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IDMA BULLETIN

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INDIAN PHARMA - GLOBAL HEALTH CARE

INDIAN DRUG MANUFACTURERS' ASSOCIATION

HIGHLIGHTS

WE DO WHAT WE SAY. AND SAY WHAT WE DO. THAT'S OUR RELIABILITY YOU CAN RELY ON.

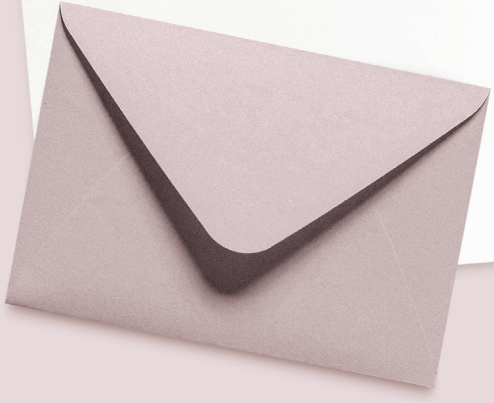
Dear Partner,

Consistency is one of the key factors of our success in the pharmaceutical excipients industry. It is why our customers have been able to trust and depend on us. And esteemed partnerships with the likes of CP Kelco and Nouryon, have only reinforced our adherence to these principles.

CP Kelco is backed by over 200 years of successful operational experience in globally diverse markets. They are trusted the world-over, for their efforts toward responsible business, ethics and environmental practices. Nouryon, formed in 2018, has swiftly become one of the world's top producers of specialty chemicals, with a keen focus on safety and sustainability in all their processes.

Signet takes immense pride in partnering with CP Kelco and Nouryon, the most reliable experts in Hydrocolloid manufacturing, modification and application, as well as Sodium CMC. They provide countless useful products such as Xanthan Gum, Gellan Gum, Pectin and Sodium CMC, that each serve a variety of functions – from viscosity modification to suspension stabilisation, as a thickening agent or gelation.

Signet-ure *reliability*



CPKelco
A HUBER COMPANY

XANTURAL - Xanthan Gum
- Xantural 75 - Fine Particle Size
- Xantural 180 - Coarse Particle Size
- Xantural 11K - Agglomerated Type

KELCOGEL - Gellan Gum
- Kelcogel CG LA - Low Acyl Type
- Kelcogel CG HA - High Acyl Type

GENU PECTIN - Pectin (Citrus)

Nouryon

CEKOL – Carboxymethylcellulose Sodium
- Cekol 30 / 700 P / 2000 P / 4000 P / 10000 P
- Cekol 20000 P / 30000 P / 40000 / 50000 P / 100000
- Majol 25000 S

CHELATES
- Dissolvine Na2-P - Disodium EDTA

Signet
The Complete Excipients Company

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IDMA BULLETIN

Vol. No. 53 Issue No. 43 15 to 21 November 2022

IDMA ACTIVITIES:

INDIAN PHARMACOPOEIA COMMISSION:

NDPS MATTERS:

GOVERNMENT NOTIFICATION:

MoEFCC MATTERS:

NATIONAL NEWS:

Research Opportunities On Repurposing For Orphan Drug Use

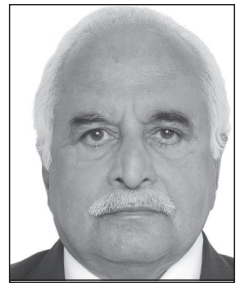
Dr. Gopakumar G. Nair, *Editor, Indian Drugs*

Dear Reader,

The Covid pandemic had its strong negative impacts and influences. However, the pandemic forced in pharma researchers to work intensely on repurposing of drugs such as Molnupiravir, Baricitinib, Tocilizumab, Ivermectin, Favipiravir, Colchicine, Remdesivir, Hydroxychloroquine (HCQ) & chloroquine for treatment of Covid patients. India succeeded in its fight against Covid largely due to the tremendous speed at which the Vaccines and repurposed drugs were launched to combat the pandemic.

Of late, India has woken up to the challenges of meeting the need for finding new drugs to treat rare diseases. USA has been in the forefront of taking encouraging measures and introducing multiple incentives for research on Orphan Drugs. The Orphan Drugs Act, 1983 and subsequent incentives such as 7yrs Market Exclusivity, Research grants, defraying costs, FDA fee waivers, Tax credits to develop such products helped in boosting the introduction and production of nearly 700 Orphan Drugs to treat nearly 7000 - 8000 rare diseases in USA. India has also identified more than 400 rare diseases prevalent in the country, most common ones being rare forms of sickle cell anaemia, some forms of muscular dystrophy, Lysosomal storage disorders, primary immunodeficiency in children, Haemophilia, Thalassemia, Cystic fibrosis and others. Early and accurate diagnosis is still a major hurdle to cross in commencement of treatment. Even then, there are not enough proven and approved drugs to treat rare diseases globally and also in India.

India provides a one-time assistance of Rs. 50,00,000/- for curative treatment of rare diseases for the patients below the poverty line. However, this also is inadequate initiative to combat rare diseases. Globally, including in USA, most of the Orphan Drugs are repurposed forms of already marketed or FDA approved drugs for other diseases. Top Orphan Drugs sales figures globally are as follows:



Dr. Gopakumar G. Nair *is a Ph.D in Organic Chemistry (1966) from National Chemical Laboratory, Pune (Pune University). He was a Post-Doctoral fellow at IIT Bombay, Powai (1967) before joining the Pharma Industry. He was Director of Bombay Drug House P. Ltd., later Chairman of BDH Industries Ltd. as well as CMD of Bombay Drugs & Pharma Ltd., which was merged with Strides Arcolab Ltd. in 2001. Dr. Nair served IDMA as office bearer for many years from 1972 onwards and was Chairman of various Committees for nearly 4 decades. He was the President of IDMA in 1999/2000. Currently, Dr. Nair is the Chairman of the IPR Committee in IDMA.*

Having moved into the Intellectual Property field, he was the Dean of IIPS (Institute of Intellectual Property Studies) at Hyderabad in 2001/2002. Later, he set up his own boutique IP firm, Gopakumar Nair Associates, as well as Gnanlex Hermeneutics Pvt. Ltd., having done his L. L. B. from Mumbai University. He is also CEO of Patent Gurukul and President of Bharat Education Society, Kurla, Mumbai, managing many educational institutions in and around Mumbai.

Top Orphan Drug Sales (13 / 20)

Sr No	Drug	Company	US$ Billion (nearly)
1	Rituxan	Roche	10
2	Revlimid (Lenlidomide caps)	Celgene	10
3	Soliris	Alexion	5
4	Afinitor	Novartis	4
5	Tasigna	Novartis	4 ↑
6	Velcade	J&J / Takeda	3.3 ↓
7	Avonex	Biogen	2 ↓
8	Alimta	Eli Lilly	2
9	Yervoy	BMS	2
10	Sprycel	BMS	2
11	Rebif	Merck/Pfizer	2
12	Kalydeco	Vertex	2
13	Jakavi	Incyte/Novartis	2

Source: https://www.fiercepharma.com/special-report/top-20-orphan-drugs-by-2018

India has been introducing generic biosimilar equivalents for Orphan Drug use promptly and speedily on respective patent expiries. The following table throws light on some of these examples.

INDIAN GENERIC BIOSIMILAR EQUIVALENT TO ORPHAN DRUGS

USA-OD Brand Name	INN/ Generic name	Indian Equivalent	Rare Disease Indications
Avastin	Bevacizumab	Reliance Life Sc , Hetero Drugs Mylan Pharma. Dr. Reddy's + 20 to 30 branded generic	11
Imbruvica	Ibrutinib	Natco	10
Gleevec	Imatinib	100's of branded generic	9
Revlimid	Lenalidomide	Natco	9
Humira	Adalimumab	Zydus Cadila	7
Ilaris	Canakinumab	No generic	6
Neupogen	Filgrastim	15 to 20 branded generic	5
Velcade	Bortezomib	15 branded generic	5
Afinitor	Everolimus	15 to 20 branded generic	5
Arzerra	Ofatumumab	No generic	4
Botox	Botulinum Toxin Type A	Allergan/ Intas /Sun	4

Source: https ://rarediseases.org/wp-content/uploads/2021/03/NORD -Avalere-Report-2021_FNL-1.pdf

Orphan Drug designations and the rare diseases for which approval is granted in USA for Sorafenib are as follows.

1. *Renal cell carcinoma (2004)*
2. *Stage IIB through stage IV melanoma (2006)*
3. *Hepatocellular carcinoma (2006)*
4. *Medullary thyroid cancer, anaplastic thyroid cancer, and recurrent or metastatic follicular or papillary thyroid cancer (2011).*

Observer Research Foundation (ORF) has raised a question if "Rare Diseases in India – 'Orphan' no more?" The prevalence of rare diseases in India is lately being admitted to be deserving serious attention by researchers, pharma industry and the government. Indian pharma researchers need to wake up to the challenges of increasing rare diseases burden (or diagnosis thereof) and come forward to take up repurposing research on more and more potential candidates to make them available as Orphan Drugs to the market. The Government of India is also working on strategies to manufacture rare-disease drugs indigenously as per the latest reports. It is hoped and prayed that India, as in successful combat of Covid, will come forward to provide succour to suffering millions of rare diseases patients in India as well as globally. Indian Pharma researchers are called upon to take up this challenge in earnest with all the urgency the cause deserves.

Courtesy: Indian Drugs, Editorial, 59 (10), October 2022

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In and Around of Process Chemistry Innovation

Dr Rakeshwar Bandichhor, PhD, FRSC, CChem

- *Vice President and Head of Chemistry, API-PR&D, IPDO, Dr. Reddy's Laboratories Limited*
- *Vice Chair, ACS-India (South) Chapter*
- *Membership Chair, ACS-BMGT Section, USA*

Dear Member,

Dr Rakeshwar Bandichhor, Member of R&D Innovation Committee, IDMA made a presentation on ***In and Around of Process Chemistry Innovation*** *during IDMA's- R&D Innovation Committee meeting held on 28th September 2022. Presentation in brief is reproduced below for member's information.*

Dr Rakeshwar Bandichhor

There is ample amount of precedence that emphasizes process chemistry innovation. Contextualizing this with pharmaceutical product and process development warrants reiteration. Innovation is constantly changing paradigm in other words ever evolving. There are various types of innovation namely disruptive, breakthrough, transform and simplification that enable the product and (or) process to have better features. Disruptive innovation signifies the strategy that no one has ever done or adopted to disrupt the industry. Whereas breakthrough innovation entails the story of the events that we (industry in the context

however it is precedented) have never performed that has potential to make us ahead in the game. Transform and simplification way of innovation leads to significant improvement in the existing practices to be among best in class. Process chemistry innovation in pharmaceutical industry is rapidly taking place and it is being exemplified through various types of catalytic transformations by employing newly emerged technologies. Processes for active pharmaceutical ingredients (APIs) have witnessed transition metal catalysed transformations, organocatalytic reactions, access to APIs by using Biocatalysis. Significant number of innovations are taking place in the area of nanomedicines either it is associated with drug substance or drug product. In order to enable all these, it is important to align with management tools for chemical management, availability of practical tools for innovations. It is also equally important to be on sustainable path by employing environmental impact tools. A decade before 2009 has witnessed low hanging fruits having lesser complex pharmaceutical product and now some of them are phasing out and decade starting from 2009 to 2019 is found to have full of relativity complex APIs posing varied degree of challenges right from polymorph, chirality, peptides, Iron nanoparticles, macrocyclic molecules, semisynthetics, natural products, complex oncho-molecules, co-crystals, and oligonucleotides. Interestingly,to mitigate the associated challenges, myriad of chemistry, simulation and engineering toolbox emerged i.e., catalytic processes, QbD (DoE) based process optimization, automated reactors, process safety, process analytical tools, high throughput screening machine, separation technology, electronic lab notebook, advanced characterization tools, engineering optimization tools for unit operation, modelling, Biocatalysis, flow technology and other sustainable practices. Beyond 2019, degree of product complexity is further increased, and newer tools are being emerged to take on the challenges towards greenifying the process. Technology revolution is in the way that would signify the application of predictive science, 3D printing, microwave assisted synthesis, electrochemistry, photocatalysis and AI/ML based approaches. In principle, 50 years from now, science and technology will be dictated by molecular editing, artificial intelligence, and machine learning.

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CDSCO's request for Extension of Timelines to Implement IP 2022 not accepted by IPC

F.No.T.11015/01/2020-AR&D, dated 31st October 2022

To,
Dr. V. G. Somani
Drugs Controller General (India)
Central Drugs Standard Control Organization
FDA Bhawan, Kotla Road
New Delhi 110 002.

1. This has reference to your letter No. 12-01/22-DC (Pt-292) dated 28th October, 2022 on the subject mentioned above. In this regard, it is to inform you that copies of Indian Pharmacopoeia (IP) 2022 were available for purchase from Indian Pharmacopoeia Commission (IPC) after its release on 1st July, 2022 by Hon'ble Union Health Minister. IP 2022 contains new additions and revisions which were already available on IPC website for a long period for public comments before their publication in the IP 2022.

2. IPC has introduced new general chapter on 'Elemental Impurities' which is not referred in the individual monographs, and therefore, remains non-mandatory requirement. However, stakeholders may adopt and implement this general chapter as an alternative to test on heavy metals as per the provisions of the IP General Notices. It is proposed that 'Elemental Impurities' will become mandatory from the next IP edition.

3. Similarly, new general chapter on `Nitrosamine Impurities' has been introduced in IP 2022 for guidance of the stakeholders. This chapter is referred in sartan API monographs of the IP and it is expected that stakeholders adopt this general chapter for determining the nitrosamine impurities in other drugs as well, wherever deemed appropriate and necessary.

4. Currently there are 660 IP Reference Substances and 365 Impurity Standards available from IPC and details may be found on www.ipc.gov.in. This list is continuously increasing and being updated in real time. In addition, IP has already given a provision in Chapter 5.4 Reference Substances to allow use of other pharmacopoeial standards if IP Reference Standard is not available.

5. This year IPC has already given sufficient time for the implementation of new standards included in IP 2022 which is in line with global practices followed by other pharmacopoeias.

In view of above, I regret to inform that request for extension for the implementation of IP 2022 is not acceptable.

Thanking you,

Dr. Rajeev Singh Raghuvanshi,
Secretary-cum-Scientific Director
Indian Pharmacopoeia Commission
Ghaziabad

Public Notice issued by CBN regarding Amendments in Import/Export application form

Dear Member,

IDMA had earlier circulated, informing its members regarding Public Notice, dated February 8th, 2022 requiring all Companies and Traders engaged in the export and import of Narcotic, Psychotropic and Controlled substances to register on the ICEGATE portal, as CBN would soon upload the export and import certificates ONLY onto e-Sanchit and physical couriering of such permits would be discontinued.

Kindly find attached a Public Notice dated November 3rd, 2022 issued by CBN amending the application forms of Import/Export applications and making this mandatory. This will enable to speed up the process of issuance of export/ import permits by CBN and also clearance from the Customs.

Members to kindly make a note of this important and positive change in import/export applications of Narcotic, Psychotropic and Controlled substances.

Regards,

Daara B. Patel
Secretary-General

Public Notice F.No.XVI/13/114/T/P/2022, dated 03rd November, 2022

Reference is invited to Public Notice No. 11/2019 dated 12th July 2019 and 8th December 2019 wherein all the beneficiaries who require to obtain export authorizations, import certificates for import/ export of narcotic drugs, psychotropic substances and NOCs for import/ export of precursor chemicals (controlled substances) are **requested to get themselves registered at ICEGATE portal to avail the benefits of hassle free services of eSANCHIT.** This will enable to speed up the process of clearance of export/ import goods from the Customs.

Once they get registered with the ICEGATE portal they are requested to share the beneficiary code with this office via e-mail to the following email IDs - narcommr@cbn.nic.in; supdt-tech@cbn.nic.in; supdt-precursor@cbn.nic.in; suptd-narco@cbn.nic.in

So that the export authorization, import certificates and NOCs for export/ import of narcotic drugs, psychotropic substances and controlled substances can be uploaded on eSANCHIT portal for faster processing at Customs.

Further, it is to also inform that the application form for Export (EXP-I) and application form for import (IMP-1) & (IMP-2) of NDPS Rules, 1985 has been modified incorporating additional information of Exporter/ Importer with reference to Import-Export Code(IEC) and Beneficiary Code of E-SANCHIT under ICEGATE Portal. The same has been uploaded on CBN Website ie **www.cbn.nic.in** for which may be seen by the Exporter/ Importer.

In view of the above, it is advised to all exporter and importer who applies for issuance of export authorizations, import certificates for import/ export of narcotic drugs and psychotropic substances, must submit their application form for export/import in new prescribed format that has already been uploaded on the CBN website and **the application for export/import received in previous format will not be entertained.**

Narcotics Commissioner, Central Bureau of Narcotics, Ministry of Finance, Government of India, Gwalior, MP

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Notification for Top 300 formulations

Notification G.S.R. 823(E), dated 17th November, 2022

G.S.R. 823(E).—Whereas a draft of certain rules further to amend the Drugs Rules, 1945 was published, as required under sub-section (1) of section 12 and sub-section (1) of section 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940) *vide* notification of the Government of India in the Ministry of Health and Family Welfare (Department of Health and Family Welfare) number G.S.R. 448(E), dated the 14th June, 2022, in the Gazette of India, Extraordinary, Part II, section 3, sub-section (i), inviting objections and suggestions from persons likely to be affected thereby, before the expiry of a period of thirty days from the date on which the copies of the Official Gazette containing the said notification were made available to the public;

And whereas, copies of the said Official Gazette were made available to the public on the 15th June, 2022;

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

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

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

(2) They shall come into force on the 1st day of August, 2023.

2. In the Drugs Rules, 1945 (hereinafter to be referred as the said rules), in rule 96, after sub-rule (5) and before the explanation, the following sub-rules shall be inserted, namely:—

"(6) The manufacturers of drug formulation products as specified in Schedule H2 shall print or affix Bar Code or Quick Response Code on its primary packaging label or, in case of inadequate space in primary package label, on the secondary package label that store data or information legible with software application to facilitate authentication.

(7) The stored data or information referred to in sub-rule (6) shall include the following particulars, namely:—

(i) unique product identification code;
(ii) proper and generic name of the drug;
(iii) brand name;
(iv) name and address of the manufacturer;
(v) batch number;
(vi) date of manufacturing;
(vii) date of expiry; and
(viii) manufacturing licence number.".

3. In the said rules, after Schedule H1, the following Schedule shall be inserted, namely:—

"**SCHEDULE H2**

[S*ee sub-rules (6) and (7) of rule 96]*

Serial number	Brand name of drug formulation
1.	ACILOC 150 MG TABLET 30
2.	ACILOC 300 MG TABLET 20

3.	ACTEMRA 400 MG INJECTION 1
4.	ACTRAPID HUMAN 40 IU INJECTION 10 ML
5.	AEROCORT WITH DOSE COUNTER 50/50 MCG INHALER 200 MDI
6.	AJADUO 25/5 MG TABLET 10
7.	ALLEGRA 120 MG TABLET 10
8.	ALLEGRA 180 MG TABLET 10
9.	AMBISOME 50 MG INJECTION 20 ML
10.	AMICIN 500 MG INJECTION 2 ML
11.	AMLOKIND-AT 50/5 MG TABLET 10
12.	ASCORIL D PLUS NEW 5/2/10 MG SYRUP 100 ML
13.	ASCORIL LS 1/30/50 MG SYRUP 100 ML
14.	ASCORIL PLUS 50/1.25/2 MG EXPECTORANT 120 ML
15.	ASTHAKIND DX 5/2/15 MG SYRUP 100 ML
16.	ASTHALIN 100 MCG INHALER 200 MDI
17.	AUGMENTIN DUO 500/125 MG TABLET 10
18.	AVOMINE 25 MG TABLET 10
19.	AXCER 90 MG TABLET 14
20.	AZEE 500 MG TABLET 5
21.	AZITHRAL 500 MG TABLET 5
22.	BECOSULES CAPSULE 20
23.	BECOSULES Z CAPSULE 20
24.	BETADINE 10 % OINTMENT 20 GM
25.	BETADINE 10 % SOLUTION 100 ML
26.	BETADINE MINT 2 % GARGLE 100 ML
27.	BETNESOL 0.5 MG TABLET 20
28.	BETNOVATE C 0.1/3 % CREAM 30 GM
29.	BETNOVATE N 0.1/0.5 % CREAM 20 GM
30.	BETNOVATE N 0.1/0.5 % CREAM 25 GM
31.	BETT 0.5 ML INJECTION 0.5 ML
32.	BEVON SYRUP 200 ML
33.	BIO D3 MAX 500 MG/0.25MCG/400MCG/120MG CAPSULE 15
34.	BRILINTA 90 MG TABLET 14
35.	BRO ZEDEX 50/1.25/4 MG SYRUP 100 ML
36.	BUDECORT 0.5 MG RESPULES 2 ML
37.	CALCIROL 60000 IU GRANULES 1 GM
38.	CALDIKIND PLUS 500 MG/0.25MCG/400MCG/60MG CAPSULE 10
39.	CALPOL 500 MG TABLET 15
40.	CALPOL 650 MG TABLET 15
41.	CALPOL PEAD 250 MG SUSPENSION 60 ML

42.	CANDIFORCE 200 MG CAPSULE 7
43.	CCM 250 MG TABLET 40
44.	CEFAKIND 500 MG TABLET 10
45.	CEFTUM 500 MG TABLET 4
46.	CEPODEM 200 MG TABLET 10
47.	CHYMORAL FORTE 100000 IU TABLET 20
48.	CIDMUS 24/26 MG TABLET 14
49.	CILACAR 10 MG TABLET 15
50.	CIPREMI 100 MG INJECTION 1
51.	CLARIBID 500 MG TABLET 10
52.	CLAVAM 500/125 MG TABLET 10
53.	CLEXANE 40 MG INJECTION 0.4 ML
54.	CLEXANE 60 MG INJECTION 0.6 ML
55.	COBADEX CZS TABLET 15
56.	CODISTAR 4/10 MG SYRUP 100 ML
57.	COMBIFLAM 400/325 MG TABLET 20
58.	CONCOR 5 MG TABLET 10
59.	COREX DX 4/10 MG SYRUP 100 ML
60.	CREMAFFIN PLUS SF 1.25 ML/3.75ML/3.33MG LIQUID 225 ML
61.	CYPON 275/2 MG SYRUP 200 ML
62.	CYRA D 30/20 MG TABLET SR 10
63.	DALACIN C 300 MG CAPSULE 10
64.	DECA DURABOLIN 50 MG INJECTION 1
65.	DEFCORT 6 MG TABLET 10
66.	DERIPHYLLIN 25.3/84.7 MG INJECTION 2 ML
67.	DEROBIN 1.15/1.15/5.3 % OINTMENT 30 GM
68.	DEXONA (VIAL) 4 MG INJECTION 2 ML
69.	DEXORANGE 160 MG/0.5MG/7.5MCG SYRUP 200 ML
70.	DOLO 650 MG TABLET 15
71.	DOLONEX 20 MG TABLET DT 15
72.	DOXINATE 10/10 MG TABLET 30
73.	DOXT SL 100 MG/5BIU CAPSULE 10
74.	DOXY 1 FORTE L DR 100 MG/5BIU CAPSULE 10
75.	DULCOFLEX 5 MG TABLET 10
76.	DUOLIN 3 1.25 MG/500MCG RESPULES 3 ML
77.	DUPHASTON 10 MG TABLET 10
78.	DYDROBOON 10 MG TABLET 10
79.	DYNAPAR AQ 75 MG INJECTION 1 ML
80.	EASY SIX PREFILLED SYRINGE 0.5 ML

81.	ECOSPRIN AV 10/75 MG CAPSULE 15
82.	ECOSPRIN GOLD 75/20/75 MG TABLET 15
83.	ELAXIM 40 MG INJECTION 1
84.	ELECTRAL SACHET 21.8 GM
85.	ELIQUIS 2.5 MG TABLET 10
86.	ELIQUIS 5 MG TABLET 10
87.	ELTROXIN 100 MCG TABLET 120
88.	ENTEROGERMINA 2 BIU ORAL SUSPENSION 5 ML
89.	EXHEP 40 MG PREFILLED SYRINGE 0.4 ML
90.	FABIFLU 200 MG TABLET 34
91.	FABIFLU 400 MG TABLET 17
92.	FABIFLU COPACK 800 MG TABLET 18
93.	FARONEM 200 MG TABLET 10
94.	FARONEM 300 MG TABLET ER 10
95.	FORACORT 20/500 MCG RESPULES 2 ML
96.	FORACORT 6/200 MCG ROTACAP 30
97.	FORACORT 6/400 MCG ROTACAP 30
98.	FORXIGA 10 MG TABLET 14
99.	GABAPIN NT 400/10 MG TABLET 15
100.	GALVUS 50 MG TABLET 15
101.	GALVUS MET 50/1000 MG TABLET 15
102.	GALVUS MET 50/500 MG TABLET 15
103.	GEFTINAT 250 MG TABLET 30
104.	GELUSIL MPS 250/50/250 MG LIQUID 200 ML
105.	GEMCAL 500 MG/0.25MCG/7.5MG CAPSULE 15
106.	GEMER 2/500 MG TABLET 10
107.	GIBTULIO 25 MG TABLET 10
108.	GLUCONORM-G 2/500 MG TABLET 15
109.	GLYCOMET GP 1/500 MG TABLET 15
110.	GLYCOMET GP 2/500 MG TABLET SR 15
111.	GLYNASE MF 5/500 MG TABLET 10
112.	GLYXAMBI 25/5 MG TABLET 10
113.	GRILINCTUS 60/2.5/5/50 MG SYRUP 100 ML
114.	GUDCEF 200 MG TABLET 10
115.	GUDCEF CV 200/125 MG TABLET 10
116.	HCQS 200 MG TABLET 15
117.	HEXAXIM INJECTION 0.5 ML
118.	HUCOG HP 5000 IU INJECTION 1 ML
119.	HUMINSULIN 30/70 100 IU CARTRIDGE 3 ML

120.	INFANRIX HEXA INJECTION 0.5 ML
121.	ISTAMET 50/500 MG TABLET 15
122.	IVABRAD 5 MG TABLET 15
123.	IVERMECTOL NEW 12 MG TABLET 2
124.	JALRA M 50/500 MG TABLET 15
125.	JANUMET 50/1000 MG TABLET 15
126.	JANUMET 50/500 MG TABLET 15
127.	JANUVIA 100 MG TABLET 7
128.	JARDIANCE 10 MG TABLET 10
129.	JARDIANCE 25 MG TABLET 10
130.	KABIMOL 1000 MG INFUSION 100 ML
131.	KARVOL PLUS CAPSULE 10
132.	KENACORT 40 MG INJECTION 1 ML
133.	KETOROL 10 MG TABLET DT 15
134.	KETOSTERIL TABLET 20
135.	LANTUS 100 IU CARTRIDGE 3 ML
136.	LANTUS SOLOSTAR 100 IU DISPOSABLE PEN 3 ML
137.	LEVERA 500 MG TABLET 15
138.	LEVIPIL 500 MG TABLET 10
139.	LIBRAX 2.5/5 MG TABLET 20
140.	LIMCEE CHEW ORANGE 500 MG TABLET 15
141.	LIPAGLYN 4 MG TABLET 10
142.	LMWX 40 MG INJECTION 0.4 ML
143.	LOBATE GM NEO 0.05/0.5/2 % CREAM 15 GM
144.	LONOPIN 40 MG INJECTION 0.4 ML
145.	LOSAR 50 MG TABLET 15
146.	LOSAR H 50/12.5 MG TABLET 15
147.	MACBERY XT 50/1.25/4 MG SYRUP 100 ML
148.	MAGNEX FORTE 1000/500 MG INJECTION 1
149.	MANFORCE 100 MG TABLET 4
150.	MANFORCE 50 MG TABLET 9
151.	MAXTRA 5/2 MG SYRUP 60 ML
152.	MEFTAL SPAS 10/250 MG TABLET 10
153.	MEGALIS 20 MG TABLET 4
154.	MEGANEURON OD PLUS 1500 MCG CAPSULE 10
155.	MENACTRA INJECTION 0.5 ML
156.	MERO 1000 MG INJECTION 1
157.	MEROMAC 1000 MG INJECTION 1
158.	MERONEM 1000 MG INJECTION 1

159.	MEROZA 1000 MG INJECTION 1 ML
160.	MIFEGEST KIT 200 MG/200MCG TABLET 1
161.	MIKACIN 500 MG INJECTION 2 ML
162.	MINIPRESS XL 5 MG TABLET XL 30
163.	MIXTARD HM PENFILL 30/70 100 IU INJECTION 3 ML
164.	MIXTARD HUMAN 30/70 40 IU INJECTION 10 ML
165.	MIXTARD HUMAN 50/50 40 IU INJECTION 10 ML
166.	MONOCEF 1000 MG INJECTION 5 ML
167.	MONOCEF O 200 MG TABLET 10
168.	MONOCEF SB 1000/500 MG INJECTION 1
169.	MONTAIR LC 10/5 MG TABLET 15
170.	MONTAZ 1000/125 MG INJECTION 1
171.	MONTEK-LC 10/5 MG TABLET 10
172.	MONTICOPE 10/5 MG TABLET 10
173.	MOX 500 MG CAPSULE 15
174.	MOX CV 500/125 MG TABLET 10
175.	MOXCLAV 500/125 MG TABLET 10
176.	MOXIKIND CV 500/125 MG TABLET 10
177.	MUCAINE MINT 10/291/98 MG GEL 200 ML
178.	MUCINAC SF ORANGE 600 MG TABLET 10
179.	NEBICARD 5 MG TABLET 10
180.	NEFROSAVE 150/500 MG TABLET 15
181.	NEUROBION FORTE TABLET 30
182.	NEXPRO 40 MG TABLET 15
183.	NEXPRO RD 30/40 MG CAPSULE 10
184.	NIKORAN 5 MG TABLET 20
185.	NISE 100 MG TABLET 15
186.	NITROCONTIN 2.6 MG TABLET CR 30
187.	NOVOMIX 100 IU CARTRIDGE 3 ML
188.	NOVOMIX 30/70 MG FLEXPEN 3 ML
189.	NOVORAPID 100 IU CARTRIDGE 3 ML
190.	NUROKIND LC 500 MG/1.5MG/1500MCG TABLET 15
191.	NUROKIND PLUS RF 1500 MCG CAPSULE 10
192.	O2 200/500 MG TABLET 10
193.	OMEZ 20 MG CAPSULE 20
194.	OMEZ D 30/20 MG CAPSULE SR 15
195.	OMNIKACIN 500 MG INJECTION 2 ML
196.	ONDERO 5 MG TABLET 10

197.	ONDERO MET 2.5/500 MG TABLET 10
198.	OROFER FCM INJECTION 10 ML
199.	OROFER-XT 100/1.5 MG TABLET 10
200.	OROFER-XT PLUS 30 MG/500MCG/500MCG SUSPENSION 200 ML
201.	OTRIVIN OXY FAST RELIEF 0.05 % SPRAY 10 ML
202.	OVRAL L 0.03/0.15 MG TABLET 21
203.	OXRA 10 MG TABLET 14
204.	PAN 40 MG TABLET 15
205.	PAN D 30/40 MG CAPSULE 15
206.	PANDERM PLUS PLUS 0.05/0.5/2 % CREAM 15 GM
207.	PANTIN IV 40 MG INJECTION 10 ML
208.	PANTOCID 40 MG TABLET 15
209.	PANTOCID DSR 30/40 MG CAPSULE 15
210.	PANTODAC 40 MG TABLET 15
211.	PANTODAC DSR 30/40 MG CAPSULE 15
212.	PANTOP 40 MG INJECTION 10 ML
213.	PANTOP 40 MG TABLET 15
214.	PANTOP D 10/20 MG CAPSULE 10
215.	PANTOP D SR 30/40 MG CAPSULE SR 10
216.	PHENSEDYL COUGH LINCTUS 4/10 MG SYRUP 100 ML
217.	PIPZO 4000/500 MG INJECTION 10 ML
218.	PRACTIN 4 MG TABLET 10
219.	PREGA NEWS KIT 6
220.	PREVENAR 13 INJECTION 0.5 ML
221.	R.B TONE SYRUP 200 ML
222.	RABLET-D 30/20 MG CAPSULE 10
223.	RANTAC 150 MG TABLET 30
224.	RAZO 20 MG TABLET 15
225.	RAZO D 30/20 MG TABLET 15
226.	REFRESH TEARS 0.5 % EYE DROPS 10 ML
227.	REJUNEX-CD3 TABLET 10
228.	REMDAC 100 MG INJECTION 1
229.	ROSUVAS 10 MG TABLET 15
230.	ROSUVAS 20 MG TABLET 10
231.	RYZODEG 2.56/1.05 MG PENFILL 3 ML
232.	SARIDON 250/50/150 MG TABLET 10
233.	SEROFLO 50/250 MCG ROTACAP 30
234.	SHELCAL 500 MG/250IU TABLET 15
235.	SHELCAL XT 500 MG/2000IU/1500MCG/1MG/20MG TABLET 15

236.	SILODAL 8 MG TABLET 10
237.	SILODAL D 8/0.5 MG TABLET 10
238.	SINAREST 125/5/1 MG SYRUP 60 ML
239.	SINAREST NEW 500/10/2 MG TABLET 10
240.	SINAREST NEW 500/10/2 MG TABLET 15
241.	SKINLITE 2/0.1/0.025 % CREAM 25 GM
242.	SOMPRAZ D 30/40 MG CAPSULE 15
243.	SPASMO PROXYVON PLUS 10/325/50 MG CAPSULE 8
244.	SPEGRA 50/200/25 MG TABLET 30
245.	STAMLO 5 MG TABLET 30
246.	STAMLO BETA 50/5 MG TABLET 15
247.	STEMETIL 5 MG TABLET MD 15
248.	SUCRAFIL O 1000/20 MG GEL 200 ML
249.	SUMO 100/325 MG TABLET 15
250.	SUMO L IV 1000 MG INFUSION 100 ML
251.	SUPRADYN TABLET 15
252.	SYNFLORIX INJECTION 1
253.	T BACT 2 % OINTMENT 15 GM
254.	T BACT 2 % OINTMENT 5 GM
255.	TARGOCID 400 MG INJECTION 1 ML
256.	TAXIM O 200 MG TABLET 10
257.	TAZOMAC 4000/500 MG INJECTION 2 ML
258.	TELEKAST-L 10/5 MG TABLET 15
259.	TELMA 40 MG TABLET 30
260.	TELMA AM 40/5 MG TABLET 15
261.	TELMA H 40/12.5 MG TABLET 15
262.	TELMIKIND 40 MG TABLET 10
263.	TELMIKIND AM 40/5 MG TABLET 10
264.	TELMIKIND H 40/12.5 MG TABLET 10
265.	THROMBOPHOB OINTMENT 20 GM
266.	THYRONORM 100 MCG TABLET 120
267.	THYRONORM 25 MCG TABLET 120
268.	THYRONORM 50 MCG TABLET 120
269.	TOSSEX NEW 4/10 MG SYRUP 100 ML
270.	TRAJENTA 5 MG TABLET 10
271.	TRESIBA FLEXTOUCH 100 IU DISPOSABLE PEN 3 ML
272.	TUSQ DX 5/2/15 MG SYRUP 100 ML
273.	UDILIV 150 MG TABLET 15
274.	UDILIV 300 MG TABLET 15

275.	ULTRACET 325/37.5 MG TABLET 15
276.	UNIENZYME TABLET 15
277.	UNWANTED 72 1.5 MG TABLET 1
278.	UNWANTED KIT 200 MG/200MCG TABLET 1
279.	UPRISE D3 60000 IU CAPSULE 8
280.	URIMAX 0.4 MG CAPSULE 20
281.	URIMAX D 0.4/0.5 MG TABLET 15
282.	URSOCOL 300 MG TABLET 15
283.	VARILRIX INJECTION 0.5 ML
284.	VELOZ D 30/20 MG CAPSULE SR 10
285.	VELPANAT 400/100 MG TABLET 28
286.	VERTIN 16 MG TABLET 15
287.	VOLINI 1.16 % SPRAY 40 GM
288.	VORIER 200 MG TABLET 4
289.	VOVERAN SR 100 MG TABLET SR 15
290.	VYMADA 24/26 MG TABLET 14
291.	WYSOLONE 10 MG TABLET DT 15
292.	WYSOLONE 5 MG TABLET DT 15
293.	XONE 1000 MG INJECTION 5 ML
294.	ZAVICEFTA 2000/500 MG VIAL 10 ML
295.	ZEDEX 4/5/50 MG SYRUP 100 ML
296.	ZERODOL P 100/325 MG TABLET 10
297.	ZERODOL SP 100/325/15 MG TABLET 10
298.	ZIFI 200 MG TABLET 10
299.	ZORYL-M 2/500 MG TABLET 20
300.	ZOSTUM 1000/500 MG INJECTION 1.”.

F.No. X.11035/32/2019-DR

Dr Mandeep K Bhandari,
Joint Secretary,
Ministry of Health and Family Welfare,
Department of Health and Family Welfare,
New Delhi

Note: *The Drug Rules, 1945 were published in the Official Gazette vide notification number F. 28-10/45-H(1), dated 21st the December, 1945 and were last amended vide notification number G.S.R. 654(E), dated the 24th August, 2022.*

Environment (Protection) Rules 1986 amended (4th Amendment of 2022)

Notification G.S.R.811(E), dated 10th November, 2022

In exercise of the powers conferred by sections 6 and 25 of the Environment (Protection) Act, 1986 (29 of 1986), the Central Government hereby makes the following draft rules, as required under sub-rule (3) of the rule 5 of the Environment (Protection) rules 1986, for the information of the public likely to be affected thereby; and notice is hereby given that the said draft notification shall be into consideration on or after the expiry of a period of sixty days from the date on which copies of the Gazette containing this notification are made available to the public.

Any person interested in making any objections or suggestions on the proposals contained in the draft notification may forward the same in writing, for consideration of the Central Government within the period specified above to the Secretary, Ministry of Environment, Forest and Climate Change, Indira Paryavaran Bhawan, Jor Bagh Road, New Delhi – 110 003, or send it to the email address: **mscb.cpcb@nic.in** and **sonu.singh@gov.in.**

1. Short title and Commencement

(1) These rules may be called **Environment (Protection) (Amendment) Rules, 2022.**

(2) They shall come into force after one year from the date of their publication in the Official Gazette.

2. In the Environment (Protection) Rules 1986, in Schedule I, at serial number 55 relating to Common Effluent Treatment Plants: B. Treated Effluent Quality Standards of Common Effluent Treatment Plant:

i. The terminology for general quality parameter "Biological Oxygen Demand (BOD)3, 27°C", (Concentration in mg/l), shall be substituted by the terminology "Biochemical Oxygen Demand (BOD)3, 270C".

ii. The general quality parameter "Fixed Dissolved Solids, FDS, (Concentration in mg/l), shall be substituted by the "Total Dissolved Solids (TDS)".

iii. The specific quality parameter "Trivalent Chromium", shall be substituted by "Total Chromium".

iv. The existing note "Shall not exceed more than 5°C above ambient water temperature" for the specific quality parameter "Temperature (◦C)", shall be substituted by note "Shall not exceed more than 5°C above ambient temperature of the receiving water body".

v. The existing Note no. 2, shall be substituted by "The maximum permissible Total Dissolved Solids (TDS) limit w.r.t. treated effluent from a Common Effluent Treatment Plant shall be 2100 mg/l. However, the limit may be relaxed by the concerned SPCB/PCC, in case where TDS in intake (supplied) water to the member industries is above 1100 mg/l and a maximum contribution up to 1000 mg/l is permitted, provided the maximum value of 3100 mg/l is not exceeded in the treated effluent from CETP".

vi. A Note no. 5 shall be inserted "For a CETP, if the sectoral norms of the predominant contributing industrial sector are stringent than the CETP norms, the same shall be applicable and supersede the CETP standards for those specific quality parameters".

Naresh Pal Gangwar, Addl. Secy. Ministry of Environment, Forest and Climate Change, New Delhi.

Note : *The principle rules were published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i) vide number S.O. 844(E), dated the 19th November, 1986 and lastly amended vide notification G.S.R. 682(E), dated the 05th September, 2022.*

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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

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DoP asks industry associations to submit tax proposals for Budget 2023-24

As Budget 2023-24 preparations have kicked off, the Department of Pharmaceuticals (DOP) has reached out to industry associations seeking tax proposals with respect to basic customs duty and income tax for the forthcoming Budget.

"The Budget 2023-24 preparations have commenced. Among other proposals for the pharmaceutical and medical device sectors, tax proposals form an important element of the Budget and the same are to be submitted to the Department of Revenue for finalization before the same are considered in the Budget announcements by the Department of Economic Affairs. Accordingly, industry associations are requested to share the following tax proposals with proper rationale for examination by the Department viz. basic customs duty proposals for drugs, medical devices and income tax proposals for drugs/medical devices sector," said Sanjay Meena, Under Secretary (Policy & FDI), Department of Pharmaceuticals.

It is further informed that the GST proposals do not come under the ambit of Budget and are taken up round the year by the GST Council separately. Therefore, GST rate proposals are not required at this stage from the associations, stated Meena.

The last date for sending tax proposals to the Department of Pharmaceuticals is October 31, 2022.

Basic customs duty is applicable on imported items that fall under the ambit of Section 12 of the Customs Act, 1962. Currently, custom duty on import of active pharmaceutical ingredients (APIs) is 7.5 per cent and IGST

for import of APIs stands at 18 per cent. There is also a 10 per cent surcharge of custom duty levied on import of APIs. Besides this, there is also anti-dumping duty on import of certain APIs. It varies from product to product. For the financial year 2020-21, imports of active pharmaceutical ingredients stood at Rs. 28,529 crore while exports were at Rs. 32,856 crore.

The Department of Pharmaceuticals is implementing three schemes for promoting domestic manufacturing of APIs to ensure their sustainable domestic supply and make India Atma Nirbhar. The schemes are -- production linked incentive (PLI) scheme for promotion of domestic manufacturing of critical key starting materials/drug intermediates and active pharmaceutical ingredients in India, Scheme for Promotion of Bulk Drug Parks, and production linked incentive scheme for pharmaceuticals.

With this, India's import dependence for APIs is likely to reduce by 25 per cent by around 2024, said sources.

The Pharmaceuticals Export Promotion Council of India (Pharmexcil) also sought inputs from members on tax proposals for Budget 2023-24. The proposals include basic customs duty proposals for drugs, medical devices and income tax proposals for drugs/medical devices sector.

Source: Laxmi Yadav, Pharmabiz, 20.10.2022

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DoP amends operational guidelines for PLI scheme to change norms on claim submission

The Department of Pharmaceuticals (DoP) has amended the operational guidelines for the production linked incentive (PLI) scheme for pharmaceuticals once again, to allow the applicants to submit the claim of disbursement of incentive on a quarterly and half yearly basis, apart from the existing norm for submission of claim on an annual basis.

DoP, in a corrigendum issued recently, said that an applicant may submit a claim for disbursement of incentive on quarterly/half yearly/annual basis, though the condition that the claims for any period shall be made only once, unless withdrawn, and no subsequent part claims shall be allowed for the same period, stands.

The clams for disbursement of incentive shall be filed along with supporting documents immediately after the end of the quarter/half year/year, within one month. According to the previous guidelines, the claims for disbursement of incentive shall be filed along with supporting documents within one month of the closure of the given financial year.

The condition that if the claim is found to be in order, 75 per cent of it shall be released and the remaining 25 per cent shall be released after submission of final audited accounts of the company, will continue to be the same after the amendment.

The timeframe for the Project Management Agency (PMA) to process the claim for disbursement has also been reduced with the amendment.

The PMA shall process claim for disbursement of incentive within 30-45 days from the date of receipt of such claim and make appropriate recommendations to the DoP. Earlier, the PMA was directed to process claim for disbursement of incentive within 60 days from the date of receipt of such claim.

The DoP, which issued the operational guidelines of the PLI scheme for pharmaceuticals on June 1, 2021, has issued corrigenda on the guidelines twice, first on June 30, and second on August 13, 2021.

The objective of the scheme is to enhance India's manufacturing capabilities by increasing investment and production in the sector and contributing to product diversification to high value goods in the pharmaceutical sector. One of the further objectives of the scheme is to create global champions out of India who have the potential to grow in size and scale using cutting edge technology and thereby penetrate the global value chains.

The scheme will provide financial incentives on the incremental sales (over Base Year) of pharmaceutical goods and in-vitro diagnostic medical devices to selected applicants based on pre-defined selection criteria.

The incentives will be paid for a maximum period of 6 years for each participant depending upon the threshold investments and sales criteria to be achieved by the applicant. The total quantum of the incentive for

the scheme is Rs. 15,000 crore. SIDBI is the Project Management Agency for the scheme.

The applications were invited in three different categories of applicants to ensure fair competition and broad coverage amongst the industry players. The categories were based on the size of the applicant as determined by the global manufacturing revenues from pharmaceutical manufacturing.

The DoP has said that the scheme received a very good response from the industry and a total of 278 applications were received by the closing date of August 31, 2021 against which a maximum of 55 applicants were to be selected.

The scheme covers three different product categories for which applicants have applied under the scheme. These products are expected to give an impetus to innovation, R&D and widening of product profile of India pharmaceutical industry.

Source: Gireesh Babu, Pharmabiz, 27.10.2022

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