

➲ **Souvenir Sponsorship – Rs. 1,00,000/-**

(**IDMA Offers**: your Company's logo and name/address on the bottom of the cover page 3" (height) x 7" (width). The Souvenir size is 9 ½" (height) x 7" (width). The space offered is one-third of the cover page. One Delegate Complimentary. One Full Page Colour Advt. in Souvenir. Company/Product brochures would also be distributed)

(i) Back Cover - Rs.30,000/-		**(ii) Inside Front - Rs.20,000/-**
(iii) Inside Back - Rs.20,000/-		**(iv) Full Page Colour - Rs.15,000/-**
(v) Bookmark - Rs.40,000/-		

For further details, please contact:

➲ **Ms. Sapna Patil** Dy. Secretary – General admin@idmaindia.com 9619802299	➲ **Mr. Melvin Rodrigues** Sr. Manager (Commercial & Admin.) actadm@idmaindia.com 9821868758
➲ **Ms. Geeta Suvarna** Technical Officer publications@idmaindia.com 9820161419	➲ **Ms. Batul** Front Office Executive technical@idmaindia.com 9920045226

Looking forward to your presence and active participation at this Convention and working with you to make this 22nd Convention a grand success!

Best Wishes,

Dr Viranchi Shah
National President

Dr Vinay G Nayak
Chairman, Quality Management & Technical Committee

Daara B Patel
Secretary – General

INDIAN DRUG MANUFACTURERS' ASSOCIATION (IDMA)
102-B, Poonam Chambers, A Wing, 1st Floor, Dr. Annie Besant Road, Worli, Mumbai - 400 018. Maharashtra, India.
Tel: +91-22-24974308 / 24944624 E-mail: actadm@idmaindia.com Website: www.idma-assn.org

Invitation For Pharma Conclave to be held on 8th January 2023 in association with BAPS, Swaminarayan Sanstha at Ahmedabad

Dear Member,

It gives us great pleasure to invite all members of "Pharma industry to participate" in "Pharma Conclave"- a special 1 day conference to be held in association with "BAPS" Swaminarayan Sanstha at Pramukh Swami Nagar on Sunday, 8th January, 2023. The conclave is organised in association with *GCCI, DMMA, GCA, GPA, FGSCDA, GAAMA, IPMMA, NDIA, Pharmexcil and other leading associations. BAPS Swaminarayan Sanstha is celebrating Pramukh Swami Maharaj's Centenary from 15th December 2022 to 15th January 2023 at Pramukh Swami Nagar, Sardar Patel Ring Road, Ahmedabad.

BAPS has invited IDMA to organize a one-day conference at the 600-acre Pramukh Swami Nagar festival site. The conference will feature talks and presentations by our leading members on most recent topics followed by enlightening talks from BAPS Sadhus.

A "personal guided" tour for all our esteemed members to the sprawling festival site has also been arranged. The Pramukh Swami Nagar comprises of several exhibition pavilions on life values, children's adventure land, light & sound show, thematic glow gardens, cultural gates, Pramukh Swami Maharaj's maha-murti, a replica of Swaminarayan Akshardham in New Delhi amongst other inspiring attractions.

Members are requested for their active participation.

Thanks & Regards,

Daara B. Patel
Secretary - General

IDMA

Indian Drugs Manufacturers' Association

Pramukh Swami Maharaj Centennial Celebrations

PHARMA CONCLAVE

8th Jan 2023

Pramukh Swami Maharaj Nagar, Nr. Ognaj Circle, SP Ring Rd, Ahmedabad

CONFERENCE THEME: NICHE-THE GROWTH STRATEGY

08:30 AM TO 9:15 AM	REGISTRATION & BREAKFAST
09:15 AM TO 09:45 AM	IDMA GSB AGM
09:45 AM TO 10:45 AM	INAUGURAL FUNCTION: KEY NOTE ADDRESS BY SHRI PANKAJBHAI PATEL. CHAIRMAN ZYDUS ADDRESS BY MINISTER
10:45 AM TO 11:15 AM	SHRI AMAN MEHTA- DIRECTOR TORRENT PHARMACEUTICALS LTD.
11:15 AM TO 11:45 AM	MS ADITI KARE - MD INDOCO REMEDIES LTD
11:45 AM TO 12:15 PM	TEA BREAK
12:15 PM TO 12:45 PM	DR. DUSHYANT PATEL- FOUNDER ASTRAL STERITECH PVT LTD
12:45 PM TO 01:00 PM	Q&A
01:00 PM TO 01:15 PM	VIDEO OF THE MAKING OF PRAMUKH SWAMI NAGAR
01:15 PM TO 02:00 PM	ADDRESS BY DR GYANVATSAL SWAMIJI ON "BEHIND THE SCENE- MANAGEMENT LEARNINGS"
02:00 PM TO 03:00 PM	LUNCH
03:00 PM TO 07:00 PM	GUIDED TOUR OF PRAMUKH SWAMI NAGAR BY BAPS VOLUNTEERS
07:00 PM ONWARDS	DINNER

SUPPORTING ASSOCIATIONS

- Gujarat Chamber of Commerce & Industry
- Federation of Gujarat State Chemist and Druggist Association
- Drugs Marketing & Manufacturing Association
- Gujarat Ayurvedic Aushadh Manufacturer's Association
- Gujarat Chemical Association
- Gujarat Pharmaceutical Association
- Pharmaceutical Export Promotion Council
- Indian Pharma Machinery Manufacturers Association
- Nutraceuticals & Dietary Supplements Industries Aid Association

Registration Link
https://pharmalivexpo.com/delegate-registration-form/

EVENT CO-ORDINATOR
PHARMA LIVE• EXPO 2023
Pharma Live Expo & Summit 2023
www.pharmaliveexpo.com

IDMA
Indian Drugs Manufacturers' Association

Pramukh Swami Maharaj Centennial Celebrations

PHARMA CONCLAVE

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CONFERENCE THEME: NICHE-THE GROWTH STRATEGY

SPEAKERS


SHRI PANKAJBHAI PATEL


SHRI AMAN MEHTA


PUJYA DR GYANVATSAL SWAMI


MS ADITI KARE


DR. DUSHYANT PATEL

ORGANISING COMMITTEE

DR. VIRANCHI SHAH - NATIONAL PRESIDENT IDMA
DR. SHRENIK SHAH - CHAIRMAN, IDMA GSB
SHRI PATHIK PATWARI - PRESIDENT, GCCI
SHRI JASVANT PATEL - PRESIDENT, FGSCDA
DR JAIMIN VASA - PRESIDENT, GCA & GPA

SHRI AMIT THAKKAR - PRESIDENT, DMMA
SHRI JAMAN MALVIA - PRESIDENT, GAAMA
SHRI NITIN PANCHAL - PRESIDENT, NDIA
SHRI HARSHIT SHAH - PRESIDENT, IPMMA
SHRI KAMLESH PATEL
SHRI JAY PATEL
MS JINKAL PATEL
SHRI DAARA PATEL
SHRI SANCHIT CHATURVEDI
SHRI SANJAY SHAH

SHRI MEHUL SHAH - HON. SECRETARY IDMA
SHRI SUMIT AGRAWAL - HON. SECRETARY IDMA GSB
SHRI ANIL JAIN - HON. SECRETARY GCCI
SHRI KIRIT PALAN - HON. SECRETARY FGSCDA
SHRI JIGNESH SHAH - HON. SECRETARY, GCA
SHRI MAYUR PARIKH - HON. SECRETARY, GPA
SHRI VIKRAM CHANDWANI - HON. SECRETARY, DMMA
SHRI DHANANJAY SHUKLA - HON. SECRETARY, GAAMA
SHRI NIKHIL KANSARA - HON. SECRETARY, NDIA
SHRI OSWIN D'SOUZA - HON. SECRETARY, IPMMA
SHRI NIRAV MEHTA
SHRI ATUL SHAH
SHRI MAULIK SHAH
SHRI CHIRAG DOSHI
SHRI VIJAY SHAH
SHRI RAJ SANGHAVI

Registration Link
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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 February 2-3, 2023

Dear Member,

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 February 2-3, 2023.**

Expenses towards travel by Air (economy)/Train (2nd AC fare)/Taxi, boarding and lodging (accommodation at Hotel Courtyard by Marriott and meals) of participants will be borne by organizers. There are no hidden costs.

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. 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.

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

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

More details about the programme are given in the attached brochure. There is NO REGISTRATION FEE, however, REGISTRATION IS MANDATORY for consideration in the training programme. Those who have registered earlier need not register again.

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

2-3 February 2023, 09:00-17:00 IST

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 be informed on CW proliferation potential of key pharmaceuticals, 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. Topics covered will include chemical security threats and chemicals of concern, KYC principles, best practices, suspicious indicators and strategies to implement KYC. 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/or using potentially lethal (e.g., fentanyl) and other incapacitating and/or dissociative agents (e.g., benzodiazepines).

Audience:

- 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:

2 February 2023	3 February 2023
• Welcome and Introduction • Course Objectives and Schedule • Industry Case Study • Chemical Security Threats • Pharmaceuticals of Concern • Illicit Procurement Tactics	• Illicit Procurement Case Studies • Overview of KYC Principles and Practices • Interactive Scenario-Based Activities on KYC Indicators • KYC Implementation • Valedictory

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

Points of Contact:

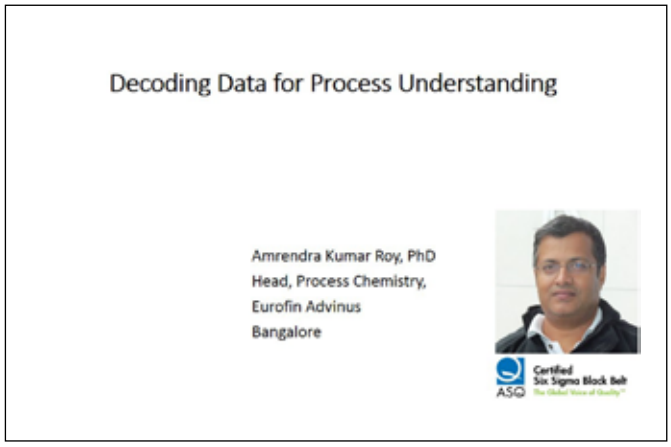
Dr. Cecelia Williams, Ph.D.
Sandia National Laboratories
cvwilli@sandia.gov

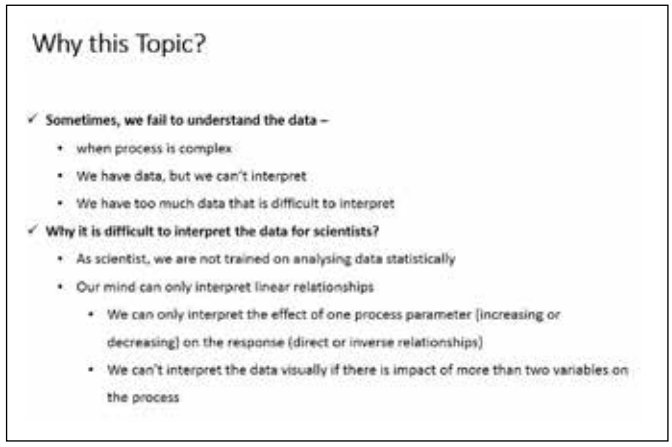
Dr. Vibha Ahuja, Ph.D.
Biotech Consortium India Limited
vibhaahuja@biotech.co.in
Phone no. 98912 44434

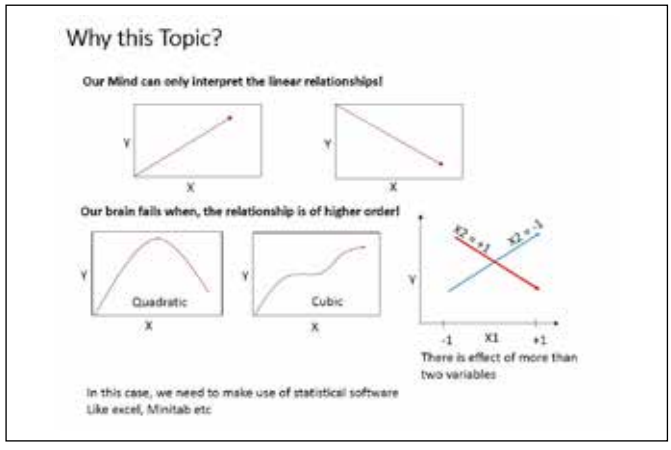
PRESENTATION

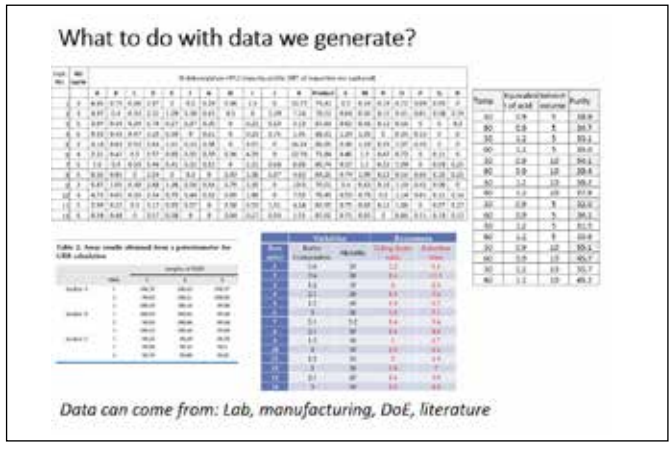
Decoding Data for Process Understanding

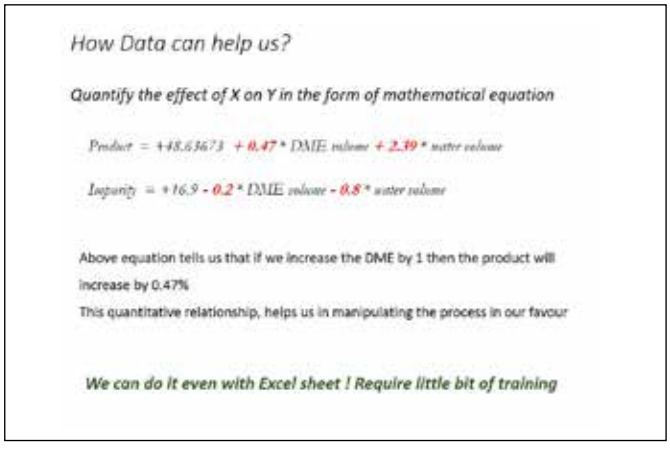
Dr Amrendra Kumar Roy, PhD, Head, Process Chemistry,
Eurofin Advinus, Bangalore and Member of R&D Innovation Committee, IDMA
at the IDMA's R&D Innovation Committee Virtual Meeting held on 28th December 2022

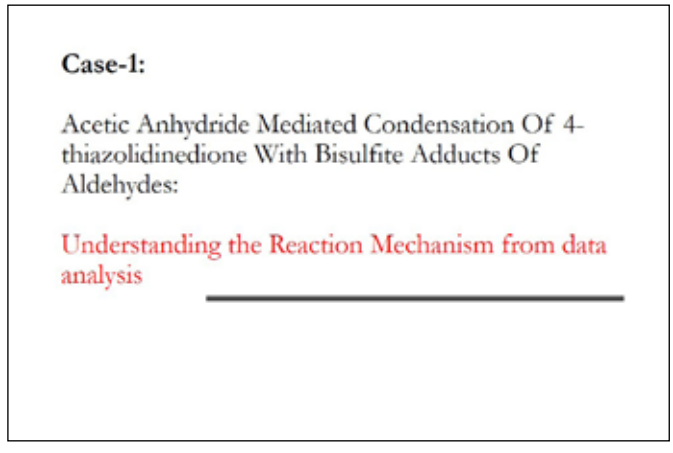






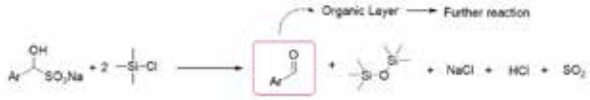






Background

Instability of aldehydes posed a serious scalability issue: use bisulphite adduct



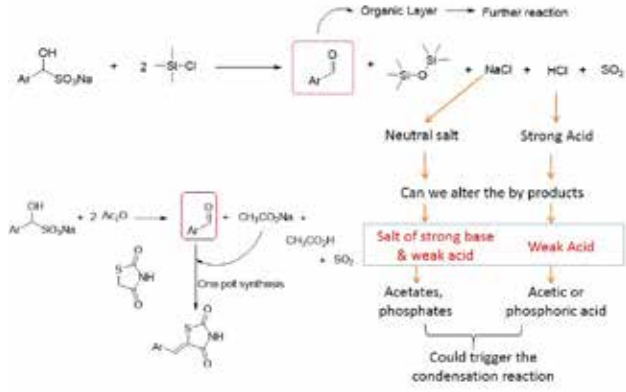
Kjell, D. P.; Slattery, B. J.; Semo, M. J. *J. Org. Chem.* **1999**, *64*, 5722–5724.

Objective:

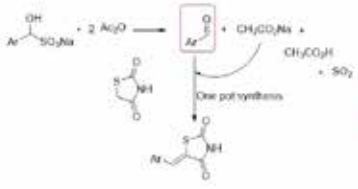
To develop a protocol were

- Deprotection and subsequent condensation is possible in same pot
- Eliminating the need of layer separation or a biphasic system.

Basis of work



Model reaction worked!



Model reaction worked as expected but with moderate yields of ~50%

Following were the variables involved in the reaction

- Type of solvent
- Ac_2O equivalents
- Reaction temperature
- Thiazolidinedione equivalents

Data was compiled from the lab experiments and DoE trials

Got the Desired Equation but unexpected

% Conversion = 74.91 + 2.86 × Reaction Time − 28.19 × thiazolidinedione

Ac_2O was missing (as per balanced equation, 2 equivalents were required)

How it is possible? As a chemist I couldn't digest it!

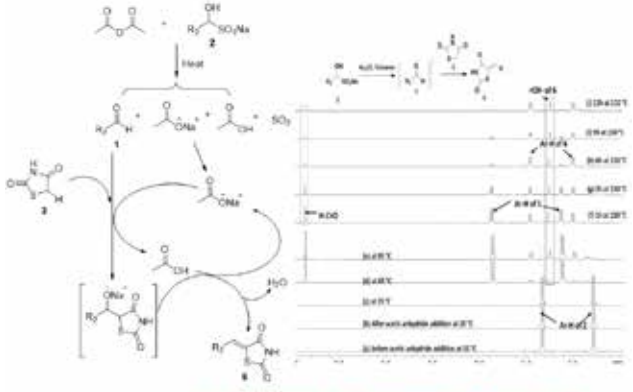
Ac_2O is required in catalytic quantity

Entry	Time	Temp.	Ac_2O equivalents	Product
1	15	110	1.5	83
2	15	110	1.0	82.3
3	15	110	0.5	81.8

No effect of decreasing Ac_2O equivalents

Yield increased from 50 to > 80%

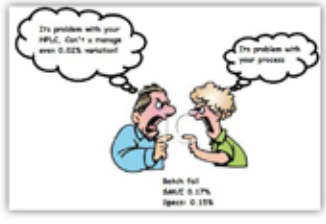
Proposed Reaction Mechanism



Amrendra Kumar Roy et. al. *Tetrahedron Letters*, **2014**, *55*,4585–4589

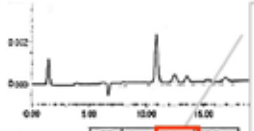
Case-2:

Is your analytical system right for your job?



Amol A Deshpande, Ramya A, Vishweshwar V, Girish Rajabhau Deshpande, and **Amrendra Kumar Roy,**
Org. Process Res. Dev., **2014**, 18, 1614-1621

What does analytical results shows?



RT	Area	% Area	RT Ratio
8.05	651	1.01	0.64
10.03	41347	64.06	0.87
12.55	6105	10.89	1.00
13.63	5359	8.30	1.09
15.46	2289	3.55	1.23
16.99	4748	7.35	1.35
26.61	2678	4.14	2.12

These are just numbers from Analytical equipment.

Does it tells us anything about the source of variation? Whether it is from the Process? Or from the Measurement system itself?

Difficult to estimate

Analytical result = true value ± error

Can be estimated Using GRR

Is your analytical system right for your job?

$$\sigma^2_{TV} = \sigma^2_{PV} + \sigma^2_{Gage\ R\&R}$$

$$\sigma^2_{Gage\ R\&R} = \sigma^2_{AV} + \sigma^2_{EV}$$

$$\%\ gage\ R\&R = \frac{Gage\ R\&R^2}{TV^2}$$

Check your MS before starting any DoE/QbD/Six Sigma

"if you can measure you can improve"

Is your analytical system right for your job?

Data Collection

	Trials	Samples 1	2	3
Analyst-A.	1	100.30	100.43	100.37
	2	99.83	100.31	100.03
	3	100.09	100.16	99.86
Analyst-B	1	100.09	100.63	99.46
	2	99.95	100.04	99.36
	3	100.53	100.46	99.68
Analyst-C	1	98.59	98.49	98.22
	2	99.66	99.35	99.2
	3	98.78	99.08	99.01

Results of Gage R&R: ANOVA method

Source	Variance component	% Contribution	
Total Gage R&R	0.56	94.76	
Repeatability	0.13	22.01	From Potentiometer
Reproducibility	0.43	72.75	From Analyst
Operators	0.43	72.75	
Part-To-Part	0.03	5.24	From Process
Total Variation	0.59	100.00	From Analysis

Conclusion:

It's clear who need to improve.
Potentiometer was not the right choice
Process was quite robust

Tried UPLC as an alternative for faster analysis

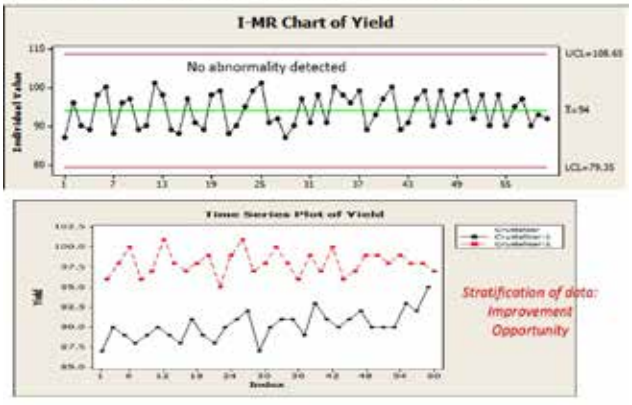
Case Study-3

Identifying the scope for improvement in the commercial process

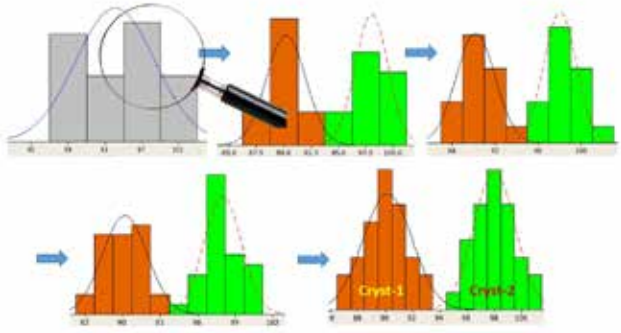
Data from the Plant

Crystallizer	Yield	batch number	Operator	Batches/day	maintenance temp	maintenance time
Crystallizer-1	87	1	1	1	43	115
Crystallizer-2	96	2	2	1	55	125
Crystallizer-3	90	3	1	2	47	117
Crystallizer-2	98	4	2	2	53	122
Crystallizer-1	89	5	1	3	47	116
Crystallizer-3	100	6	2	3	55	130
Crystallizer-3	88	7	1	4	48	110
Crystallizer-2	96	8	2	4	51	123
Crystallizer-1	89	9	1	5	48	123
Crystallizer-2	97	10	2	5	53	123
Crystallizer-3	99	11	1	6	48	122
Crystallizer-3	101	12	2	6	60	134
Crystallizer-2	98	24	2	18	51	122
...	...	...	...	...	...	...
Crystallizer-3	90	48	1	26	47	118
Crystallizer-2	95	50	2	26	50	132
Crystallizer-1	90	51	1	27	48	118
Crystallizer-2	98	52	2	27	53	125
Crystallizer-1	90	53	1	28	48	123
Crystallizer-2	99	54	2	28	53	134
Crystallizer-1	93	55	1	29	49	117
Crystallizer-2	98	56	2	29	53	125
Crystallizer-1	92	57	1	30	48	118
Crystallizer-2	96	58	2	30	52	123
Crystallizer-1	91	59	1	31	52	120
Crystallizer-2	97	60	2	31	51	122

Directly Plotting Control Chart: Conclusions?



Data Resolution: two process were in action



Crystallizer-2 was always maintained at lower temperature and for longer time BUT within the BPR range

Case 4: Identifying the source of impurity

Don't get upset by the Failure of DoE

From where these impurities were coming from? Case of Complex molecules

DOE indicated that these impurities are independent of reaction conditions.

⬇

Hence these were being carried from earlier stages.

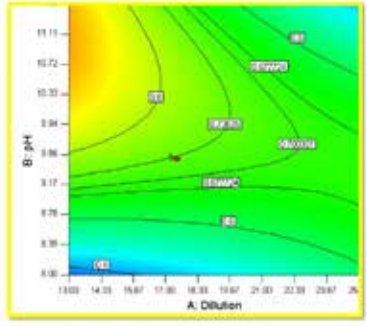
⬇

Challenge was to identify their precursor in N-1 or N-2 stages

⬇

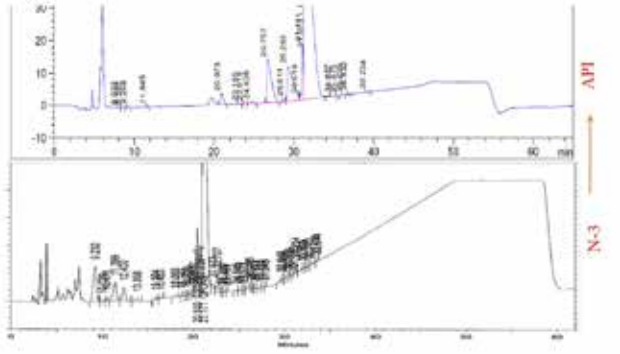
HPLC contains ~30-50 peaks and impurities was present at 0.2-0.5% levels

⬇



Difficult to establish any correlation and pin point to a particular impurities N-1

HPLC chromatogram of N and N-3 stage



Correlating Impurities of two stages

	N-3							API Imp-1	
A	N-3	B	C	D	E	F	G	Actual	Calculated
0.14	62.31	0.17	1.4	0.32	13.67	8.94	0.40	1.54	1.16
0.62	67.45	1.09	0.58	0	0	0	0.04	4.43	3.27
0.08	21.7	1.48	1.40	0.08	0.07	0.2	3.44	1.5	1.91
0.23	77.16	1.67	0.15	0.19	0.13	0	0.07	0.02	1.79
0.23	77.16	0.29	2.88	0.22	0.21	4.7	0.08	2.3	2.78
0.94	86	0	0.17	0.21	0	0.09	0.19	0.12	0.17
2.68	91.88	0.21	0	0	0	0	1.11	0.17	0.01
0.78	64.08	0.31	0.67	0.19	0.15	0.04	0.17	0.74	0.65
0.03	89.82	0	0.6	0.29	0.07	0.07	0.21	0.74	0.58
10.83	77.62	0	0.73	0.13	0.08	0.04	0.12	0.6	0.70

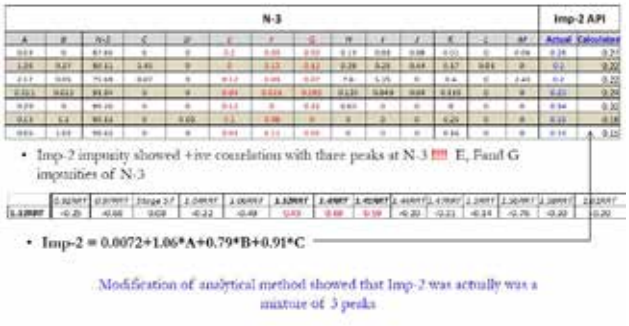
- Impurity-1 shows +ve correlation with C impurity at N-3

		N-3						
		A	N-3	B	C	D	E	F	G
API	Imp-1	0.12	0.43	0.78	0.99	-0.09	-0.07	0.08	-0.26

- Correlation data was further augmented by regression → shows that relation with 1.06RRT is insignificant;

Imp-1 = 0.007 + 0.955*C

Example-2: Correlation of Imp-2 with N-3 impurities



- Imp-2 impurity showed +ive correlation with three peaks at N-3 RRT E, Fand G impurities of N-3

- Imp-2 = 0.0072+1.06*A+0.79*B+0.91*C

Modification of analytical method showed that Imp-2 was actually was a mixture of 3 peaks

Conclusion

1. We are generating lot of data every day. It's in lab, in manufacturing etc
2. These data, if analyzed properly could reveal the quantitative relationships between variables and responses
3. Once we have the quantitative relationship, it could be exploited in our favor

● ● ●

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In Lok Sabha & In Rajya Sabha

In Lok Sabha

Manufacturing of Indigenous Medical Equipment

Lok Sabha Unstarred Question No. 463 Shri Komati Reddy Venkat Reddy:

Q. Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether the Government has called upon the industries to focus more on the healthcare sector and make efforts to manufacture medical equipment in the States across the country and if so, the details thereof;

(b) whether several equipment such as CT scan, MRI scan, high-end digital Xray, digital mammography, linear accelerator, brachytherapy and such high end machined ventilators are only imported and if so, the steps taken by the Government to boost indigenous manufacturing of such medical equipment and the funds sanctioned and spent in this regard, State-wise;

(c) whether the Indian manufacturers (individually or jointly with foreign partners) have shown interest in setting up manufacturing units for production of medical devices for which the country is dependent majorly on imports; and

(d) if so, the details thereof?

Answered on 09th December, 2022

(a) to (d): Several manufacturing licenses have been issued for high-end equipments such as CT scan, MRI scan, high-end digital X-ray, digital mammography, linear accelerator. At the same time these high end equipments are also imported from various countries.

Department of Pharmaceuticals has informed that they have taken the following programmatic interventions to encourage domestic manufacturing to reduce import dependency of medical devices:

i. Under the scheme "Promotion of Medical Devices Parks", final approval for financial assistance of Rs. 100 crore each has been given to the States of Uttar Pradesh, Tamil Nadu, Madhya Pradesh and Himachal Pradesh for establishment of common facilities in their Medical Device Parks. The Parks will provide common testing and laboratory facilities / centre at one place reducing the manufacturing cost significantly and help in creating a robust ecosystem for medical device manufacturing in the country. First installment of Rs. 30 crore has been released to each of the selected States.

ii. Under the sub-scheme "Assistance to Medical Device Industry for Common Facility Centre", approval for grant-in-aid of Rs. 25 crore was provided to Andhra Pradesh Medtech Zone Ltd. (AMTZ), Andhra Pradesh for establishment of Common Facility for Super conducting magnetic coil testing and research facility.

iii. Under the Production Linked Incentive (PLI) scheme for Pharmaceuticals, with the tenure from FY 2020-2021 to 2028-29, five (5) industry applicants have been selected under the scheme for in-vitro diagnostic medical devices.

iv. Under the Production Linked Incentive (PLI) Scheme for Promoting Domestic Manufacturing of Medical Devices with a financial outlay of Rs. 3,420 Cr and with the tenure from FY 2020-21 to FY 2027-28, financial incentive is given to selected companies at the rate of 5% of incremental sales of medical devices manufactured in India for a period of five (5) years. The following four segments under the scheme, cover high-end medical devices –

a. Cancer care/Radiotherapy medical devices

b. Radiology & Imaging medical devices (both ionizing & non-ionizing radiation products) and Nuclear Imaging Devices

c. Anaesthetics & Cardio-Respiratory medical devices including Catheters of Cardio-respiratory Category & Renal Care Medical Devices

d. All Implants including implantable electronic devices. In total 21 applicants have been approved under the scheme. The list of selected applicants is also available on Department of Pharmaceuticals website (https://pharmaceuticals.gov.in/sites/

default/files/List%20of%20approved%20applicants%20MD%20_0.pdf)

The Minister of State in the Ministry of Health And Family Welfare (Dr. Bharati Pravin Pawar)

Fixation of Prices of Essential Drugs

Lok Sabha Unstarred Question No. †528 Shri Dileshwar Kamait:

Q. Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) the details of the criteria/guidelines for fixing of prices of Essential Drugs including those used for the treatment of Cancer, Diabetes, HIV, Cardiovascular and Kidney diseases;

(b) whether the prices of Essential Drugs have come down;

(c) if so, the details thereof; and

(d) the details of Jan Aushadhi Kendras established in each district of Bihar including Supaul for sale of generic drugs at cheaper prices under the Pradhan Mantri Jan Aushadhi Yojana?

Answered on 09th December, 2022

(a): As informed by Department of Pharmaceuticals, the National List of Essential Medicines (NLEM) is adopted as the primary basis for determining essentiality and is incorporated in the First Schedule of Drugs (Prices Control) Order (DPCO), 2013, which constitutes the list of scheduled medicines, including the medicines used for the treatment of cancer, diabetes, HIV and Heart and kidney diseases for the purpose of price control. The key principles for regulation of prices in the National Pharmaceuticals Pricing Policy, 2012 are essentiality of drugs; control of formulations prices only; and Market Based Pricing. National Pharmaceutical Pricing Authority (NPPA), fixes the ceiling price of scheduled medicines specified in the first schedule of the DPCO, 2013. All manufacturers of scheduled medicines have to sell their products within the ceiling price (plus applicable Goods and Service Tax) fixed by the NPPA. DPCO, 2013 allows an annual price rise for scheduled formulations based on Wholesale Price Index (WPI). NPPA also fixes retail price of a new drug under DPCO, 2013 for existing manufacturers of scheduled formulation. Hence, the annual increase allowed in the case of Scheduled formulations is upto the level of annual revision in WPI. Further, in case of non-scheduled formulation, no manufacturers can increase MRP by more than 10% of MRP during preceding 12 months. Instances of overcharging are dealt with by NPPA under the relevant provisions of DPCO 2013.

(b) & (c): The details of drugs brought under price control/ regulation by NPPA are given below:

i. Ceiling prices of 890 scheduled formulations across various therapeutic categories under NLEM 2015 which includes four scheduled medical devices i.e. Intra Uterine

The Minister of State in the Ministry of Health And Family Welfare (Dr. Bharati Pravin Pawar)

Artificial Intelligence In Health Sector

Lok Sabha Unstarred Question No-550 Shri Maddila Gurumoorthy:

Q. Will the Minister of HEALTH and FAMILY WELFARE be pleased to state:

(a) whether the Government has taken any steps to incorporate Artificial Intelligence (AI) in the health sector;

(b) if so, the details thereof and if not, the reasons therefor;

(c) the total budgetary allocation and spending towards AI in the health sector during the last three years;

(d) whether the Government proposes to forge any partnerships with the private sector for promoting AI in the health sector; and

(e) if so, the details thereof and if not, the reasons therefor?

Answered on 09th December, 2022

(a) to (e): Government of India has launched Ayushman Bharat Digital Mission (ABDM) which aims to create a platform enabling interoperability of health data within the health ecosystem so as to create longitudinal Electronic Health Record (EHR) of every citizen.

Under ABDM, multiple registries are made to ensure that data silos can be broken and longitudinal electronic health record (EHR) of citizen is created. Further it will integrate cutting edge technologies

such as Artificial Intelligence, IoTs, blockchain etc. with existing health IT applications as per need for improving the performance of the health services.

NITI Ayog has published two approach documents on AI for India, "Responsible AI" approach documents in February 2021 and "Operationalizing Principles for Responsible AI" in August 2021.

Ministry of Health has also recently designated AIIMS Delhi, PGIMER Chandigarh and AIIMS Rishikesh as Centre of Excellence for Artificial Intelligence with an aim to promote creation and use of AI based solutions in Health.

The Minister of State in the Ministry of Health And Family Welfare
(Dr. Bharati Pravin Pawar)

Renaming of Schemes

Lok Sabha Unstarred Question No. 584
Shri Nakul Kamalnath:

Q. Will the Minister of CHEMICALS AND FERTILIZERS be pleased to state:

(a) the names of the schemes of the Ministry which have been renamed by the Government after 2014; and

(b) the details of allocation of budget to these schemes since 2014, year-wise?

Answered on 9th December, 2022

(a): The details of the names of the Schemes of the Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers which have been renamed are as under:

(i) Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJP): Government revamped the Jan Aushadhi Scheme in September 2015 as Pradhan Mantri Jan AushadhiYojana (PMJAY). Further, with effect from 2016, Pradhan Mantri Jan AushadhiYojana (PMJAY) has been renamed as Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJP).

(ii) Promotion of Medical Devices Parks: The scheme on "Assistance to Medical Device Industry for Common Facility Center" was approved by the Cabinet in 2020 and was renamed as "Promotion of Medical Devices Parks".

(iii) Promotion of Bulk Drug Parks: The Scheme on "Assistance to Bulk Drug Industry for Common Facilitation Center" was approved by the Cabinet in 2020 and was renamed as "Promotion of Bulk Drug Parks".

(iv) Pharmaceutical & Medical Devices Promotion and Development Scheme (PMPDS): The Scheme on "Pharmaceutical Promotion and Development Scheme (PPDS)" was renamed as "Pharmaceutical & Medical Devices Promotion and Development Scheme (PMPDS)".

Assistance to Pharmaceuticals Industry for Common Facilities (API-CF):The scheme on "Cluster Development Programme for Pharma Sector (CDP-PS)" has been renamed as "Assistance to Pharmaceuticals Industry for Common Facilities (API-CF)".

There are no schemes of the Department of Fertilizers and Department of Chemicals & Petrochemicals which has been renamed after 2014.

(b): The year-wise details of budgetary allocations to the Schemes of Department of Pharmaceuticals since 2014-15 are at Annexure.

Annexure

1. The details of budget allocation for Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJP) Scheme implemented by Department of Pharmaceuticals are as under:-

Budget allocation for Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJP) Scheme

(Amount in Rs. Crores)

SL. No	Financial Year	Budget Estimates	Revised Estimates
1	2014-15	30.00	9.67
2	2015-16	35.00	16.92
3	2016-17	35.00	49.75
4	2017-18	75.62	75.62
5	2018-19	84.00	42.50
6	2019-20	42.00	35.51
7	2020-21	50.00	65.00
8	2021-22	65.00	68.50

2. The details of budget allocation for Promotion of Medical Devices Parks implemented by Department of Pharmaceuticals are as under:-

Budget allocation for Promotion of Medical Devices Parks		
		(Amount in Rs. Crores)
Financial Year	**Budget Estimates**	**Revised Estimates**
2020-21	7.50	21.05
2021-2	60	225.80

3. The details of budget allocation for Promotion of Bulk Drug Parks implemented by Department of Pharmaceuticals are as under:-

Budget allocation for Promotion of Bulk Drug Parks		
		(Amount in Rs. Crores)
Financial Year	**Budget Estimates**	**Revised Estimates**
2020-21	21.52	1.69
2021-22	36.24	36.24

4. The details of budget allocation for "Pharmaceutical & Medical Devices Promotion and Development Scheme (PMPDS)"implemented by Department of Pharmaceuticals are as under:-

Budget allocation for Pharmaceutical & Medical Devices Promotion and Development Scheme (PMPDS)		
		(Amount in Rs. Crores)
Financial Year	**Budget Estimates**	**Revised Estimates**
2020-21	1.00	0.50
2021-22	2.00	2.00

5. The details of budget allocation for "Assistance to Pharmaceuticals Industry for Common Facilities (API-CF)" implemented by Department of Pharmaceuticals are as under:-

Budget allocation for Assistance to Pharmaceuticals Industry for Common Facilities (API-CF)		
		(Amount in Rs. Crores)
Financial Year	**Budget Estimates**	**Revised Estimates**
2017-18	10.00	10.00
2018-19	10.90	2.93
2019-20	6.23	2.23
2020-21	12.00	7.23
2021-22	18.00	15.61

Minister of State for Chemicals & Fertilizers (Shri Bhagwanth Khuba)

In Rajya Sabha

Closure of MSMEs

Rajya Sabha Unstarred Question No. 1389 Shri Derek O' Brien:

Q. Will the Minister of MICRO, SMALL AND MEDIUM ENTERPRISES be pleased to state:

(a) the number of Micro, Small and Medium Enterprises (MSMEs) shut down since 2017, yearwise;

(b) the biggest contributing factors in the shutting down of these MSMEs, the details thereof ;

(c) whether closure of MSMEs is concerning Government;

(d) if so, the details thereof and if not, reasons therefor; and

(e) steps that have been taken to address the closure of MSMEs and details thereof?

Answered on 19th December, 2022

(a)&(b): The details of number of Micro, Small and Medium Enterprises (MSMEs) shut down since 2017, as per Udyog Aadhaar Memorandum (UAM) and Udyam Registration Portals, are as under:

Financial Year	Number of MSME shutdown
2017-18	0
2018-19	0
2019-20	245
2020-21(1-04-2020 to 30-06-2020 (UAM)	155
2020-21(01.07.2020 -31.03.2021)	175
2021-22	6,222
2022-23(as on 14.12.2022)	8,232

The factors contributing to shut down are not captured on Udyam Registration Portal.

(c) & (d): From the launch of Udyam Registration Portal on 01.07.2020 to 14.12.2022, 1.27 crore enterprises have registered, of which 14,454 shut down business which constitutes 0.001% of the total MSMEs registered on Udyam Registration Portal.

(e): The Government has taken a series of initiatives to support the MSME Sector in the country.

i. Rs. 5 lakh crore Collateral Free Automatic Loans under Emergency Credit Line Guarantee Scheme (ECLGS) for business, including MSMEs.

ii. Rs. 50,000 crore equity infusion through Self-Reliant India Fund.

iii. New revised criteria for classification of MSMEs.

iv. No global tenders for procurement up to Rs. 200 crores.

v. "Udyam Registration" for MSMEs, for Ease of Doing Business

vi. Launching of an online Portal "Champions" in June, 2020 to cover many aspects of egovernance including redressing grievances and handholding of MSMEs.

vii. Inclusion of Retail and Wholesale traders as MSMEs w.e.f. 02.07.2021.

viii. Non-tax benefits extended for 3 years in case of an upward change in status of MSMEs.

Minister of State for Micro, Small and Medium Enterprises (Shri Bhanu Pratap Singh Verma)

Data on Employment In MSMEs

Rajya Sabha Unstarred Question No. 1390 Shri A. A. Rahim:

Q. Will the Minister of MICRO, SMALL AND MEDIUM ENTERPRISES be pleased to state:

(a) the data on total employment in Micro, Small and Medium Enterprises (MSMEs) sector, annually, over last five years;

(b) the data on number of new MSMEs opened during the last five years, annually; and

(c) the data on number of MSMEs which ceased operation during the said period?

Answered on 19th December, 2022

(a): As per Udyam registration portal, the number of persons employed in the MSMEs which are incorporated during last 5 years are as follows:

Year	Number of persons employed
2017-18	7770469
2018-19	6010653
2019-20	6622941
2020-21	11297690
2021-22	13118896

(b): As per Udyam registration portal, the number of MSMEs which are incorporated during last 5 years are as follows:

Year	Number of MSMEs
2017-18	1246027
2018-19	1016723
2019-20	1103970
2020-21	1841253
2021-22	2078882

(c): The number of MSMEs which were registered on Udyam Registration Portal and cancelled their Udyam registration are as follows:

Period	Number of MSMEs who have cancelled their Udyam Registration
01.07.2020 to 31.03.2021	931
01.04.2021 to 31.03.2022	24075
01.04.2022 to 14.12.2022	30597

Minister of State for Micro, Small and Medium Enterprises (Shri Bhanu Pratap Singh Verma)

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Ash Utilisation Notification No. S.O.5481(E), dated 31st December, 2021 amended – reg.

Environment Order's S.O.6169(E) dt. 30/12/2022

Whereas, the Government of India, Ministry of Environment, Forest and Climate Change, in exercise of the powers conferred by sub-section (1) and clause (v) of sub-section (2) of section 3 of the Environment (Protection) Act, 1986 (29 of 1986) read with clause (d) of sub-rule (3) of rule (5) of the Environment (Protection) Rules, 1986, issued a notification published in the Gazette of India, Extraordinary, Part II, Section 3, sub-section (ii) *vide* S.O.5481(E), dated the 31st December, 2021 (herein after referred to as the ash utilisation notification);

And whereas, requests have been received from Ministry of Power, thermal power plants and various stakeholders regarding implementation of provisions of the ash utilisation notification;

And whereas, it is expedient to make amendments to certain provisions of the said notification to have smooth transitioning in implementation of the ash utilisation notification;

Now, therefore, in exercise of the powers conferred by sub-section (1) and clause (v) of sub-section (2) of section 3 of the Environment (Protection) Act, 1986 (29 of 1986) read with of sub-rule (1), (2) and (4) of rule (5) of the Environment (Protection) Rules, 1986, the Central Government hereby makes the following amendments in the ash utilisation notification namely:-

In the ash utilisation notification,-

(1) in paragraph A,-

(i) in sub-paragraph (4), after the third proviso, the following shall be inserted, namely,-

"Provided also that new thermal power plants commissioned on or after the date of publication of this notification shall follow the first compliance cycle similar to the compliance cycle specified for thermal power plants having utilisation per cent. less than 60 per cent. as specified in the table.

Note: The utilisation targets as per the applicable compliance cycle shall commence from 1st April, 2022.".

(ii) in sub- paragraph (5),-

(a) in the opening paragraph, for the words "the date of publication of this notification", the figures, letters and word "1st April, 2022" shall be substituted;

(b) in the second proviso, -

(i) after the words "green belt or plantation", the words, brackets, letters and figure "or solar power plant or wind power plant as per the guidelines issued by the Central Pollution Control Board (CPCB) as specified in sub-para (6)" shall be inserted,

(ii) the words, brackets and letters "Central Pollution Control Board (CPCB) or" shall be deleted,

(iii) for the words "a year", the words "three years" shall be substituted,

(iv) for the words "the date of publication of this notification", the figures, letters and word "1st April, 2022" shall be substituted.

(c) after the second proviso, the following proviso shall be inserted, namely:

"Provided that ash stored in all ash ponds or dykes other than operational ash pond or dyke designated for temporary storage of ash as specified in sub-para (6) shall constitute the legacy ash and either to be reclaimed or stabilised or utilised.".

(iii) for sub- paragraph (6), the following sub-para shall be substituted, namely,-

"(6) Any new as well as operational thermal power plant may be permitted operational ash pond or dyke for temporary storage of ash within an area of 0.1 hectare per Mega Watt (MW). Technical specifications of operational as well as stabilised and reclaimed ash ponds or dykes shall be as per the guidelines of the Central Pollution Control Board (CPCB) made in consultation with the Central Electricity Authority (CEA) and these guidelines

shall also lay down a procedure for annual certification of the operational as well as stabilised and reclaimed ash pond or dyke on its safety, environment pollution, available volume, mode of disposal, water consumption or conservation in disposal, ash water recycling and green belt, etc. and shall be put in place within three months from the date of publication of this notification:

Provided that up to two operational ash ponds or dykes for thermal power plants commissioned before 31st December, 2021, having installed capacity less than or equal to 1600 MW, and up to four operational ash ponds or dykes for thermal power plants having installed capacity more than 1600 MW, having multiple lagoons, within the specified area from the existing ash ponds or dykes, may be designated with clear demarcation along with coordinates, and shall inform to Central Pollution Control Board (CPCB) and concerned State Pollution Control Board (SPCB) or Pollution Control Committee (PCC) by 31st March, 2023:

Provided further that one ash pond or dyke shall be permitted in case of new thermal power plants or expansion of existing thermal power plants commissioned on or after 31st December, 2021, which shall inform the details of demarcation along with coordinates to Central Pollution Control Board (CPCB) and concerned State Pollution Control Board (SPCB) or Pollution Control Committee (PCC) within 3 months from the date of commissioning of thermal power plant or by 31st March, 2023, whichever is later:

Provided also that coal and lignite based thermal power plants shall not be allowed to further establish or designate any new operational ash pond or dyke:

Provided also that specification of 0.1 hectare per Mega Watt (MW) of an operational ash pond or dyke shall not be applicable for the thermal power plants commissioned before 03rd November, 2009.".

(2) in paragraph B,-

(i) in sub- paragraph (1), for the words, figures and letters "within 300 kms", the words, figures and letters "within a radius of 300 kms" shall be substituted,

(ii) in sub- paragraph (8), for the words "higher than the price of alternative products", the words, brackets and letters "more than the price mentioned in the Schedule of Rates as specified by Central Public Works Department (CPWD) or concerned Public Works Department (PWD) or price of alternative products, if not mentioned in the Schedule of Rates." shall be substituted.

(3) in paragraph -D, -

(i) for sub- paragraph (2), the following sub-paragraph shall be substituted, namely,-

"(2) Persons or user agencies who have been served notice by owner of thermal power plants, if they have already tied up with other agencies for the purpose of utilisation of ash, shall inform the thermal power plant accordingly, and if they cannot use any ash or may use reduced quantity.".

(ii) after sub- paragraph (2), the following sub-para shall be inserted, namely,-

"(3) Persons or user agencies who have been served notice by manufacturers of ash bricks or tiles or sintered ash aggregate or other ash based products, if they have already tied up with other agencies for the purpose of utilisation of ash based products, shall inform the manufacturer of ash bricks or tiles or sintered ash aggregate or other ash based products, accordingly, and if they cannot use ash based products, or may use reduced quantity.".

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

F.No.HSM-9/1/2019-HSM

Sd/-
(Naresh Pal Gangwar)
Addl. Secy.
Issued by:
Ministry of Environment, Forest and Climate Change
New Delhi

Note : *The principal notification was published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (ii), dated the 31st December, 2021, vide number S.O.5481 (E), dated the 31st December, 2021.*

Pharma industry asks govt to exclude freebies to doctors from ambit of I-T

Govt, in a major setback to pharma companies, had early this year decided to bring gifts and other freebies given to the doctors by pharmaceutical companies under the ambit of taxation

The pharmaceutical industry in the country has recommended to the Union Finance Minister to exclude freebies like medicine samples and product reminders meant for doctors from the ambit of Income Tax in the Union Budget 2023-24. In its recommendation to the Union Budget 2023-24, the Indian Drug Manufacturers Association (IDMA) has strongly recommended to the Union Finance Ministry to exclude freebies to doctors from the ambit of I-T.

The Union Finance Ministry, in a major setback to the pharmaceutical companies in the country, had early this year decided to bring gifts and other freebies given to the doctors by pharmaceutical companies under the ambit of taxation. The Finance Bill, 2022 clarified that the gifts and freebies to doctors shall not be treated as business expenditure under section 37 of the Income Tax Act, 1961. In its recommendation, the industry argues that distribution of free samples is directly related to business promotion activity of the pharmaceutical company and no benefit/ perquisite arises to the doctors from such samples.

The industry further argues that Drugs and Cosmetics (D&C) Rules, 1945 also recognizes the practice of providing drugs for distribution to medical professionals as a free sample by providing specific labelling requirements, requiring such samples to be labelled with the words 'Physician's Sample – Not to be sold.

In order to boost the innovation and alternative drugs and raw material, the industry has recommended reinstating the weighted deduction to 200 per cent on the expenditure incurred on scientific research on in-house R&D facilities. Removal of section 206C (1H) in the IT Act and discontinuation of the provisions of section 145A in the IT Act are other issues which have been highlighted by the industry in its recommendation to the Union Budget. The provisions for section 206C (1H) of the IT Act applicable on sale of goods which were made applicable from October 1, 2020 have not been discontinued.

The government has introduced a new section 206C (1H) through Finance Act 2020 to extend the tax collection at source (TCS) provisions to the seller of goods. As per this provision, a seller whose turnover is above Rs 10 crore is required to collect tax, when he receives more than Rs 50 lakh from one buyer during a financial year. It has therefore been recommended to discontinue section 206C (1H) of the IT Act as 194Q covers all the transactions related to goods.

The industry has recommended discontinuing the provisions of section 145A as it becomes an onerous exercise requiring restatement of purchases, sales and inventory. Applicability of both the sections has created complexity and resulted issues faced by the industry in the proper applicability of Tax Deducted at Source (TDS) law. Further industry is required to monitor each and every transaction to avoid TDS and Tax Collection at Source (TCS) issues. Section 145A of the Income Tax Act provides that the valuation of purchase and sales of goods and inventory for the purpose of computation of income from business or profession shall be made on the basis of method of accounting regularly employed by the assessee but this shall be subject to certain adjustments.

The Finance Act 2022 inserted a new Section 194R in the IT Act, 1961 with effect from July 1, 2022. The new Section 194R makes the doctor liable for providing any benefit or perquisite to the patient or consumer in the form of tax deduction at source at 10 per cent, whether the benefit or perquisite is in cash or in kind. Domestic Companies opting for concessional tax rate under Section 115 BAA and Section 115 BAB are not eligible to claim deduction under Section 35(2AB) of the Act. It is also recommended to allow the above weighted deduction benefit under Section 35(2AB) of the Act even to those companies.

Under the provisions of Section 35(2AB) of the Income-tax Act, a company is allowed a weighted deduction at the rate of 200 per cent of expenditure (not being in the nature of cost of any land or building) incurred on approved in-house research and development facilities. Section 32AC of the IT Act provides a deduction of 15 per cent of the actual cost of new assets acquired and installed by a company, if the amount of investment exceeds Rs.25 crores. It has also been recommended that Corporate Social Responsibility (CSR) costs be allowed as a deduction under section 37 of the IT Act. The IT Act expressly stipulates that all expenditure incurred by companies in accordance with Section 135 of the Companies Act 2013 and the CSR Rules be allowed as a deduction under the law of the land. (The author is a freelance journalist with varied experience in different fields)

Source: Sreeja Ramesh, Bizz Buzz, 29.12.2022

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Government plans Rs 2,500-crore PLI scheme to boost Covid vaccine production

The government is likely to unveil a Rs 2,500 crore financial assistance to boost domestic production of vaccine raw materials

With an aim to boost domestic production of vaccine and enhance self-reliance amid a resurgence of Covid cases in neighbouring China, the government is likely to unveil a Rs 2,500-crore financial assistance programme, *Mint* reported, quoting two officials familiar with the development.

The proposal would be similar to the existing production-linked incentive (PLI) schemes. The assistance is likely to be part of the budget and would aim to reduce import dependency for filters, cassettes and cartridges used in vaccine manufacturing and increase production of immunisation shots in the country, the report added.

"We are proposing to expand atmanirbharta (self-reliance) in vaccine manufacturing. We have proposed a financial assistance support scheme for vaccine input material to boost domestic manufacturing. The Budget allocation is expected at Rs 2,500 crore. We have been pursuing this project for a year with multiple departments like finance and biotechnology. This may be proposed in the coming budget," *Mint* quoted one of the two officials.

In 2021, the Department of Pharmaceuticals rolled out three PLI schemes —bulk drugs with an outlay of Rs 6,940 crore, medical devices (Rs 3,420 crore) and pharmaceuticals Rs 15,000 crore) to help cut dependency on China. In March, the government extended the last date for applications for manufacturing Active Pharmaceuticals Ingredients (APIs) under the same PLI scheme.

The Production-Linked Incentive or PLI scheme aims to give companies incentives on incremental sales from products manufactured in domestic units.

Apart from these measures, the Centre is also running a scheme for bulk drug parks for pharma and medical device firms.

In September, the Department of Pharmaceuticals conveyed 'in-principle' approval to three States Viz, Himachal Pradesh, Gujarat and Andhra Pradesh under the Scheme for "Promotion of Bulk Drug Parks." With a financial outlay of Rs 3,000 crores notified in 2020, the scheme would provide financial assistance to three States for establishing Bulk Drug Parks aiming to bring down the cost of manufacturing of bulk drugs.

Maharashtra food and drug administration (FDA), too, is planning to set up a bulk drug park in the state, which alreay accounts for around 20 percent of India's pharmaceutical output.

Source: Money Control News, 22.12.2022

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Trade in rupee with Russia: A good start with tea, pharma, engg goods items

The much-awaited trade settlement in the rupee with sanctions-hit Russia has started, with exporters witnessing such transactions fructifying for items, such as tea,

pharmaceuticals, and engineering goods, people aware of the matter said.

Such transactions kicked off a week ago and are gradually expected to pick up pace amid the government's efforts towards ironing out the teething troubles related to the implementation of the rupee trade mechanism, said one of the persons cited above.

As on December 14, nine Indian banks had received approval to open 17 special vostro rupee accounts for trade settlement with Russia. These Indian banks are UCO Bank, Indian Bank, HDFC Bank, YES Bank, SBI, IndusInd Bank, IDBI Bank, Canara Bank, and Union Bank of India. Two more vostro accounts were opened with Russia's two largest banks --Sberbank and VTB Bank.

After the announcement by the Reserve Bank of India (RBI) in July, the implementation of overseas trade settlement in the rupee was much-awaited, especially in the case of Russia. This was because exports to the country nosedived from March onwards due to the imposition of economic sanctions on it by the United States and its allies.

Exports to the country fell nearly 16 per cent year-on-year to $1.57 billion during the first seven months of the current fiscal year, according to commerce and industry ministry data. Russia was the fifth-largest trade partner during April-October, up from the 25th position in FY22, although this was driven by oil imports by India.

"We are looking at the rupee trade mechanism to pave the way for greater trade between India and Russia. Over a period, we also expect diversification of exports to Russia," said Ajay Sahai, director general and chief executive office of the Federation of Indian Exports Organisation (FIEO).

Even before the Russia-Ukraine conflict, India's top exports to Russia included items, such as electrical machinery, nuclear reactors, pharmaceutical products, iron and steel, and organic and inorganic chemicals. Over the past few months, orders for consumer products, such as tea, coffee, and vegetables, have also started pouring in.

Apart from Russia, overseas trade in the rupee is soon expected to kick start for smaller countries, such as Sri Lanka and Mauritius. Last month, the RBI allowed the opening of eight special vostro rupee accounts with four banks -- State Bank of India, Bank of Ceylon, Indian Bank, and HDFC Bank -- for transactions related to trade with Mauritius and Sri Lanka.

India is also in touch with other nations, such as the United Arab Emirates, Cuba, Sudan, and Luxembourg, to settle international trade in its currency. But nothing has materialised as yet.

Source: Shreya Nandi, Business Standard, 02.01.2023

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IDMA PUBLICATIONS

Sr. No.	Name of Publications	Cost in ₹
1.	**IDMA BULLETIN:** A weekly communication medium for members and other interested readers now in 53rd year. **(Annual Subscription – 48 Issues)** *(Published on 7th, 14th, 21st and 30th of every month)*	
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