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IDMA BULLETIN

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INDIAN PHARMA - GLOBAL HEALTH CARE

INDIAN DRUG MANUFACTURERS' ASSOCIATION

IDMA & APTAR Pharma Webinar on
Container Closure Systems Testing: Leak detection and Extractable/ Leachable studies in an age of complex drug formulations
to be held on 26th May 2022, 5.00 pm to 6.30 pm
(Details on Page No. 6)

HIGHLIGHTS

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• NUTRIOSE

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IDMA BULLETIN

Vol. No. 53 **Issue No. 18** **08 to 14 May 2022**

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Report of Technical Program on Role of Indian Pharmacopeia in Effecting Quality Control of Drugs by IPA, IDMA & LMCP

Indian Pharmaceutical Association, Gujarat State Branch jointly with Indian Drug Manufacturers' Association-Gujarat State Board and L M College of Pharmacy organized Technical Education Program on the Role of Indian Pharmacopeia in Effecting Quality Control of drugs on 6th May 2022 at Ahmedabad University Auditorium, Ahmedabad in the presence of the Indian Pharmacopeia Commission, Ghaziabad senior officials.

The program was organized in three parts. One, the keynote address by Dr Rajeev Singh Raghuvanshi, Secretary cum Scientific Director, IPC, Felicitation of keynote speaker and two septuagenarian analysts, and a Panel discussion on Indian Pharmacopeia-Opportunities & Challenges where seven experts deliberated.

After the invocation, Dr Jayant Dave gave a welcome address on behalf of all organizing units and conveyed that IP is perhaps the most frequently used acronym by all connected with the pharma industry and IP is on way to becoming at par with global pharmacopeias in tune with the recent utterance of Prime Minister's in Europe that India is going global.

Dr Rajiv Singh Raghuvanshi, Secretary cum scientific Director, IPC made a very lucid presentation on the Role of Indian Pharmacopeia in ensuring the availability of quality medicines. He explained the pre-approval role of IPC in terms of setting up General chapters and testing new drugs prior to approval by CDSCO. He laid more focus on the post-approval role of IPC in setting up monographs and providing Reference substances and impurity standards and gave an account of the huge progress made by IPC in these areas. He lamented that only 7 percent of the manufacturers are sourcing impurities from IPC which is the only official source of procuring them. He held that IP standards of quality are at par with international quality standards. He gave a thrust on the importance of the dissolution test and conveyed that the dissolution test should be both discriminatory and biorelevant as it is an important QC tool for ensuring batch-to-batch uniformity and ensuring adequate bioavailability. He conveyed that a new edition of IP which is expected to be released in June 2022 will have specifications of Drug release for modified release drug products, unlike previous editions. He presented case studies of Albendazole tablets, and Itraconazole capsules to impress upon the importance of the dissolution test. The speaker also expressed happiness at his first visit to Gujarat and appreciated the contribution of LMCP in development of pharmacy profession and the entrepreneurial spirit of Gujrat.

Dr Raghuvanshi was felicitated by offering citation and shawl by all organizing units particularly for expediting development and availability of IP Reference Standards and impurity standards to facilitate testing as per pharmacopeial specifications and ensure high quality of medicines. Dr H G Koshia, Commissioner Food and Drugs Control Association, Gujarat and Sri Jayantkumar, Deputy Drugs Controller, Ahmedabad gave brief address on the occasion referring to IPC contribution since its inception in 2005 and future directions.

In the context of Azadi ka Amrit Mahotsav in progress, the organizers felicitated Mr Dhananjay H Brahmbhatt and Mr Haresh C Ray for continuing to render analytical services to industry at the right age of 75+ years by offering citation at the hands of Chief guest Dr Raghuvanshi.

This was followed by Panel discussion on Indian Pharmacopeia- Opportunities and Challenges where seven professionals shared their expert views. Dr Robinsingh, Principal Scientific Officer, IPC gave a brief account of IP reference substances and monographs of fixed dose combinations by IPC to ensure quality control of drugs. Dr Viranchi Shah, National President, IDMA stressed on the need of industry to work in sync with regulators and academia and volunteered all support of IDMA for development and implementation of drug standards. Mr Anurag Mehta, Chief Operating Officer, Synbiotics Ltd, Vadodara talked about key points in microbiological attributes of non-sterile products and establishing correlation between microbiological and HPLC methods of analysis. Mr Paresh Parmar, Government analyst

and Quality Manager at Food and Drugs Laboratory, Vadodara talked about evolution in quality specifications and testing methodology with every new edition of IP. Mr Gaurang Oza, CEO Vaibhav Analytical Services and member of IP committee emphasized on developing specifications commensurate with requirements in India and also referred to improving testing specifications and methods for testing of herbal drugs. Dr Shrinivas Savale, Director, AIC LMCP Foundation referring to Rifampicin fixed dose combinations emphasized on the need for specific methods for dissolution testing and also touched upon testing requirements for biosimilars and biologics in view of their increasing role in therapy. Dr Rajeev Singh Raghuvanshi welcomed any meaningful contribution from stake holders for improvement of IP contents and invited interested professionals to join one pharmacopeial group on Telegram platform and help mutually solve the problems. He also expressed the need for expanding the scope of general chapter on Impurities to expand its scope to include FDCs or products not official in IP. Dr Jayant Dave, Adjunct professor at LMCP and President IPA GSB effectively moderated the panel discussion and presented some relevant scientific points from regulatory standpoint. The panel members addressed questions from audience. Prof Maheshwari and Mr V R Shah also shared some suggestions and clarifications.

Dr Praful Bharadia, Professor at LMCP and Hon. Secretary, IPA GSB presented a hearty vote of thanks. Dr Mahesh Chhabria, Principal LMCP, Dr Sandip Dholakia, Joint Secretary IPA GSB, Dr Shrenik Shah, Chairman IDMA GSB,Mr Sumit Agrawal, Hon Secretary, IDMA GSB, Mr Rajiv Shah, Office Secretary, IDMA GSB, Mr Gaurang Oza, active member of IPA and IDMA GSB, faculty and PG students of LMCP rendered dedicated services to make the program a grand success. Dr Ketan Ranch and Dr Palak Parikh, faculty at LMCP effectively anchored the program. Over 200 persons from industry, regulatory bodies and academia enthusiastically participated and greatly benefited from the proceedings.

Glimpses of Seminar

INDIAN DRUG MANUFACTURERS' ASSOCIATION (IDMA)
102, Poonam Chambers, A Wing, 1st Floor, Dr. Annie Besant Road, Worli, Mumbai - 400 018. Maharashtra, India.
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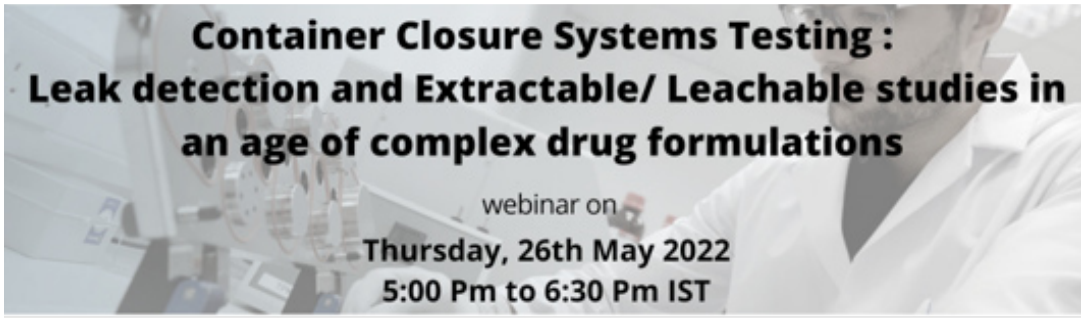
IDMA and APTAR Pharma Webinar on Container Closure Systems Testing: Leak detection and Extractable/ Leachable studies in an age of complex drug formulations

Dear Member,

Aptar Pharma and Indian Drug Manufacturers' Association (IDMA) is organizing a webinar the above mentioned subject on Thursday, 26th May 2022 at 5:00 PM to 6:30 PM.

The Moderator of the Webinar : Dr. Prasant Bodhe, Principal Consultant CliniSearch.



Speakers for the Webinar

Kindly note that there are no registration fees for this webinar but prior registration is compulsory.

Here is your Registration link : **REGISTER NOW**

Webinar Registration page link :
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Looking forward to your support and participation in making this webinar a grand success.

Thanks & regards,

Daara B Patel, *Secretary – General*
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Trade Notice - For delay in clearance of import consignment at AIASL (Air India) shed at ACC Mumbai

Trade Notice No. BCBA/KR/107:174/2022, date 11th May 2022

To
All Trade Bodies / importers / Exporters

Attention of Importer Exports, Trade Association. This is to bring to your kind notice that at ACC Mumbai, there are 2 Custodians operating, one is MIAL and Air India. However, the performance standards with AIASL (AI Airport Services Ltd) {Formerly known as Air India Air Transport Services Ltd.,- AIATSL} are not upto the mark and the trade and industry is facing following issues:

- Replacement of old Forklifts with better battery management and additional new Forklifts to existing fleet.
- Adequate Racking and binning systems
- Ventilation in both warehouses with adequate lighting in examination and storage areas
- Repair of warehouse roofing/ceiling which has continuous water leakage during monsoon
- Installation of CCTV system for security and safety of cargo
- Resurfacing of warehouse flooring and filling of potholes,clearing of mud and oil accumulated in the warehouse for safe maneuvering of forklifts and trolleys
- Shortage of Loaders, forklift operators, and supervisory staff
- Delay in flight segregation
- Delay in handling of consignments for examination and delivery

Brihanmumbai Custom Brokers Association (BCBA) has been addressing this issue with Ministry of Civil Aviation and Air India for past 5 years as well as in PTFC, CCFC meeting being held under chairmanship of Customs.

Letter Ref	Date	Addressed to
BCBA/KS/406/2017	19.7.2017	CMD Air India
BCBA/DM/283/2017	18.5.2017	Regional Director, Air India, Mumbai
BCBA/SH/553/2018	06.9.2018	CMD Air India
BCBA/KS/425/2018	27.10.2018	Secretary, Ministry of Civil Aviation, New Delhi
BCBA/KS/428/2018	Q4.12.2018	Secretary, Ministry of Civil Aviation, New Delhi
BCBA/SH/674/2018	15.10.2018	CMD Air India
BCBA/DM/803/2018	14.12.2018	Economic Advisor, Ministry of Civil Aviation
BCBA/DM/810/2018	19.12.2018	Economic Advisor, Ministry of Civil Aviation
BCBA KR/34:187/2021	22.5.2021	CMD Air India
BCBA/SH/21:318/2021	05.10.2021	CMD Air India
BCBA/SH/30:143/2022	13.4.2022	Sr Eco Advisor, Civil Aviation
BCEIA/SH:29:140/2022	13.4.2022	CMD Air India

At present, following flights are being handled by AIASL (AI Airport Services Ltd) (Formerly known as Air India Air Transport Services Ltd.,-AIATSL)

- *Air India*
- *Air Mauritius*
- *Egypt Air*
- *Fly Dubai*
- *Air Tanzania*

- *TYO Airlines*

Foreign Carriers

- *Thai Airways*
- *Kuwait Airlines*
- *Malaysian Airlines*
- *Korean Air*
- *United Airlines*
- *Lot Polish Airlines, etc to name a few*

All Trade Bodies, Importers, Exporters are requested to note that for any import or export consignment being booked on above flights, may result in delay in clearance till the time performance standards, man power, material handling equipment's, like forklifts, trolleys etc are augmented by AIASL (AI Airport Services Ltd) [Formerly known as Air India Air Transport Services Ltd.,-AIATSL). Inspite of assurance past several years, there has been no progress.

In such a scenario, Custom Brokers at Mumbai Air Cargo Complex, shall not responsible for any issues of delay in clearance, damage / pilferage to import cargo, and any handling related problems due to reasons cited above.

Regards,

For Brihanmumbai Custom Brokers Association

Kiran Rambhia, President

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Anti-dumping duty imposed on 'Amoxycillin' also known as 'Amoxycillin Trihydrate' from People's Republic of China PR revoked

Notification No.13/2022-Customs (ADD), dated 11th May 2022

In exercise of the powers conferred by sub-sections (1) and (5) of section 9A of the Customs Tariff Act, 1975 (51 of 1975), the Central Government revokes the anti-dumping duty imposed on **'Amoxycillin' also known as 'Amoxycillin Trihydrate',** falling under tariff item 2941 10 30 of the First Schedule to the said Act, originating in or exported from **China PR** and imported into India and hereby rescinds the notification of the Government of India in the Ministry of Finance (Department of Revenue) No. 21/2017-Customs(ADD) dated the 16th May, 2017, published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i) vide number G.S.R.476(E), dated 16th May, 2017, except as respect things done or omitted to be done before such rescission.

F.No.CBIC-190354/76/2022-TRU

Nitish Karnatak, Under Secretary, Ministry of Finance, Department of Revenue, New Delhi.

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The Legal Metrology (Packaged Commodities) Amendment Rules, 2022

Notification G.S.R. 226(E), dated 28th March, 2022

In exercise of the powers conferred by sub-sections (1),read with clauses (j) and (q) of sub-section (2), of section 52 of the Legal Metrology Act, 2009 (1 of 2010), the Central Government hereby makes the following rules further to amend the Legal Metrology (Packaged Commodities) Rules, 2011, namely:-

1. (1) These rules may be called the Legal Metrology (Packaged Commodities) Amendment Rules, 2022.

(2) They shall come into force on the 1st day of October, 2022.

2. In the Legal Metrology (Packaged Commodities) Rules, 2011 (hereinafter referred to as the said rules), in rule 1, in sub-rule (2), for the figures, letters and words "1st day of April, 2022", the figures, letters and words "1st Day of October, 2022" shall be substituted.

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

"(11) The unit sale price in rupees, rounded off to the nearest two decimal place, shall be declared on every pre-packaged commodities in the following manner, namely:-

(i) per gram where net quantity is less than one kilogram and per kilogram where net quantity is more than one kilogram;

(ii) per centimeter where net length is less than one metre and per metre where net length is more than one metre;

(iii) per mililitre where net volume is less than one litre and per litre where net volume is more than one litre;

(iv) per number or unit if any item is sold by number or unit:

Provided that for packages containing alcoholic beverages or spirituous liquor, the State Excise Laws and the rules made thereunder shall be applicable within the State in which it is manufactured.

Provided further that declaration of unit sale price is not required for the pre-packaged commodities in which retail sale price is equal to the unit sale price."

4. In the said rules, in rule 33, sub-rule (2) shall be omitted.

5. In the said rules, THE SECOND SCHEDULE shall be omitted.

6. No prosecution shall be initiated against the manufacturer or packer or importer of pre packaged commodities for making declaration with effect from the 1st April, 2022 in accordance with Legal Metrology (Packaged Commodities) Rules, 2011, as amended by the Legal Metrology (Packaged Commodities) Amendment Rules, 2021 published vide number G.S.R. 779 (E), dated the 2nd November, 2021.

F.No.WM-10/22/2021

Anupam Mishra,
Joint Secretary,
Ministry of Consumer Affairs,
Food and Public Distribution,
Department of Consumer Affairs,
New Delhi.

Note: The principal rules were published in the Gazette of India, Extraordinary, Part II, Section 3, Subsection (i) vide G.S.R. number 202 (E). dated the 7th March, 2011 and last amended vide notification number G.S.R. 779 (E). dated the 2nd November, 2021.

DGFT MATTERS

Alignment of Appendix 4R with the Finance Act, 2021 with effect from 01.01.2022

Notification No. 04/2015-2020, S.O. 2185(E), dated 11th May, 2022

1. In exercise of the powers conferred by Section 5 of the Foreign Trade (Development and Regulation) Act, 1992 read with Para 1.02 of the Foreign Trade Policy 2015-20, the Central Government hereby notifies an Appendix 4R which is aligned with the Finance Act , 2021. This Appendix 4R shall be effective from 01.01.2022.

2. This new Appendix 4R, with effect from 01.01.2022, containing the eligible RoDTEP export items, rates and per unit value caps, wherever applicable is available at the DGFT portal www.dgft.gov.in under the link 'Regulatory Updates >RoDTEP'.

Effect of this Notification: A new RoDTEP schedule (Appendix 4R) has been notified for implementation with effect from 01.01.2022 after aligning the earlier schedule with the Customs tariff Schedule as per Finance Act, 2021.

This issues with the approval of the Minister of Commerce and Industry.

F. No. 01/61/180/155/AM21/PC-3]

Santosh Kumar Sarangi, Director General of Foreign Trade, Ex-Officio Addl. Secretary, Ministry of Commerce And Industry, Department of Commerce, Director General of Foreign Trade, New Delhi.

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CDSCO MATTERS

Special Condition under which the permission for import of drug with residual shelf life less than 60% is allowed

Circular File No. DCGI/Misc/2020 (110), dated 06th May 2022

To
All port offices of CDSCO.

In light of representation received and Covid-19 pandemic situation, the effective date of the circular of even no. dated 13.09.2021 issued on subject cited above is extended up to 31st October 2022 or till further order whichever is earlier.

Dr V G Somani, Drugs Controller General (India), Directorate General of Health Services, Central Drugs Standard Control Organization (DCGI Secretariat), FDA Bhawan, Kotla Road, New Delhi-110002.

● ● ●

NPPA fixes the Retail Price of Specified 66 Formulation/ Brand Name under the Drugs (Price control) order, 2013

NPPA Order S.O.2164(E) dated 09th May 2022

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

Sl. No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
1	Glimepiride and Metformin Hydrochloride sustained release tablets	Each uncoated bilayer tablet contains: Glimepiride IP 2mg Metformin Hydrochloride IP 500mg (As sustained release)	1 Tablet	M/s Indu Drugs Private Limited / M/s. Maxbien Pharma Private Limited	9.55
2	Glimepiride and Metformin Hydrochloride sustained release tablets	Each uncoated bilayer tablet contains: Glimepiride IP 1 mg Metformin Hydrochloride IP 500mg (As sustained release)	1 Tablet	M/s Indu Drugs Private Limited / M/s. Maxbien Pharma Private Limited	6.78
3	Gastro-Resistant Omeprazole and Domperidone Sustained Release Capsules	Each hard gelatin capsule contains: Omeprazole IP 20mg (as gastro- resistant pellets) Domperidone IP 30mg (as sustained release pellets)	1 Capsule	M/s Indu Drugs Private Limited / M/s. Ma Lara Healthcare Pvt. Ltd.	9.53
4	Gastro-Resistant Pantoprazole and Domperidone Sustained Release Capsules	Each hard gelatin capsule contains: Pantoprazole Sodium IP eq. to Pantoprazole 40mg (as gastro-resistant pellets) Domperidone IP 30mg (as sustained release pellets)	1 Capsule	M/s Indu Drugs Private Limited / M/s. Ma Lara Healthcare Pvt. Ltd.	9.21

5	Gastro-Resistant Rabeprazole and Domperidone Sustained Release Capsules	Each hard gelatin capsule contains: Rabeprazole Sodium IP 20mg (as gastro-resistant pellets) Domperidone IP 30mg (as sustained release pellets)	1 Capsule	M/s Indu Drugs Private Limited / M/s. Ma Lara Healthcare Pvt. Ltd.	9.67
6	Gastro-Resistant Esomeprazole and Domperidone Sustained Release Capsules	Each hard gelatin capsule contains: Esomeprazole Magnesium Trihydrate IP eq. to Esomeprazole 40mg (As gastro-resistant pellets) Domperidone IP 30mg (As Sustained Release pellets)	1 Capsule	M/s Indu Drugs Private Limited / M/s. Ma Lara Healthcare Pvt. Ltd.	10.17
7	Thyroxine Sodium Tablets	Each uncoated tablet contains: Thyroxine Sodium IP eq. to anhydrous Thyroxine Sodium 200mcg (Synthetic Thyroid Hormone)	1 Tablet	M/s Abbott India Ltd.	1.98
8	Atorvastatin & Ezetimibe Tablets	Each film coated tablet contains: Atorvastatin Calcium IP eq. to Atorvastatin 10mg Ezetimibe IP 10mg	1 Tablet	M/s Akums Drugs & Pharmaceuticals Ltd. /M/s German Remedies Pharmaceuticals Private Limited	16.23
9	Atorvastatin & Clopidogrel Tablets	Each Uncoated Bilayered tablet contains: Atorvastatin Calcium IP eq. to Atorvastatin 10mg Clopidogrel Bisulphate IP eq. to Clopidogrel 75mg	1 Tablet	M/s Pure and Cure Healthcare Pvt. Ltd. /M/s German Remedies Pharmaceuticals Private Limited	11.62
10	Dextromethorphan hydrobromide, Chlorpheniramine Maleate & Phenylephrine Hydrochloride Syrup	Each 5 ml contains: Dextromethorphan hydrobromide IP 10mg Chlorpheniramine Maleate IP 2mg Phenylephrine Hydrochloride IP 5mg	1 ML	M/s Akums Drugs & Pharmaceuticals Ltd. /M/s German Remedies Pharmaceuticals Private Limited	0.86
11	Atorvastatin, Clopidogrel & Aspirin Capsules	Each hard gelatin capsule contains: Atorvastatin Calcium IP eq. to Atorvastatin 10mg (As film coated tablet IP) Clopidogrel Bisulphate IP eq. to Clopidogrel 75mg Aspirin IP 75mg (As GastroResistant Tablet IP)	1 Capsule	M/s Safetab Life Science / M/s Ajanta Pharma Ltd.	4.68

12	Atorvastatin, Clopidogrel & Aspirin Capsules	Each hard gelatin capsule contains: Atorvastatin Calcium IP eq. to Atorvastatin 20mg (As film coated tablet IP) Clopidogrel Bisulphate IP eq. to Clopidogrel 75mg Aspirin IP 75mg (As GastroResistant Tablet IP)	1 Capsule	M/s Safetab Life Science / M/s Ajanta Pharma Ltd.	6.32
13	Paracetamol Infusion IP	Each 100ml contains: Paracetamol IP 1000mg water for Injection IP	1 ML	M/s Pure and Cure Healthcare Pvt. Ltd. / M/s Mankind Life Sciences Pvt. Ltd.	2.88
14	Norethisterone Acetate controlled release Tablets	Each film coated controlled release tablet contains: Norethisterone Acetate BP 15mg	1 Tablet	M/s Synokem Pharmaceuticals Ltd. / M/s Obsurge Biotech Ltd.	19.20
15	Atorvastatin & Clopidogrel Capsules	Each Hard Gelatin Capsule Contains: Atorvastatin Calcium IP eq to Atorvastatin 40mg (As green coloured spherical pellets) Clopidogrel Bisulphate IP eq. to Clopidogrel 75mg (As two brown coloured film coated tablets Each containing 37.5mg Clopidogrel Tablets)	1 Capsule	M/s Windlas Biotech Limited. / M/s Mankind Pharma Ltd.	30.74
16	Ivermectin & Albendazole Tablets	Each uncoated Chewable tablet contains: Ivermectin IP 6mg Albendazole IP 400mg	1 Tablet	M/s Next Wave (India) / M/s Mankind Prime Labs Pvt. Ltd.	22.52
17	Aceclofenac, Paracetamol & Thiocolchicoside tablets	Each film coated tablet contains: Aceclofenac IP 100mg Paracetamol IP 325mg Thiocolchicoside IP 4mg	1 Tablet	M/s Synokem Pharmaceuticals Ltd. / M/s Troikaa Pharmaceuticals Ltd.	16.27
18	Etoricoxib & Paracetamol Tablets	Each Film Coated tablet contains: Etoricoxib IP 60 mg Paracetamol IP 325 mg	1 Tablet	M/s Haelwood Laboratories Pvt. Ltd. / M/s Eris Healthcare Pvt. Ltd.	7.67
19	Metformin Hydrochloride prolonged-release and Glimepiride Tablets	Each uncoated bilayered tablet contains: Glimepiride IP 1 mg Metformin Hydrochloride IP 500 mg (as prolonged-release form)	1 Tablet	M/s Akum Drugs & Pharmaceuticals Limited/M/s German Remedies Pharmaceuticals Pvt. Ltd.	6.93

20	Ivermectin & Albendazole Oral Suspension	Each 5 ml contains: Ivermectin IP 1.5 mg Albendazole IP 200 mg	1 ML	M/s Next Wave (India) / M/s Mankind Prime Labs Pvt. Ltd.	2.20
21	Cilnidipine & Telmisartan tablets	Each film coated tablet contains: Cilnidipine IP 10mg Telmisartan IP 40 mg	1 Tablet	M/s Mediforce Healthcare Pvt. Ltd./ M/s Mankind Prime Labs Pvt. Ltd.	9.92
22	Nimesulide & Paracetamol tablets	Each uncoated tablet contains: Nimesulide BP 100mg Paracetamol IP 325 mg	1 Tablet	M/s Softdeal Pharmaceutical Private Limited	4.27
23	Travoprost & Timolol Maleate Eye Drops	Each ml contains: Travoprost IP 40 mcg Timolol Maleate eq. to Timolol IP 5 mg	1 ML	M/s East African (India) Overseas/ M/s Alkem Laboratories Limited	123.68
24	Dorzolamide & Timolol Eye Drops	Composition: Dorzolamide Hydrochloride IP eq. to Dorzolamide 2% w/v Timolol Maleate eq. to Timolol IP 0.5 % w/v Water for Injection	1 ML	M/s East African (India) Overseas/ M/s Alkem Laboratories Limited	63.67
25	Brimonidine Tartrate & Timolol Maleate Ophthalmic Solution	Each ml contains: Brimonidine Tartrate IP 2 mg Timolol Maleate eq. to Timolol IP 5 mg	1ML	M/s East African (India) Overseas/ M/s Alkem Laboratories Limited	49.04
26	Atorvastatin & Clopidogrel Tablets	Each uncoated bilayered tablet contains: Atorvastatin Calcium IP eq. to Atorvastatin 20 mg Clopidogrel Bisulphate eq. to Clopidogrel IP 75 mg	1 Tablet	M/s Pure and Cure Healthcare Pvt. Limited/M/s German Remedies Pharmaceuticals Pvt. Ltd.	17.17
27	Telmisartan & Chlorthalidone Tablets	Each film coated tablet contains: Telmisartan IP 80mg Chlorthalidone IP 12.5mg	1 Tablet	M/s Akums Drugs & Pharmaceuticals Limited/M/s Abbott Healthcare Pvt. Ltd.	10.55
28	Voglibose, Glimepiride and Metformin Hydrochloride (sustained release)Tablets	Each uncoated bilayered tablet contains: Voglibose IP 0.2mg Glimepiride IP 2mg Metformin Hydrochloride IP 1000mg (as sustained release form)	1 Tablet	M/s Swiss Garnier Genexiaa Sciences Pvt Ltd. / M/s Mankind Pharma Ltd.	13.31
29	Vitamin D3 Oral Solution	Each 5ml contains: Cholecalciferol IP (In nano Droplet form) 60000IU	1 ML	M/s Ravenbhel Healthcare Pvt. Ltd. / M/s Mankind Pharma Limited	13.94
30	Vitamin D3 Oral Solution	Each 5ml contains: Cholecalciferol IP (In nano Droplet form) 60000IU	1 ML	M/s Ravenbhel Healthcare Pvt. Ltd. / M/s Mankind Prime Labs Pvt. Ltd.	13.94

31	Calcium & Vitamin D3 Suspension	Each 5ml contains: 625mg Calcium Carbonate from an Organic Source (Oyster Shell) eq. to Elemental Calcium 250mg Vitamin D3 IP 125IU	1 ML	M/s Shivalik Remedies Pvt. Ltd. / M/s Mankind Prime Labs Pvt. Ltd.	0.51
32	Voglibose, Glimepiride and Metformin Hydrochloride (sustained release) Tablets	Each uncoated bilayered tablet contains: Voglibose IP 0.2mg Glimepiride IP 1mg Metformin Hydrochloride IP 1000mg (as sustained release form)	1 Tablet	M/s Swiss Garnier Genexiaa Sciences Pvt Ltd. / M/s Mankind Pharma Ltd.	11.43
33	Diclofenac Diethylamine, Methyl Salicylate, Linseed Oil & Menthol Tropical Spray	Composition: Diclofenac Diethylamine IP 1.16% w/w eq. to Diclofenac Sodium IP 1% w/w Virgin Linseed Oil BP 3% w/w Methyl Salicylate IP 10% w/w Menthol IP 5% w/w	1 GM	M/s Pontika Aerotech Ltd./M/s Zuventus Healthcare Ltd.	2.69
34	Diclofenac Diethylamine, Linseed Oil, Methyl Salicylate & Menthol Gel	Composition: Diclofenac Diethylamine IP 1.16% w/w eq. to Diclofenac Sodium IP 1% w/w Virgin Linseed Oil(Oleum Lini) BP 3% w/w Methyl Salicylate IP 10% w/w Menthol IP 5% w/w	1GM	M/s Nanz Med Science Pharma Pvt. Ltd./M/s Zuventus Healthcare Ltd.	2.83
35	Tramadol & Paracetamol Tablets	Each film coated tablet contains: Tramadol Hydrochloride IP37.5mg Paracetamol IP 325mg	1 Tablet	M/s Hab Pharmaceuticals & Research Limited / M/s German Remedies Pharmaceuticals Private Limited	8.35
36	Telmisartan & Amlodipine Tablets	Each uncoated bilayered tablet contains: Telmisartan IP 40mg Amlodipine Besylate IP eq. to Amlodipine 5mg	1 Tablet	M/s Indchemie Health Specialities Pvt. Ltd.	9.49
37	Telmisartan & Metoprolol Succinate ER Tablets	Each film coated bilayered tablet contains: Telmisartan IP 40mg Metoprolol Succinate IP eq. to Metoprolol Tartrate 50mg (as Extended Release form)	1 Tablet	M/s Akum Drugs & Pharmaceuticals Limited/M/s German Remedies Pharmaceuticals Pvt. Ltd.	13.66

38	Telmisartan + Hydrochlorothiazide Tablets	Each uncoated bilayered tablet contains: Telmisartan IP 40mg Hydrochlorothiazide IP 12.50mg	1 Tablet	M/s Indchemie Health Specialities Pvt. Ltd.	9.95
39	Paracetamol & Chlorzoxazone Tablets	Each uncoated tablet contains: Paracetamol IP 500mg Chlorzoxazone USP 250mg	1 Tablet	M/s The Madras Pharmaceuticals/M/s Sun Pharmaceutical Industries Ltd.	10.31
40	Diclofenac Diethylamine, Methyl Salicylate, Menthol & Absolute Alcohol Topical Spray	Composition: Diclofenac Diethylamine IP 2.32% w/v eq. to Diclofenac Sodium IP 2% w/v Methyl Salicylate IP 10% w/v Menthol IP 5% w/v Absolute Alcohol IP 10% v/v	1 GM	M/s Pontika Aerotrch Limited / M/s Mankind Pharma Ltd.	3.22
41	Sitagliptin Phosphate & Metformin Hydrochloride Tablets	Each film coated tablet contains: Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50mg Metformin Hydrochloride IP 500mg	1 Tablet	M/s Aristo Pharmaceuticals Pvt. Ltd.	18.34
42	Sitagliptin Phosphate & Metformin Hydrochloride Tablets	Each film coated tablet contains: Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50mg Metformin Hydrochloride IP 1000mg	1 Tablet	M/s Aristo Pharmaceuticals Pvt. Ltd.	20.02
43	Sitagliptin Phosphate & Metformin Hydrochloride Tablets	Each film coated tablet contains: Sitagliptin Phosphate Monohydrate IP 64.25mg eq. to Sitagliptin 50mg Metformin Hydrochloride IP 500mg	1 Tablet	M/s Bajaj Healthcare Ltd. / M/s Lupin Limited	18.34
44	Sitagliptin Phosphate & Metformin Hydrochloride Tablets	Each film coated tablet contains: Sitagliptin Phosphate Monohydrate IP 64.25mg eq. to Sitagliptin 50mg Metformin Hydrochloride IP 1000mg	1 Tablet	M/s Bajaj Healthcare Ltd. / M/s Lupin Limited	20.02
45	Sitagliptin & Metformin Hydrochloride	Each film coated tablet contains: Sitagliptin Phosphate	1 Tablet	M/s Intas Pharmaceuticals Ltd.	18.34

	Tablets	Monohydrate IP eq. to Sitagliptin 50mg Metformin Hydrochloride IP 500mg			
46	Sitagliptin & Metformin Hydrochloride Tablets	Each film coated tablet contains: Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50mg Metformin Hydrochloride IP 1000mg	1 Tablet	M/s Intas Pharmaceuticals Ltd.	20.00
47	Sitagliptin & Metformin Hydrochloride Tablets	Each film coated tablet contains: Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50mg Metformin Hydrochloride IP 500mg	1 Tablet	M/s Optimus Pharma Pvt. Ltd. / M/s Mankind Pharma Ltd.	18.34
48	Sitagliptin & Metformin Hydrochloride Tablets	Each film coated tablet contains: Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50mg Metformin Hydrochloride IP 1000mg	1 Tablet	M/s Optimus Pharma Pvt. Ltd. / M/s Mankind Pharma Ltd.	20.02
49	Sitagliptin & Metformin Hydrochloride Tablets	Each film coated tablet contains: Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50mg Metformin Hydrochloride IP 850mg	1 Tablet	M/s Optimus Pharma Pvt. Ltd. / M/s Mankind Pharma Ltd.	19.14
50	Sitagliptin Phosphate & Metformin Hydrochloride Tablets	Each film coated tablet contains: Sitagliptin Phosphate Monohydrate IP 64.25mg eq. to Sitagliptin 50mg Metformin Hydrochloride IP 500mg	1 Tablet	M/s Windlas Biotech Limited / Wockhardt Limited	8.92
51	Sitagliptin Phosphate & Metformin Hydrochloride Tablets	Each film coated tablet contains: Sitagliptin Phosphate Monohydrate IP 64.25mg eq. to Sitagliptin 50mg Metformin Hydrochloride IP 1000mg	1 Tablet	M/s Windlas Biotech Limited / Wockhardt Limited	9.82
52	Sitagliptin Phosphate & Metformin Hydrochloride Tablets	Each film coated tablet contains: Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50mg Metformin	1 Tablet	M/s Sun Pharma Laboratories Limited	18.34

		Hydrochloride IP 500mg			
53	Sitagliptin Phosphate & Metformin Hydrochloride Tablets	Each film coated tablet contains: Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50mg Metformin Hydrochloride IP 1000mg	1 Tablet	M/s Sun Pharma Laboratories Limited	20.02
54	Sitagliptin Phosphate & Metformin Hydrochloride Extended Release Tablets	Each film coated tablet contains: Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 100mg Metformin Hydrochloride IP 1000mg (As Extended Release form)	1 Tablet	M/s Sun Pharma Laboratories Limited	19.81
55	Sitagliptin Phosphate & Metformin Hydrochloride Tablets	Each film coated tablet contains: Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50mg Metformin Hydrochloride IP 500mg	1 Tablet	M/s Exemed Pharmaceuticals / M/s Eris Life Sciences Limited	18.34
56	Sitagliptin Phosphate & Metformin Hydrochloride Tablets	Each film coated tablet contains: Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50mg Metformin Hydrochloride IP 1000mg	1 Tablet	M/s Exemed Pharmaceuticals / M/s Eris Life Sciences Limited	20.02
57	Sitagliptin Phosphate & Metformin Hydrochloride Tablets	Each film coated tablet contains: Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50mg Metformin Hydrochloride IP 850mg	1 Tablet	M/s Exemed Pharmaceuticals / M/s Eris Life Sciences Limited	19.14
58	Linagliptin & Metformin Hydrochloride Tablets	Each Film Coated tablet contains: Linagliptin 2.5 mg Metformin Hydrochloride 500 mg	1 Tablet	M/s Mediforce Healthcare Pvt. Ltd. / M/s Mankind Pharma Ltd.	14.65
59	Linagliptin & Metformin Hydrochloride Tablets	Each film coated bilayered tablet contains: Linagliptin 2.5mg Metformin Hydrochloride IP 500mg	1 Tablet	M/s Alkem Healthscience (A unit of Alkem Laboratories Ltd.) / M/s Alkem Laboratories Ltd.	14.65
60	Linagliptin & Metformin	Each film coated bilayered tablet	1 Tablet	M/s Alkem Healthscience (A unit of	16.33

	Hydrochloride Tablets	contains: Linagliptin 2.5mg Metformin Hydrochloride IP 1000mg		Alkem Laboratories Ltd.) / M/s Alkem Laboratories Ltd.	
61	Linagliptin & Metformin Hydrochloride Tablets	Each Film Coated tablet contains: Linagliptin 2.5 mg Metformin Hydrochloride IP 1000 mg	1 Tablet	M/s Mediforce Healthcare Pvt. Ltd. / M/s Mankind Pharma Ltd.	16.33
62	Linagliptin & Metformin Hydrochloride Tablets	Each Film Coated tablet contains: Linagliptin 2.5 mg Metformin Hydrochloride IP 850 mg	1 Tablet	M/s Mediforce Healthcare Pvt. Ltd. / M/s Mankind Pharma Ltd.	15.45
63	Vildagliptin + Metformin Hydrochloride Tablet	Each film coated tablet contains: Vildagliptin 50mg Metformin Hydrochloride IP 500mg	1 Tablet	M/s Associated Biotech / M/s Unistretch Pharmaceuticals Pvt. Ltd.	6.75
64	Vildagliptin + Metformin Hydrochloride Tablet	Each film-coated tablet contains: Vildagliptin IP 50mg Metformin Hydrochloride IP 1000mg	1 Tablet	M/s Windlas Biotech Limited / M/s Mankind Prime Labs Pvt. Lttd.	7.60
65	Vildagliptin (as Immediate release) and Metformin Hydrochloride (as sustained release) Tablets	Each uncoated bilayer tablets contains: Vildagliptin IP (as Immediate release) 50mg Metformin Hydrochloride IP (as sustained release) 1000mg	1 Tablet	M/s Pure and Cure Healthcare Pvt. Ltd. M/s German Remedies Pharmaceuticals Pvt. Ltd.	8.06
66.	Vildagliptin (as Immediate release) and Metformin Hydrochloride (as sustained release) Tablets	Each uncoated bilared tablets contains: Vildagliptin IP (as Immediate release) 50mg Metformin Hydrochloride IP (as sustained release) 500mg	1 Tablet	M/s Pure and Cure Healthcare Pvt. Ltd. M/s German Remedies Pharmaceuticals Pvt. Ltd.	7.21

Note:

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

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

(c) The retail price for a pack of the aforesaid formulation shall be arrived at by the concerned manufacturer in accordance with the retail price specified in column (6) of the above table as per provisions contained in paragraph 11 of the DPCO, 2013. The manufacturer shall issue a price list in Form–V from date of Notification as per paragraph 24 of the DPCO, 2013 to NPPA through IPDMS and submit a copy to State Drug Controller and dealers.

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

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

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

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

PN/229/97/2022/F/F. No. 8(97)/2022/D.P./NPPA-Div.-II

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

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NPPA fixes the Retail Price of Specified 18 Formulation/ Brand Name under the Drugs (Price control) order, 2013

NPPA Order S.O.2165(E), dated 09th May 2022

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

TABLE

Sl. No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
1.	Linagliptin + Metformin Hydrochloride Tablet	**Each film coated tablet contains:** Linagliptin 2.5mg Metformin Hydrochloride IP 500mg	1 Tablet	M/s Optimus Pharma Pvt. Ltd. / M/s Natco Pharma Ltd.	8.04

2.	Linagliptin + Metformin Hydrochloride Tablet	**Each film coated tablet contains:** Linagliptin 2.5mg Metformin Hydrochloride IP 500mg	1 Tablet	M/s MSN Laboratories Private Limited / M/s Emcure Pharmaceuticals Limited	14.65
3.	Linagliptin + Metformin Hydrochloride Tablet	**Each film coated tablet contains:** Linagliptin 2.5mg Metformin Hydrochloride IP 500mg	1 Tablet	M/s MSN Laboratories Private Limited / M/s Eris Lifesciences Limited	14.65
4.	Linagliptin + Metformin Hydrochloride Tablet	**Each film coated tablet contains:** Linagliptin 2.5mg Metformin Hydrochloride IP 500mg	1 Tablet	M/s Micro Labs Limited	10.63
5.	Linagliptin + Metformin Hydrochloride Tablet	**Each film coated tablet contains:** Linagliptin 2.5mg Metformin Hydrochloride IP 1000mg	1 Tablet	M/s Optimus Pharma Pvt. Ltd. / M/s Natco Pharma Ltd.	8.37
6.	Linagliptin + Metformin Hydrochloride Tablet	**Each film coated tablet contains:** Linagliptin 2.5mg Metformin Hydrochloride IP 1000mg	1 Tablet	M/s MSN Laboratories Private Limited / M/s Emcure PharmaceuticalsLimited	16.33
7.	Linagliptin + Metformin Hydrochloride Tablet	**Each film coated tablet contains:** Linagliptin 2.5mg Metformin Hydrochloride IP 1000mg	1 Tablet	M/s Micro labs Limited	11.52
8.	Linagliptin + Metformin Hydrochloride Tablet	**Each film coated tablet contains:** Linagliptin 2.5mg Metformin Hydrochloride IP 850mg	1 Tablet	M/s MSN Laboratories Private Limited / M/s Emcure Pharmaceuticals Limited	15.45
9.	Sitagliptin Phosphate + Metformin Hydrochloride Tablet	**Each film coated tablet contains:** Sitagliptin Phosphate Monohydrate IP 64.25mg is eq. to Sitagliptin 50mg Metformin Hydrochloride IP 1000mg	1 Tablet	M/s Alkem Healthsciences (A Unit of Alkem Laboratories Ltd.) / M/s Alkem Laboratories Limited	20.02
10.	Sitagliptin Phosphate + Metformin Hydrochloride Tablet	**Each film coated tablet contains:** Sitagliptin Phosphate Monohydrate IP 64.25mg is eq. to Sitagliptin 50mg Metformin Hydrochloride IP 500mg	1 Tablet	M/s Alkem Healthsciences (A Unit of Alkem Laboratories Ltd.) / M/s Alkem Laboratories Limited	18.34
11.	Sitagliptin Phosphate + Metformin Hydrochloride (Extended release) Tablet	**Each film coated bilayered tablet contains:** Sitagliptin Phosphate eq. to Sitagliptin 100mg Metformin Hydrochloride IP 500mg (As an Extended release form)	1 Tablet	M/s Alkem Healthsciences (A Unit of Alkem Laboratories Ltd.) / M/s Alkem Laboratories Limited	20.17
12.	Sitagliptin Phosphate + Metformin Hydrochloride (Extended release) Tablet	**Each film coated bilayered tablet contains:** Sitagliptin Phosphate eq. to Sitagliptin 100mg Metformin Hydrochloride IP 1000mg (As an Extended release form)	1 Tablet	M/s Alkem Healthsciences (A Unit of Alkem Laboratories Ltd.) / M/s Alkem Laboratories Limited	19.81
13.	Sitagliptin Phosphate + Metformin Hydrochloride Tablet	**Each film coated tablet contains:** Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50mg Metformin Hydrochloride IP 500mg	1 Tablet	M/s Exemed Pharmaceuticals / M/s Emcure Pharmaceuticals Limited	18.34
14.	Sitagliptin Phosphate + Metformin Hydrochloride Tablet	**Each film coated tablet contains:** Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50mg Metformin Hydrochloride IP 1000mg	1 Tablet	M/s Exemed Pharmaceuticals / M/s Emcure Pharmaceuticals Limited	20.02

15.	Sitagliptin + Metformin Hydrochloride Tablet	**Each film coated tablet contains:** Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50mg Metformin Hydrochloride IP 500mg	1 Tablet	M/s Zydus Healthcare Limited	18.34
16.	Sitagliptin + Metformin Hydrochloride Tablet	**Each film coated tablet contains:** Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50mg Metformin Hydrochloride IP 1000mg	1 Tablet	M/s Zydus Healthcare Limited	20.02
17.	Sitagliptin + Metformin Hydrochloride Tablet	**Each film coated tablet contains:** Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50mg Metformin Hydrochloride IP 500mg	1 Tablet	M/s Morepen Laboratories Limited	18.34
18.	Sitagliptin + Metformin Hydrochloride Tablet	**Each film coated tablet contains:** Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50mg Metformin Hydrochloride IP 1000mg	1 Tablet	M/s Morepen Laboratories Limited	20.02

Note:

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

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

(c) The retail price for a pack of the aforesaid formulation shall be arrived at by the concerned manufacturer in accordance with the retail price specified in column (6) of the above table as per provisions contained in paragraph 11 of the DPCO, 2013. The manufacturer shall issue a price list in Form–V from date of Notification as per paragraph 24 of the DPCO, 2013 to NPPA through IPDMS and submit a copy to State Drug Controller and dealers.

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

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

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

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

PN/229/97/2022/F/F. No. 8(97)/2022/D.P./NPPA-Div.-II

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

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NPPA fixes the Retail Price of Darunavir + Ritonavir tablet under the Drugs (Price control) order, 2013

NPPA Order S.O.2166(E), dated 9th May, 2022

In line with the directions given by the Department of Pharmaceuticals (DOP) vide review order and letter specified in column (6) of the table herein below and in exercise of the powers conferred by paragraphs 5, 11 and 15 of

the Drugs (Prices Control) Order, 2013, read with S.O. 1394(E) dated the 30th May, 2013 and S.O.701(E) dated 10th March, 2016 issued by the Government of India in the Ministry of Chemicals and Fertilizers, and in supersession of the Order(s) of the Government of India in the Ministry of Chemicals and Fertilizers (National Pharmaceutical Pricing Authority) specified in the Column (7) of the table, the National Pharmaceutical Pricing Authority (hereinafter referred as NPPA), hereby fixes, the price as specified in column (5) of the table herein below as the retail price, exclusive of Goods and Services Tax, if any, in relation to the formulation specified in the corresponding entry in column (2) of the said Table with the strength, unit and name of manufacturer & marketing company, as specified in the corresponding entries in columns (3), (4) and (8) thereof;

Table

Sl. No.	Name of the Formulation	Dosage form & Strength	Unit	Retail Price (Rs.)	DoP (i) Review no. & Date (ii) Letter no. and Date	Existing SO number & date	Manufacturer & Marketing Company respectively
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)
1.	Darunavir + Ritonavir tablet	Each film coated tablet contains: Darunavir Ethanolate eq. to Darunavir 800mg, Ritonavir IP 100mg Tablet	1 Tablet	212.91	(i) 31015/16/2019 Pricing dated 25.06.2021 (ii) 31015/16/2019-Pricing (E-14046) dated 05.04.2022	4062(E) dated 08.11.2019 (at Sl.No. 25)	M/s Hetero Labs Limited / M/s Emcure Pharmaceuticals Ltd.

Note:

(a) The manufacturer of above mentioned formulations i.e. "new drug" under paragraph 2(u) of the DPCO, 2013 shall fix the retail price as specified in column (5) of the table hereinabove.

(b) The manufacturer may add Goods and Services Tax only if they have paid actually or it is payable to the Government on the retail price mentioned in column (5) of the above said table.

(c) The retail price for a pack of the aforesaid formulation shall be arrived at by the concerned manufacturer in accordance with the retail price specified in column (5) of the above table as per provisions contained in paragraph 11 of the DPCO, 2013. The manufacturer shall issue a price list in Form–V from date of Notification as per paragraph 24 of the DPCO, 2013 to NPPA through IPDMS and submit a copy to State Drug Controller and dealers.

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

(e) The above mentioned retail prices are applicable only to the manufacturer / marketer as mentioned above for generic/any brand of the same composition / strength of the subject formulations, subject to fulfillment of all the applicable statutory requirements as laid down by the Govt. under relevant statutes/ rules, including manufacturing license permission from the Competent Authority i.e. the Central/State Licensing Authority, as may be applicable, by the concerned manufacturers/ marketing companies.

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

PN/229/97/2022/F/
F. No. 8(97)/2022/D.P./NPPA-Div.-II

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

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- Best Innovation in Health care technologies
- Best Innovation in Information Technology
- Best Innovation in Power/Energy
- Best Innovation in Product Design
- Best Innovation in Sustainability
- Best Innovation in Telecommunications
- Best Innovation in Computing Systems
- Best Innovation in Consumer Electronics
- Best Innovation in Marketing
- Best Innovation in Brand Management
- Best Innovation in Internet
- Best Innovation in Mobile & Digital marketing
- Best Innovation in HR
- Best Innovation in Social Media
- Best Innovative Planning Practices Award
- Best Innovative Startup of the Year
- Best Innovative Service of the Year
- Best Innovative New Product Award
- Best Innovative Internet and Mobile Retail Sites
- Best Innovative Practices in HR / Talent Acquisition
- Best Innovative Practices in Marketing & Operations
- Best Innovative Practices in Research & Development
- Best Innovative Practices in Digital & Social Media
- Best Innovation & Creativity Technology in E-Commerce
- Best Innovation & Creativity Technology in M-Commerce

INDIVIDUAL AWARD CATEGORIES

- Best CEO of the Year
- Best CTO of the Year
- Best CIO of the Year
- Best Young Entrepreneur of the Year
- Best Young Innovator of the Year
- Best Innovative Business Idea
- Innovation Leadership Award
- Excellence in Innovative Technology Award
- Excellence in Information Technology Award
- Entrepreneurial Leadership Award
- Excellence in Software Innovation Award
- Outstanding Innovative Business Leader Award
- Innovative Business Leadership Award
- Outstanding R&D Leadership Award
- Business Excellence Through Innovative Industrial Practices
- Lifetime Achievement Award
- Women in IT / ITeS Leadership Award

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In Rajya Sabha & In Lok Sabha

In Rajya Sabha

Impact on Bilateral Trade with Ukraine and Russia

Rajya Sabha Unstarred Question No. 2590

Smt. Priyanka Chaturvedi:

Q. Will the Minister of **COMMERCE & INDUSTRY** be pleased to state:

(a) whether bilateral trade with Ukraine and Russia will be impacted by Ukraine - Russia conflict;

(b) whether the ongoing Ukraine-Russia conflict would impact negatively on the trade of automobile components, pharmaceuticals, engineering goods, agricultural products and telecom equipments;

(c) the details of import and export of automobile components, pharmaceuticals, engineering goods, agricultural products and telecom equipments from Russia and Ukraine; and

(d) whether Government has prepared any roadmap and strategy to control the expected loss in the trade industry due to Ukraine-Russia conflict, if so, the details thereof?

Answered on 25th March, 2022

A. (a) & (b): The impact on bilateral trade can be assessed only after the situation stabilizes

(c): The details of import and export of automobile components, pharmaceuticals, engineering goods, agricultural products and telecom equipments in respect of Russia and Ukraine of current year and previous three years are given below:

India's bilateral trade with Russia commodity wise:

Value in USD million

Years/ Commodity	Export				Import			
	2018-19	2019-20	2020-21	2021- 22 (April-January)	2018-19	2019-20	2020-21	2021-22 (April-January)
Automobile Components	92.46	67.54	62.33	95.80	2.48	1.38	1.99	2.12
Pharmaceuticals	485.56	552.41	590.7	518.6	3.69	6.36	6.73	96.98
Engineering goods	581.69	782.83	672.8	789.5	1246.5	1218.4	791.55	833.63
Agriculture products	559.60	623.45	513.16	517.09	82.06	358.83	329.77	336.10
Telecom equipment	236.05	496.65	182.10	352.12	6.52	13.51	5.58	0.82

Source: DGCI&S.

India's bilateral trade with Ukraine commodity wise:

Value in USD million

Years/ Commodity	Export				Import			
	2018-19	2019-20	2020-21	2021-22 (April-January)	2018-19	2019-20	2020-21	2021-22 (April-January)
Automobile Components	6.27	5.39	5.48	5.56	0.00	0.01	0.04	0.32
Pharmaceuticals	108.2	126.2	181.2	133.1	6.1	7.36	5.43	0.90
Engineering goods	79.71	90.11	71.1	95.5	129.6	119.84	77.22	94.2
Agriculture products	77.57	82.42	81.4	73.3	1966.6	1591.24	1620.9	1716.91
Telecom equipment	16.98	50.74	17.39	13.50	0.00	0.09	0.00	2.02

Source: DGCI&S.

(d): Department is holding regular meetings with stakeholders to draw a road map and strategy to control the expected loss in the trade industry due to Ukraine-Russia conflict.

The Minister of State in the Ministry of Commerce and Industry (Smt. Anupriya Patel)

Impact of Ukraine Crisis on Industry and Commerce

Rajya Sabha Starred Question No. 243

* 243. Shri K.J. Alphons:

Q. Will the Minister of **COMMERCE & INDUSTRY** be pleased to state:

(a) the impact of Ukraine crisis on Indian industry and commerce; and

(b) the steps that are being taken by Government to reduce the adverse consequences?

Answered on 25th March, 2022

A. (a) & (b): A Statement is laid on the Table of the House.

Statement Referred to in Reply to Parts (A) & (B) of Rajya Sabha Starred Question No. 243 for Answer on 25th March, 2022 Regarding "Impact of Ukraine Crisis on Industry and Commerce".

(a) &(b): The impact can be assessed only after the situation stabilizes. However, Department of Commerce is holding regular consultation with all stakeholders to ensure availability of essential imports and to find alternate destinations for our exports.

The Minister of Commerce and Industry (Shri Piyush Goyal)

Trade Deficit of India

Rajya Sabha Unstarred Question No. 2597

Shri Vivek K. Tankha:

Q. Will the Minister of **COMMERCE & INDUSTRY** be pleased to state:

(a) whether it is a fact that trade deficit of India is constantly growing,

(b) the percentage of increase of India's trade deficit during the last three years,

(c) the percentage of trade deficit with China during the last three years, and

(d) the steps taken to balance the trade deficit in the last three years?

Answered on 25th March, 2022

A. (a) & (b): India's overall (merchandise plus services) trade deficit alongwith percentage change for last three years are as follows:

Years	Trade Deficit (in USD Billion)	% Change
2018-19	102.06	----
2019-20	76.43	-25.12
2020-21	14.06	-81.60

Source: RBI and DGCI&S

The data in the above table shows that India's trade deficit decreased by 25.12 percent in 2019-20 over 2018-19 and 81.60 percent in 2020-21 over 2019-20.

(c): India's merchandise trade deficit with China alongwith percentage change for last three years are as follows:

Years	India's Trade Deficit with China (in USD Billion)	% Change
2018-19	53.57	---
2019-20	48.65	-9.19
2020-21	44.02	-9.50

Source: DGCI&S

The data reflects that India's trade deficit with China has a declining trend.

(d): In order to boost India's exports and bring down trade deficit, Government has taken following steps:

(i) The mid-term review (2017) of the Foreign Trade Policy (2015-20) was carried out and corrective measures were undertaken.

(ii) Foreign Trade Policy (2015-20) extended by one year i.e. upto 31-3-2022 due to the COVID-19 pandemic situation.

(iii) Assistance provided through several schemes to promote exports, namely, Trade Infrastructure for Export Scheme (TIES) and Market Access Initiatives (MAI) Scheme.

(iv) A Central Sector Scheme, 'Transport and Marketing Assistance for Specified Agriculture Products' was launched for providing assistance for the international component of freight to mitigate the freight disadvantage for the export of agriculture products.

(v) Remission of Duties and Taxes on Exported Products (RoDTEP) scheme and Rebate of State and Central Levies and Taxes (RoSCTL) Scheme have been implemented with effect from 01.01.2021.

(vi) Common Digital Platform for Certificate of Origin has been launched to facilitate trade and increase Free Trade Agreement (FTA) utilization by exporters.

(vii) 12 Champion Services Sectors have been identified for promoting and diversifying services exports by pursuing specific action plans.

(viii) Districts as Export Hubs has been launched by identifying products with export potential in each district, addressing bottlenecks for exporting these products and supporting local exporters/ manufacturers to generate employment in the district.

(ix) Active role of Indian missions abroad towards promoting India's trade, tourism, technology and investment goals has been enhanced.

(x) Package announced in light of the COVID pandemic to support domestic industry through various banking and financial sector relief measures, especially for MSMEs, which constitute a major share in exports.

The Minister of State in the Ministry of Commerce and Industry (Smt. Anupriya Patel)

In Lok Sabha

Prices of Life-Saving Drugs

Lok Sabha Unstarred Question No. 3790

Shri Ashok Mahadeorao Nete:

Shri Sadashiv Kisan Lokhande:

Shri Shriniwas Patil:

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

(a) whether life-saving and some other drugs are being sold at very high prices due to their scarcity in the country;

(b) if so, the details thereof along with the percentage of increase in the prices of each medicine and the steps taken to ensure their prices under affordable limits;

(c) whether the Government has fixed any norms for maintaining minimum stock of life-saving drugs in the country and if so, the details and the estimated stock thereof;

(d) whether the Government has constituted or proposes to constitute any high powered committee to review the price control system of medicines and if so, the details thereof; and

(e) the steps taken to strengthen research and development so as to find out the possibility of the production of medicines at low cost?

Answered on 25th March, 2022

A. (a) and (b): The essential medicines included in the National List of Essential Medicines (NLEM) published by the Ministry of Health & Family Welfare are included in Schedule-I of the Drugs (Prices Control) Order, 2013 (DPCO, 2013) and their ceiling price are fixed by the National Pharmaceutical Pricing Authority (NPPA) under the Department of Pharmaceuticals (DoP). No manufacturer can sell these medicines at a price more than the ceiling prices fixed by the NPPA. No reports have been received recently by NPPA regarding selling of drugs at high prices due to scarcity in the country.

(c): Ministry of Health & Family Welfare (MoHFW) has prepared 'Guidelines for Buffer Stock Management of COVID-19' and forwarded the same to all States/ UTs on 13th July, 2021. Further, financial resources were also made available to the States under 'Emergency COVID Response Package-II' for the purpose. States/ UTs were given flexibility to suitably customise their buffer stock requirements in accordance with their needs. MoHFW and DoP monitored the buffer stock available with States/ UTs.

(d): As per its mandate, the NPPA, a body of experts, controls/ regulates the prices of medicines in accordance with provisions of DPCOs.

(e): R&D and innovation in pharma sector is done by number of institutions and organizations under various scientific ministries/ departments. The Department of Pharmaceuticals has set up seven National Institutes of Pharmaceutical Education & Research (NIPERs) as institutes of national importance, which besides imparting postgraduate and doctorate education, conduct high end research in various pharma specializations. NIPERs, after detailed inter departmental consultations, have formulated a programme on Drug Discovery for Affordable Healthcare in mission mode. Further, the department has set up an Inter- Departmental Committee (IDC) to ensure economy, efficiency, effectiveness and transparency and to coordinate research in a collaborative, synchronized and synergized way for optimum utilization of funds.

Minister of State in the Ministry of Chemicals & Fertilizers (Shri Bhagwanth Khuba)

Shortage of Essential Medicines

Lok Sabha Unstarred Question No. 3791

Prof. Sougata Ray:

(a) whether the country is facing acute shortage of essential medicines in the country;

(b) if so, the details thereof and the steps taken to enhance the production of essential medicines in order to meet the demand thereof;

(c) whether the Government has any proposal to set up new units for production of essential medicines in the country; and

(d) if so, the details thereof?

Answered on 25th March, 2022

A. (a): No, Sir. The production and availability of essential medicines, which are included as Schedule-I of the Drugs Prices Control Order, 2013 are monitored by the National Pharmaceutical Pricing Authority (NPPA) through Drugs Control Administration of the State Governments. The manufacturers of scheduled formulations are also required to submit quarterly returns of production / import of scheduled formulation and their bulk drugs/ active pharmaceutical ingredients. Regular surveys of chemists shops are conducted by the officials of the Drug Controller General (India) and the Price Monitoring and Resource Units (PMRUs) set-up in 22 States/UTs by NPPA. Whenever shortage is reported by the State Drug Controllers or when the matter comes to the notice of NPPA, remedial steps are taken for ensuring availability of drug by impressing upon manufacturers to rush the stocks to the places of shortage. However, no reports have been received recently by NPPA regarding scarcity of essential medicines in the country.

(b) to (d): In order to make the country Atmanirbhar in pharmaceutical sector, the Department of Pharmaceuticals has launched the 'Production Linked Incentive (PLI) Scheme for promotion of domestic manufacturing of critical Key Starting Materials (KSMs)/ Drug Intermediates (DIs) and Active Pharmaceutical Ingredients (APIs)' with a total financial outlay of Rs. 6,940 cr. In total, 49 applicants have been approved under the scheme, out of which 8 projects have already been commissioned. Another 'Production Linked Incentive Scheme for Pharmaceuticals' has been launched by the Department with total financial outlay of Rs. 15,000 cr. to enhance India's manufacturing capabilities by increasing investment and production in the sector. In total, 55 applications have been approved under the scheme. Further, the Department has launched a scheme for 'Promotion of Bulk Drug Parks' with a total financial outlay of Rs. 3,000 cr.

Minister of State in the Ministry of Chemicals and Fertilizers (Shri Bhagwanth Khuba)

Upgradation of NIPERs

Lok Sabha Unstarred Question No. 3796

Shri Rajeshbhai Chudasama:

Shri Mohanbhai Kalyanji Kundariya:

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

(a) whether the Government has any proposal for improvement/upgradation of the National Institute of Pharmaceutical Education and Research (NIPER) in various cities of the country and if so, the details thereof;

(b) whether the Government is planning to upgrade the equipment and machinery in the NIPER, if so, the details thereof and if not, the reasons therefor; and

(c) the details of various upgradation that have taken place and funds allocated by Government during the last three years for development of NIPERs as a model pharmaceutical research organisation?

Answered on 25th March, 2022

A. (a) & (b): The Government has set up seven National Institutes of Pharmaceutical Education and Research (NIPERs) as institutes of national importance at Mohali (Punjab), Ahmedabad (Gujarat), Guwahati (Assam), Hyderabad (Telangana), Hajipur (Bihar), Kolkata (West Bengal) and Raebareli (Uttar Pradesh).

NIPER Mohali already has a regular permanent campus, well equipped laboratories and regular faculty. The construction of campuses of NIPERs at Ahmedabad and Guwahati was approved in March, 2018 and funds were allocated for up-gradation of laboratories alongwith creation of faculty and administrative posts in six NIPERs (excluding NIPER Mohali). Further, an outlay of Rs. 1,500 crore has been approved for construction of campuses of the remaining four NIPERs and up-gradation of facilities at existing seven NIPERs during the period 2021-22 to 2025-26.

(c): All seven NIPERs now have well-equipped laboratories and sanctioned regular faculty and administrative posts, most of which have been filled up as per the guidelines. About 95% of construction of campus of NIPER Guwahati and 30% of construction of NIPER Ahmedabad has been completed. The details of funds released for development of NIPERs during the last three years, i.e., 2018-19 to 2020-21 are as under:

(Rs. in cr.)

NIPER	2018-19	2019-20	2020-21
Mohali	29.00	30.60	60.55
Ahmedabad	12.00	18.50	60.50
Guwahati	33.50	43.90	79.45
Hyderabad	24.00	27.00	44.50
Hajipur	9.50	5.00	26.00
Kolkata	12.00	18.00	34.82
Raebareli	15.00	17.01	28.00
Total	**135.00**	**160.01**	**333.82**

Minister of State in the Ministry of Chemicals & Fertilizers (Shri Bhagwanth Khuba)

Funds for Treatment of Rare Diseases

Lok Sabha Unstarred Question No. 3830

Shri Ravneet Singh Bittu:

(a) whether the Government is cognizant of the reduction in donations leading to delay in treatment of children suffering from rare diseases in the country and if so, the details thereof;

(b) the total amount mobilised by the Government in this regard during the last three years, year-wise;

(c) whether the Government proposes to extend the benefits of the Rashtriya Arogya Nidhi (RAN) scheme to Group 3(a) patients too;

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

(e) the other measures being taken by the Government to ensure availability of sufficient funds for timely treatment of the children suffering from rare diseases in the country?

Answered on 25th March, 2022

A. (a) to (e) The National Policy for Rare Diseases (NPRD), 2021 was published on 30.03.2021. As per provisions envisaged in the policy, for the diseases/disorders amenable to one time curative treatment (listed under Group-I), financial support under umbrella scheme of RAN, an amount upto Rs. 20 lakh for entitled beneficiaries is provided by the Central Government. The diseases requiring long term/ lifelong treatment having relatively lower cost of treatment (listed under Group 2), the financial support is envisaged to provide by the State Governments. The diseases for which definite treatment is available but involves very high cost and lifelong therapy (listed under Group 3), the policy provides assistance to the patients through Digital Platform inviting voluntary donations from individuals and corporate donors. Donors have a choice to make donations to different Centres of Excellence (CoEs) and for the patients treated by these CoEs.

The total amount released by the Government for treatment of Rare Disease Patients during the last three years, is as follows:

(i) Year 2019-20 – Rs. 1.30 Crore

(ii) Year 2020-21 – Rs. 10 Crore

(iii) Year 2021-22 – Rs. 03 Crore

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

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Drug companies may take a hit, too

Indian pharmaceutical companies are staring at a possible write-off of their receivables from Sri Lanka, as they are struggling to repatriate money from the South Asian island country which is facing severe dollar crunch and a devaluation of local currency due to ongoing economic crisis.

One of India's leading drug maker said it took a charge of around Rs 40 crore in Q4FY22 on its forex line, on account of receivables from Sri Lanka.

"We have the money in Sri Lanka, but we can't repatriate it because of currency reasons, this is between our subsidiary and us, so our numbers have taken a charge of Rs 40 crore, because the forex rates have changed from the time the money is due to us to the situation now, so those charges will keep coming," said Umang Vohra, MD and Global CEO of Cipla.

Another executive of a drug company with exposure to Sri Lanka who is facing similar issues, said he is waiting for the government to act quickly so they will be able to continue shipping medicines to Sri Lanka. "The government has announced extending the $1 billion credit line, but we still don't know how to avail it," the executive said.

Source: Viswanath Pilla, The Economic Times, 12.05.2022

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You can be denied US entry if you're carrying medicines without prescription

Indians travelling overseas, especially to the US, are known to carry a mini dispensary with them – not just for their regular medicines but also for medical contingencies ranging from fever and stomach problems to more serious ailments.

They do it mainly for two reasons: (a) medicines in the US are way more expensive than in India (they are covered by insurance for Americans), and (b) they are difficult to access – not only do a wider range of medicines need a doctor's prescription in the US, drugstores are stricter in enforcing this requirement (whereas in India, the friendly neighbourhood pharmacy tends to be relatively 'relaxed').

And yet, most Indians don't bother to carry prescriptions when they go abroad, not even to the US. That's primarily because they don't think their stash of medicines will be checked at airports when they arrive – or that they could be denied entry. They should know they are taking a big risk – and their luck might turn for the worse the next time they touch down in New York or DC or San Francisco or Chicago – or any other city in the US.

If you don't believe us, read this recent tweet by a partner in a top-tier law firm: "If anyone/family etc travelling to the US, please be careful about the medicine that is being carried. Yesterday, a client of ours was deported from San Francisco for carrying two strips of Zolfresh (which has Zolpidem) and Tramadol without a prescription. These are apparently Schedule 4 controlled substances in the US and require a prescription. Her visa has been revoked and a five-year ban on travel to the US has been imposed. She is part of a very well known Indian family. " TOI is aware of the identity of the 'client' in question, but has chosen not to disclose it so as to protect her privacy. So here's the deal: While most US airports allow Indians to carry their pickles and garam masalas, medicines carried without the mandatory doctor's note could result in revocation of your American visa. In the case of the Indian lady who was deported, her pleas to airport staff that they simply throw away her medicines fell on deaf ears. While in India many medicines, including high potency antibiotics, can be bought over the counter, the rules for OTC sales and scheduled drugs in the US are clearly stated and followed.

The stringency spills over to medications brought in by international fliers as well. International passengers flying into the US with medications fall under the purview of the US Food and Drug Administration (FDA), Customs and Border Protection (CBP) and the Transportation Security Administration (TSA). There are varying restrictions imposed by different agencies, but the general rule is the passenger should carry a valid prescription or doctor's note

— written in English — in order to bring medi- cation to the US, states the FDA on its website.

The general rule of thumb is: Carry no more than a 90-day supply of medication needed for personal use. A senior airline commander, requesting anonymity, said: "Other countries in Europe and Asia, too, have similar rules on carrying medication. But in my three decades of flying international, I have not seen any other country impose it with as much rigour as the US. " Some frequent-flier Indians, say local doctors, are aware of the need to keep prescriptions ready.

Others like 23-year-old Sunaina (name changed), who got an elaborate prescription written by her former classmate-turned-doctor before flying to Nashville for higher studies in biochemistry, heeded advice from more "Seniors in my college had warned me that I should get prescriptions for any painkiller I may need for my period pains," she said. Dr Suhas Pingle, who heads the Maharashtra chapter of the Indian Medical Association, said people often visit him before flying out. "The standard demand is that I should write down drugs for headaches, toothaches and, of course, any chronic illness such as diabetes," said Dr Pingle. Many even seek prescriptions for Vicks VapoRub, Eno or some ayurvedic pills but doctors are wary about writing out non-allopathic drugs. A senior Mumbai-based doctor said problems arise when scheduled drugs are carried without proper documents. "Paperwork is very important for drugs containing psychotropic components written for sleep or psychiatric disorders," he added.

Dos and don'ts for travel to the US

A valid prescription or doctor's note — written in English —is needed to bring medication to the US The medication should be in its original container with the doctor's instructions printed on it.

If you don't have the original container, bring a copy of your prescription or a letter from your doctor explaining your condition and why you need this medication Travel with no more than you need for your personal use during your stay.

A rule of thumb: Bring no more than a 90-day supply of medication. Medications in liquid or solid forms are allowed in carry-on bags and are exempt from the ban on liquids beyond 11.3 grams in cabin bags. Medical accessories such as freezer packs, IV bags, pumps and syringes are allowed in cabin bags but the items should be clearly labelled Note: Based on norms laid down by US FDA, CBP and TSA.

Source: The Times of India, 12.05.2022

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Oman to fast-track approval for Indian pharma products

Although India's pharmaceutical exports to Oman stood at just $30 million until February last fiscal, industry executives have pointed out that there is a huge scope for scaling up such supplies if non-tariff barriers like the time-consuming registration process are removed.

India-Oman trade jumped from $5.4 billion in FY21 to $9.94 billion in FY22, having witnessed an 82.6% rise.

Oman on Wednesday decided to fast-track the approval process for the registration of Indian pharmaceutical products that are already registered by the relevant authorities in the US, the UK and the EU. After the India-Oman Joint Commission meeting (JCM) here, both the sides decided to "comprehensively address all issues pertaining to tariff/non-tariff Barriers". The meeting was co-chaired by Commerce and Industry Minister Piyush Goyal and Qais bin Mohammed al Yousef, minister of commerce, industry and investment promotion of Oman.

Although India's pharmaceutical exports to Oman stood at just $30 million until February last fiscal, industry executives have pointed out that there is a huge scope for scaling up such supplies if non-tariff barriers like the time-consuming registration process are removed. The two countries also agreed to expedite the implementation of all memorandums of understanding (MoUs) and agreements under discussion, including on standards, India-Oman Double Taxation Avoidance Agreement, India-Oman Bilateral Investment Treaty, Invest Oman and Invest India, and Rupay card acceptance in Oman, among others.

Separately, another delegation, led by Abdulla Bin Touq Al Marri, the UAE's minister of economy, is also on a visit to India from Wednesday. The Oman minister's visit comes days after India's free trade agreement (FTA) with the UAE entered into force on May 1. Sources have said Oman is keen on an FTA between India and the Gulf Cooperation Council, of which it is a member. India-Oman trade jumped from $5.4 billion in FY21 to $9.94 billion in FY22, having witnessed an 82.6% rise.

Source: Financial Express, 12.05.2022

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DoP released common guidelines on pharma innovation for NIPERs

The Department of Pharmaceuticals has released Common Guidelines on Pharmaceutical Innovation and Entrepreneurship for academic institutions under its control, in order to encourage innovation and research and to facilitate the entrepreneurship in National Institutes of Pharmaceutical Education and Research (NIPERs).

The guideline is formed after considering the National Innovation & Startup Policy 2019, National IPR Policy 2016 and similar policies of other institutes. It aims to transform the academic research into innovative and commercially applicable technologies/products; build strong ecosystem for nurturing creativity and entrepreneurial activities and contribute to self-reliant India mission (Atmanirbhar Bharat).

It aims to encourage the faculty/staff members and students to pursue entrepreneurship; formulate policies and foster an ecosystem to generate ideas across disciplines that can be transformed into successful technologies, products, and services; establish a mechanism for technology development and technology transfer; create institutional framework for effective implementation, monitoring, and evaluation of the policy; and promote pharmaceutical innovation and entrepreneurship to foster the unmet therapeutic, socially impactful technologies delivering benefits to mankind.

These Policy Guidelines, finalised with approval of the Minister for Chemicals and Fertilizers have been forwarded to all NIPERs for taking up further steps for their speedy and effective implementation, said the DoP.

The vision of the DoP is to promote Indian pharma sector as the global leader for quality medicines and to ensure availability, accessibility and affordability of drugs and medical devices in the country. One of the measures to achieve the vision is to concentrate on Research & Development and innovation. In order to achieve the same, the Department, amongst various other measures, has set up seven National Institutes of Pharmaceutical Education and Research as institutes of national importance all across the country for imparting quality education and conducting high-end research.

NIPERs have recently launched a common Research portal for industry and researchers and have also prepared a Common Research Programme based on the national needs and their own expertise and facilities. The department is also soon coming up with a 'Policy to Catalyze Research & Development and Innovation in the Pharma- MedTech Sector in India'.

Source: Pharmabiz, 07.05.2022

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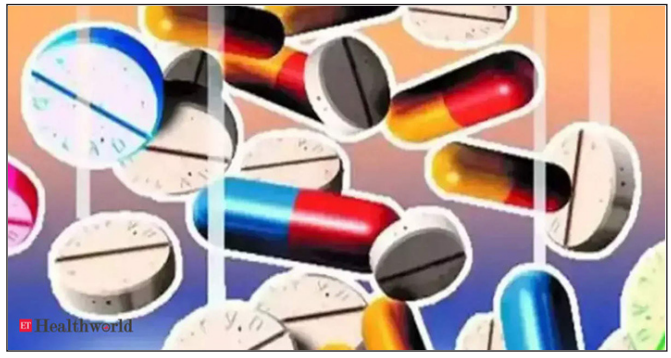
Pharma department suggests allocation of funds by institutes to promote startups



The Department of Pharmaceuticals has beneficial allocation of a hard and fast share of not lower than 1 per cent of annual price range of institutes to fund and promote innovation and startup-related actions within the sector.

In its frequent pointers on pharmaceutical innovation and entrepreneurship for tutorial establishments, the Department of Pharmaceuticals (DoP) additionally stated that institutes might take a hard and fast share of (2 per cent to 9.5 per cent) fairness in startup/spin-off corporations in return for the companies and services they supply.

In order to encourage innovation and analysis and to facilitate entrepreneurship in NIPERs (National Institutes

of Pharmaceutical Education and Research), the DoP has ready the 'frequent pointers on pharmaceutical innovation and entrepreneurship' for tutorial establishments underneath its management, an official assertion stated.

The pointers have been ready after contemplating the National Innovation & Startup Policy 2019, National IPR Policy 2016 and related insurance policies of different institutes, departments, it added. "The coverage goals to rework the educational analysis into progressive and commercially relevant applied sciences/merchandise; construct a powerful ecosystem for nurturing creativity and entrepreneurial actions and contribute to the self-reliant India mission (Atmanirbhar Bharat)," the assertion stated.

It goals to encourage college/workers members and college students to pursue entrepreneurship, whereas formulating insurance policies and fostering an ecosystem to generate concepts throughout disciplines that may be reworked into profitable applied sciences, merchandise, and companies, it added. For institutes, as per the rules, the supply of assets wants to be ensured for pre-incubation and offering frequent services as half of the institute's monetary technique for potential inventors and entrepreneurs.

Budgetary provisions ought to be accessible in phrases of allocation of a hard and fast share (equivalent to not lower than 1 per cent) of institute's annual price range for funding, selling and supporting innovation and startup-related actions. In return for the companies and services supplied, an institute might take a hard and fast share of (2 per cent to 9.5 per cent) fairness within the startup/spin-off firm, based mostly on worker contribution, help supplied and use of the institute's Intellectual Property (IP).

According to the rules, the entrepreneurial initiatives shall be evaluated regularly utilizing well-defined affect evaluation parameters equivalent to IP filed, merchandise developed and commercialised and quantity of employment generated, and startups created. To encourage college students, rest in attendance ought to be supplied to allow them to dedicate time for entrepreneurial actions, and they need to be allowed to sit for the examination, even when their attendance is lower than 75 per cent, it stated, including institutes ought to present rest to the PhD college students in phrases of a semester/yr break or extra, if wanted, to commit time on startup ventures.

The pointers additionally requested institutes to facilitate startups based by graduated college students until a specific time interval equivalent to 3 years from their commencement, whereas additionally permitting college or workers members to take a semester or a yr break or extra if wanted as sabbatical go away for engaged on expertise switch/startups. "A most interval of 2 years of such break could also be permissible," it added.

The imaginative and prescient of the DoP is to promote the Indian pharma sector as the worldwide chief for high quality medicines and to guarantee availability, accessibility and affordability of medication and medical gadgets within the nation, the official assertion stated. One of the measures to obtain the imaginative and prescient is to consider analysis and growth and innovation, and the DoP has arrange seven NIPERs as institutes of nationwide significance all throughout the nation for imparting high quality training and conducting high-end analysis, it added. These coverage pointers, finalised with approval of the minister for chemical compounds and fertilizers have been forwarded to all NIPERs for taking on additional steps for his or her speedy and efficient implementation, the assertion stated.

Source: India News Online Team, 07.05.2022

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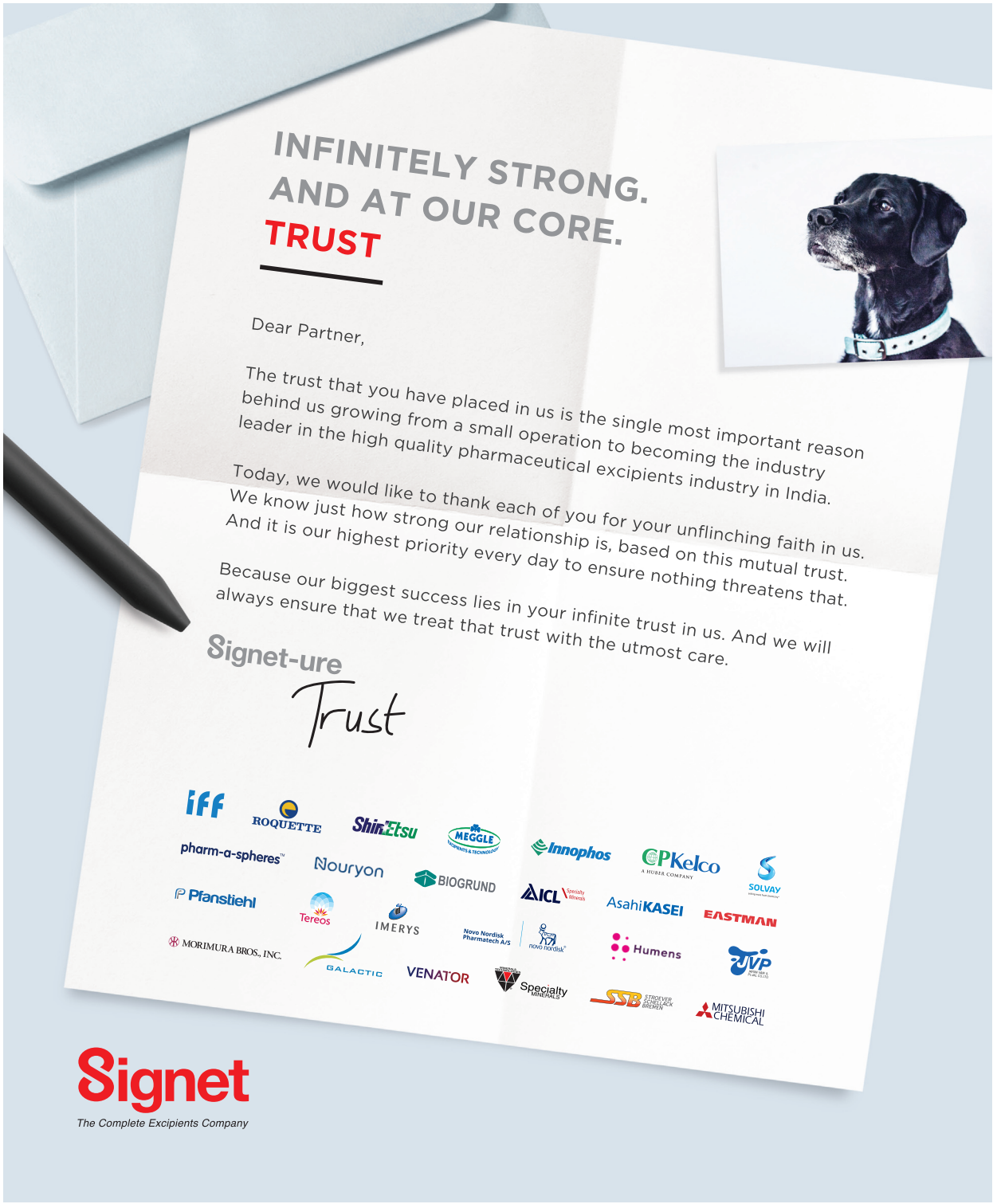
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