GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

LOK SABHA
UNSTARRED QUESTION NO. †1431
TO BE ANSWERED ON 20th September, 2020

Pharma Companies

†1431. SHRI ANIL FIROJIYA:

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

(a) whether it has been assessed from Indian Pharma Companies that there is no shortage of medicines in the country;
(b) if so, the details thereof and if not, the reasons therefor;
(c) whether any plan has been formulated to tackle the environmental challenges likely to be faced by the pharma industry; and
(d) if so, the details thereof?

ANSWER

MINISTER IN THE MINISTRY OF CHEMICALS AND FERTILIZERS
(SHRI D.V. SADANANDA GOWDA)

(a) & (b): The Department of Pharmaceuticals (DoP) played a crucial role in ensuring the availability of essential drugs Generic or branded at reasonable prices before and during the COVID-19 pandemic. Timely and effective steps were taken to ensure no shortage of drugs during the lockdown period throughout the country. The National Pharmaceutical Pricing Authority (NPPA) under the DoP has taken various steps to ensure the availability of life saving essential drugs like Hydroxychloroquine, Paracetamol, Vaccines, Anti-Tuberculosis drugs, Anti-diabetic drugs, cardiac drugs, imported Anti-epileptic drugs and COVID-19 drugs like FDC Lopinovir & Ritonavir, Remdesivir, Favipiravir, Zinc Sulphate, Methylprednisolone, Enoxparin, Dexamethasone etc. Further, on the intervention of NPPA and DCG(I) manufacturers of Remdesivir have set up a Helpline to make available the Remdesivir. However, both these drugs are not part of Covid-19 Protocol and continue as part of investigational therapy Drugs.

To ensure seamless availability of drugs, the NPPA set up a 'Control Room' with Helpline No. 1800111255 and issues like Non-availability of medicines, masks, gloves, hand sanitizers etc., and price violation of medicines, masks, gloves, hand sanitizers, etc., were resolved promptly. Also, a COVID-19 dashboard on the NPPA's website i.e.www.nppaindia.nic.in, having latest Office orders, circulars, helpline no., Email for sending grievances etc., was created for convenience of public and other stakeholders.

The NPPA ensured the availability of drugs by coordinating with State Health Authorities like SDCs and Central Govt. Authorities like the Central Drugs Standard Control Organisation (CDSCO), the Directorate General of Health Services

(DGHS), Department for Promotion of Industry and Internal Trade (DPIIT) etc. The NPPA also collected the critical information from drug manufacturers for decision making to ensure drug availability.

The NPPA also coordinated issues related to production of raw material, medicines, medical devices, packaging material, etc. by manufacturers and movement of raw material, packing material, finished goods and manpower etc to ensure availability of life saving essential drugs during the lockdown.

The details of various steps taken by the NPPA are at Annexure 1.

(c) & (d): The Ministry of Environment Forest and Climate Change in consultation with the Central Pollution Control Board (CPCB) has notified discharge norms for pharmaceutical industries in January 2020 under the Environment (Protection) Act, 1986, a copy of which is at Annexure 2. These norms are reviewed and revised periodically. The notified norms are enforced by State Pollution Control Boards (SPCB) / Pollution Control Committees in the consent order (CTO-Consent to operate) issued under the Air Act (PCP), 1981 and the Water Act, 1974. Further the units are encouraged to reduce their waste water generation by technological advancement and reuse/recycle of wastewater.

All highly polluting 17 categories of industries, including bulk drugs and formulations (pharmaceutical) industry, have been directed to install online continuous effluent/emission monitoring systems (OCEMS). These OCEMS are connected to CPCB & SPCB. Based upon the SMS alert, industries are selected for manual monitoring. The CPCB, time to time carry out surprise inspection of the industries for checking performance and operational status of pollution control measures adopted by the industries. During the inspection/manual monitoring, if any industry is found non-complying the norms, then closure direction is issued under section 5 of the Environment (Protection) Act, 1986 to the unit for rectification or up-gradation of Effluent Treatment Plant (ETP)/ Air Pollution Control devices (APCDs).

Annexure 1

MEASURES TAKEN FOR ENSURING AVAILABILTY OF DRUGS

1. The NPPA vide D.O. letter dated 20th Feb, 2020 requested all Chief Secretaries of States/UTs to closely monitor the production and availability ofActive Pharmaceutical Ingredients (APIs) and their formulations, and necessary action shouldbe taken under the provisions of the Drugs (Prices Control) Order, 2013 (DPCO, 2013) to ensure availability of life saving essential drugs to the consumers at all times.

2. In order to address the issues related to availability and pricing of critical Medical Devices such as Masks, Sanitizers and Gloves to deal effectively with COVID-19 situation, the NPPA vide letter dated 13th March 2020 requested MoHFW to prepone the effective date of consideration of Medical Devices as Drugs.

3. The NPPA vide order dated 13th March, in exercise of powers under clause (l) of sub section (2) of section 10 of the Disaster Management Act directed all States/UTs and concerned State Authorities to take necessary steps to ensure sufficient availability of surgical and protective masks, hand sanitizers and gloves at prices not exceeding MRP printed on pack sizes. Ministry of Consumer Affairs had, issued order dated 13th March 2020 to regulate the production, quality, distribution, logistics of masks and hand sanitizers.

4. In the effort of continuous monitoring, a letter dated 18th March, 2020 was also issued to all State Drug Controllers (SDCs) directing them to take immediate action through field officers to restrain acts of hoarding of surgical and protective masks, hand sanitizers and gloves and profiteering by manufacturers, distributors, stockists and retailers of these items as well as to ensure availability and distribution of these items at prices not exceeding MRP.

5. In its effort to maintain seamless availability of critical drugs and Medical Devices related to COVID-19, NPPA vide letter dated 19th March, requested Secretary (Textile) to put temporary Export restrictions on critical inputs (PP MELTBLOWN Non Woven Fabric, the Nosewire and Loop Elastic non latex) for Masks. Further, at the intervention by NPPA, DCGI vide Order dated 19th March directed all Port Offices of CDSCO to take proactive measures for clearance of imported stock of gloves in coordination with Customs in expedited manner in public interest.

6. The issue regarding availability of N95 Masks and PPE kits is entrusted to Empowered Group 3 and the issues of 2 ply/3 ply Masks and Hand Sanitizers is being monitored by Ministry of Consumer Affairs and Department of Food respectively. NPPA undertook database creation in respect of said Medical Devices and shared with concerned Authorities for effective monitoring.

7. The NPPA made efforts to collect information regarding Domestic Manufacturers of Masks, Gloves, Hand Sanitizers, PPE Kits and Ventilators in the Country. In this regard, various meetings were held at NPPA as well as through

Video conferencing with the stakeholders including industry associations. The compiled information was placed on NPPA's website & also disseminated to MoHFW and all States/UTs to assist in procurement of these devices required for treatment of COVID-19.

MEASURES TAKEN FOR ENSURING AFFORDABILITY OF N-95 MASKS

1. In order to ensure availability of N95 mask at affordable prices in the Country, NPPA vide O.M dated 21.05.2020, directed Manufacturers/ Importers/Suppliers of N95 Mask to maintain parity in prices for non-government procurements and to make available the same at reasonable prices and any violation of the same would invite action under Essential Commodities Act, 1955.

2. After issuing such an Advisory, major manufacturers/importers of N-95 Masks have reduced their prices significantly up to 67%. Further, a Press Release in this regard was released on 25.05.2020 for dissemination of information to general public.

NPPA's CONTROL ROOM AND HELPLINE

1. As a measure to deal with the emerging situation arising due to outbreak of COVID- 19, to ensure seamless availability of drugs including masks, hand sanitizers and gloves, the NPPA set up a 'Control Room' with Helpline No. 1800111255 and e-mail ID monitoring- nppa@gov.in on 20th March 2020. The Control Room has attended 1867 calls and addressed all types of the complaints in coordination with the State Drug Control Departments, AIDCD, Aimed etc.till 31.08.2020.

2. The NPPA's Control Room team worked vigorously on 24 x 7 basis, in 3 shifts, on virtual basis through remote locations and has made serious efforts, in coordination with O/o Chief Secretaries of States/UTs, SDCs, District/ State Administration and other State Authorities, for prompt resolution of number of issues. The summary of the issues resolved through the NPPA Control Room is given below:

Sl. no.	**Issues**
1	Non-availability of medicines, masks, gloves, hand sanitizers, etc.
2	High price of medicines, masks, gloves, hand sanitizers, etc.
3	Coordination in permission for production of raw material, medicines, medical devices, packaging material, etc. by manufacturers
4	Coordination in movement of raw material, packing material, finished goods and manpower.

MEASURES FOR LOGISTIC MANGEMENT FOR AVAILABILTY OF DRUGS

1. NPPA associated with Empowered Group 5 headed by Shri Parameswaranlyer, Secretary, DWS, regarding 'Facilitating supply chain & Logistics Management for availability of necessary items such as Food &

Medicines' to flag the logistics issues of Pharmaceutical Industry to ensure the seamless availability of drugs across the Country.

2. In lockdown period which also includes sealing of State borders at various places, Pharmaceutical sector faced serious challenges relating to logistics raw materials and manpower in an effort to provide seamless availability of drugs and medical devices across country. In this regard, NPPA took many initiatives in management of logistic disruption faced by the Pharmaceutical Industry which has led to increased availability of Medicines and Medical Devices across the Country.

3. The NPPA took measures for availability of Drugs for COVID-19 and other Essential Drugs including HCQ, Paracetamol, Vaccines, TB, Insulin and other cardiac drugs. NPPA is also dealing with issues related to sub optimal production, logistics, MIS, shortages and exports.

4. The shortage of imported Anti-epileptic drugs (particularlySabril 500) was reported by MoHFW and some NGO groups. NPPA immediately took necessary action and the issue was addressed promptly. Similarly, the issue of availability of imported drug Acterma of COVID treatment, was facilitated through discussion with Cipla, the importer.

5. NPPA vide D.O. letter No. 37001/2020/Div.-III/NPPA/Part dated 25thApril, 2020 to Administrator, Daman & Diu and Chief Secretary Maharashtra, has requested to take immediate necessary action in respect of resolution of bottlenecks to mitigate the risk of shortage of Anti-TB medicines in the country.

6. Further, based on communication dated 21st April, 2020 from Joint Secretary (RCH) referring to the letter dated 14th April 2020 of the Secretary (Health), requesting to address transportation issues due to nationwide lockdown to ensure seamlessavailability of vaccines required to successfully conduct Universal Immunization Programme (UIP), NPPA vide letter dated 21st April, 2020 requested Ministry of Civil Aviation, GoI to take immediate steps regarding airlifting of necessary supplies of vaccines, at the earliest, as it is critical for the smooth operation of UIP.

7. The grievances received at micro and macro level from individuals as well as from Associations/ Industry and Institutions/ Departments were taken care of to address all issues. During the lockdown, complaints were received regarding non access to critical medicines. These were got home delivered through coordination with SDCs.

8. On 26th March, 2020, NPPA requested all States/UTs to ensure unobstructed movement of Raw material, packing material, finished products and manpower related to manufacturing and distribution of drugs and medical devices.

CREATION OF DASHBOARD FOR COVID-19

NPPA created a COVID-19 dashboard on its website having latest Office orders, circulars, helpline no., Email for sending grievances etc. for convenience of public and other stakeholders. Link: http://www.nppaindia.nic.in/en/whats-new-about-coronavirus/.

CREATION OF COVID AND COVID PLUS DRUGS DATABASE

NPPA in coordination with DCGIdeveloped a comprehensive database for COVID & COVID plus (55+97) drugs as a measure of preventive preparedness for fighting COVID-19. This will be immensely useful in current scenario as well as future needs of the organization. DCGI has been directed to create a state wise mechanism to obtain timely alerts (ring the bell) in case of shortages to take remedial action.

MEASURES TAKEN TO ENSURE AVAIALBILITY OF MEDICAL OXYGEN

NPPA also coordinated the issue of availability of Medical Oxygen. The Empowered Group of Secretaries Group-3 (EGoS) considered the representation of All India Industrial Gas Manufacturer Association (AIIGMA) regarding cost impact of production of medical oxygen by the major manufacturers on 27th May, 2020. Tariff Commission was asked to examine the claim.

NPPA coordinated the data for medical oxygen from companies to Tariff Commission and ensured that examination of claim is done timely. In its report, Tariff Commission has mentioned that the claim of AIIGMA relies mainly on venting of various gases on account of production of oxygen and increase in electricity consumption cost. However both grounds are prima facie not substantiated based on data provided by AIIGMA / manufactures and reject the price increase claim.

MEASURES TAKEN TO ENSURE AVAIALBILTY OF DRUGS UNDER EXPORT RESTRICTION

1. Paracetamol and Hydroxychloroquine along with other drugs were put under export prohibition to ensure drug security in the country.NPPA made all out efforts to collect data regarding manufacturing capacity, domestic requirement, current stock, procurement orders of APIs/KSMs/Intermediates in respect these drugs under Export restriction.

2. Based on detailed examination of the stock position, manufacturing capacity and domestic requirement of Paracetamol, DoP/NPPA vide letter dated 15th May,2020 recommended to DGFT for lifting of ban on Export of Paracetamol API with the condition for Major Manufacturers to maintain supply of equivalent quantity in the domestic market. NPPA is regularly monitoring the details regarding manufacturing, stock position and supplies of Paracetamol API made to domestic market by major manufacturers.

3. Further, also vide dated 11.06.2020 recommended to DGFT for lifting of ban on Export of Hydroxychloroquine API and Formulations with the condition for Major Manufacturers to maintain sufficient availability in the domestic market**.**

4. The NPPA is regularly monitoring the details regarding manufacturing, stock position and supplies of Hydroxychloroquine made to various authorities/ agencies by major manufacturers**.** Further, NPPA is submitting a daily report to Cabinet Minister, MoC&F regarding Hydroxychloroquine based on reports received from the concerned major manufacturers of the drugs.

MONITORING THROGH SURVEY

The availability of key medicines is also monitored through CDSCO chemist level surveys, AIOCD surveys and Pharmatrac reports.

MEASURES TAKEN TO ENSURE AVAIALBILTY OF OTHER COVID-19 DRUGS

1. As and when any drug (e.g. FDC Lopinovir& Ritonavir, Remidesivir, Favipiravir, Zinc Sulphate, Mythyleprednisolone, Enoxparin, Dexamethasone etc)come into consideration for treatment protocol of COVID-19, NPPA pro-actively initiated task of collection of information to assess availability situation in the Country.

2. NPPA, on receiving of estimated quantity required from MoHFW, vide letter dated 03.07.2020 and 16.07.2020 directed Major manufactures of Mythyleprednisolone, Enoxparin, Dexamethasoneto ensure sufficient production and availability of these drugs across the country**.**

MEASURES TAKEN TO COORDINATE WITH SDCs

NPPA conducts regular meeting through VC with SDCs and Drug Manufacturers to monitor the availability of drugs and takes appropriate action. NPPA also coordinates with SDCs through WhatsApp group.

MEASURES TAKEN TO ENSURE AVAIALBILTY OF HEPARIN:

NPPA received representations from several manufacturers for upward revision of ceiling prices of Heparin Injection 5000IU/ ml which has been considered as an essential COVID plus medicine by Ministry of Health &Family Welfare. To ensure the availability, NPPA increased the ceiling price of Heparin for a period of six month.

MEASURES TAKEN TO STOP PRICE RISE OF DRUGS

1. National Pharmaceutical Pricing Authority (NPPA) issued necessary instructions to DCGI, States/ UTs to ensure adequate supply of APIs and formulations including surgical and protective masks, hand sanitizers and gloves at affordable prices in the market and to prevent black marketing and hoarding which could create artificial shortages in the country.
2. NPPA took cognizance of reports of **black marketing** of Remedesvir and Toclizumab and directed DCGI to issue necessary instruction to SDCs to take appropriate action in this respect.

3. Several requests from State Governments, NGOs and general public were received regarding fixation of prices for N-5 Masks as the same were available in the market at exorbitant and differential prices. In order to ensure availability of N95 mask at affordable prices in the Country, NPPA vide O.M dated 21.05.2020, directed Manufacturers/ Importers/Suppliers of N95 Mask to maintain parity in prices for non-government procurements and to make available the same at reasonable prices and any violation of the same would invite action under Essential

Commodities Act, 1955.

4. After issuing such an Advisory, major manufacturers/importers of N-95 Masks have reduced their prices significantly up to 67%. Further, a Press Release in this regard was released on 25.05.2020 for dissemination of information to general public.

5. The NPPA also took cognizance of complaints of black marketing and hoarding of N- 95 Masks and directed SDC Maharashtra to take necessary action. SDC conducted raid on the company doing black marketing and hoardingof N-95 Masks.

Annexure 2

रजिस्ट्री सं. डी.एल.- 33004/99 REGD. NO. D. L.-33004/99

भारत का राजपत्र
The Gazette of India

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असाधारण
EXTRAORDINARY
भाग II—खण्ड 3—उप-खण्ड (i)
PART II—Section 3—Sub-section (i)

प्राधिकार से प्रकाशित
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पर्यावरण, वन और जलवायु परिवर्तन मंत्रालय

अधिसूचना

नई दिल्ली, 23 जनवरी, 2020

सा. का. नि. 44(अ).—अधिसूचना, जिसे केन्द्रीय सरकार, पर्यावरण (संरक्षण) अधिनियम, 1986 (1986 का 29) की धारा 6 और धारा 25 में प्रदत्त शक्तियों का प्रयोग करते हुए जारी करने का प्रस्ताव करती है, का निम्नलिखित प्रारूप पर्यावरण (संरक्षण) नियम, 1986 के नियम 5 के उपनियम (3) की अपेक्षानुसार, जनसाधारण जिनके उसके द्वारा प्रभावित होने की संभावना है, की जानकारी के लिए, एततद्वारा प्रकाशित किया जाता है; और एततद्वारा सूचना दी जाती है कि उक्त प्रारूप अधिसूचना पर उस तारीख से, जिसको भारत के राजपत्र की प्रतियां, जिसमें यह अधिसूचना अंतर्विष्ट है, जनसाधारण को उपलब्ध करा दी जाती है, साठ दिन की अवधि की समाप्ति पर या उसके पश्चात विचार किया जाएगा।

ऐसा कोई व्यक्ति, जो प्रारूप अधिसूचना में अंतर्विष्ट प्रस्तावों पर कोई आपत्ति या सुझाव देने में हितबद्ध है, इस प्रकार ऊपर विनिर्दिष्ट की गई अवधि के भीतर, केन्द्रीय सरकार द्वारा विचार किए जाने के लिए, आपत्ति या सुझाव सचिव, पर्यावरण, वन और जलवायु परिवर्तन मंत्रालय, इंदिरा पर्यावरण भवन, जोर बाग रोड, नई दिल्ली - 110003 को या ई-मेल पते अर्थात mscb.cpcb@nic.in और h.kharkwal@nic.in पर सदस्य सचिव, केन्द्रीय प्रदूषण नियंत्रण बोर्ड और मंत्रालय के वैज्ञानिक 'ई' को लिखित रूप में भेज सकेगा।

प्रारूप अधिसूचना

केन्द्रीय सरकार, पर्यावरण (संरक्षण) अधिनियम, 1986 में और अधिक संशोधन करने के लिए एततद्वारा निम्नलिखित नियम बनाती है, अर्थात्-

1 **संक्षिप्त शीर्षक और प्रारम्भ—**(1) इन नियमों को पर्यावरण (संरक्षण) संशोधन नियम, 2019 कहा जाएगा। (2) ये आधिकारिक राजपत्र में उनके अंतिम प्रकाशन की तारीख से लागू होंगे।

2. पर्यावरण (संरक्षण) अधिनियम, 1986 में, अनुसूची-। में क्रम संख्या 73 और उससे संबंधित प्रविष्टियों के लिए निम्नलिखित क्रम संख्या और प्रविष्टियां प्रतिस्थापित की जाएगी अर्थात:-

क्रम सं.	**उद्योग**	**पैरामीटर**	**मानक**
1	**2**	**3**	**4**
" 73	**थोक दवा और निर्माण)फार्मास्युटिकल(**	**क. बहिस्राव मानक**	
			ईटीपी का अंतिम आउटलेट सांद्रण के लिए सीमित मान) पीएच और जैव परख को छोड़कर मिलीग्राम / एल में(
		i) अनिवार्य पैरामीटर	
		पीएच	6.0 -8.5
		बीओडी) 3 दिन 27 डिग्री सेल्सियस(	30
		सीओडी	250
		टीएसएस	100
		टीडीएस	2100
		तेल और चिकनाई (ग्रीज)	10
		जैव - परख परीक्षण**	100% बहिस्राव में पहले 96 घंटों के बाद मछली की 90% उत्तरजीविता
		ii) अतिरिक्त पैरामीटर	
		अमोनिकल नाइट्रोजन	50
		नाइट्रेट नाइट्रोजन	10
		**** बेंजीन*	*0.05*
		**** टाल्विन*	*0.05*
		**** ज़ाइलीन*	*0.06*
		****मीथाइलीन क्लोराइड*	*0.9*
		फॉस्फेट पी के रूप में	5
		क्लोराइड	1000
		सल्फेट SO_4 के रूप में	1000
		फ्लोराइड	2
		एस के रूप में सल्फाइड	2
		फेनोलिक यौगिक	1
		कुल अवशिष्ट क्लोरीन	1
		जस्ता	5
		लोहा	3
		तांबा	3
		कुल क्रोमियम	2
		हेक्सावलेंट क्रोमियम) Cr^{6+})	0.1

		साइनाइड	0.1
		आर्सेनिक	0.2
		पारा	0.01
		लेड	0.1
		**** सक्रिय दवा संघटक) एपीआई(	*0.05*
		iii) साझा बहिस्राव शोधन संयंत्र में निस्सारित कर रहे उद्योगों के अंतिम आउटलेट के लिए	
		दिनांक 1 जनवरी, 2016 की अधिसूचना का के अनुसार प्रत्येक (अ) 4 .आ.साझा बहिस्राव शोधन संयंत्र) सीईटीपी) के लिए, राज्य बोर्ड साझा बहिस्राव शोधन संयंत्र) सीईटीपी) के डिजाइन और स्थानीय जरूरतों और स्थितियों के अनुसार सामान्य मापदंडों, अमोनियम नाइट्रोजन और हैवी मेटल्स के लिए इनलेट क्वालिटी स्टैंडर्ड्स निर्धारित करेगा ।	
		टिप्पणी: **जेडएलडी=** *थोक दवा और निर्माण* उद्योग में शून्य तरल निस्सारण प्रणाली पर विचार किया जाता है, जब अनिवार्य पैरामीटरों के लिए निर्धारित की गई सीमाओं को पूरा करते है। शोधित बहिस्रावों को प्रक्रिया अथवा उपयोगिताओं के प्रयोग में लाया जाएगा। (कूलिंग टॉवरो आदि/बॉयलर) बागवानी / बागवानी में शोधित अपशिष्ट के पुन :उपयोग को थोक दवा और निर्माण उद्योगों में जेडएलडी नहीं माना जाएगा। **** जैव परख परीक्षण** आईएस :6582-1971 के अनुसार आयोजित किया जाएगा **"अतिरिक्त पैरामीटर "के** रूप में सूचीबद्ध **पैरामीटर** प्रक्रिया और उत्पाद के आधार पर निर्धारित किए जाएंगे। *** ये *सीमाएं उन उद्योगों पर लागू होंगी जो बेंजीन,* टाल्विन, ज़ाइलीन, मिथाइलीन क्लोराइड, क्लोरोबेंजीन *का उपयोग कर रहे हैं*। *** * एपीआई सीमाएं एंटीबायोटिक दवाओं के अलावा एपीआई बनाने वाली इकाइयों के लिए लागू होगी।	
		ख प्रक्रिया .रिएक्टर वेंटस / टैंक फार्म वेंटस से उत्सर्जन मानक	
		पैरामीटर	**सांद्रण के लिए सीमित मान)मिलीग्राम/एनएम ^{3})**
		क्लोरीन	15
		हाइड्रोक्लोरिक एसिड वाष्प	35
		अमोनिया	30
		बेंजीन	5
		टाल्विन	100
		ऐसिटोनाईट्राईल	1000
		डिकलोरोमीथेन	200
		ज़ाइलीन	100
		एसीटोन	2000
		ग विलायक का कुल .नुकसान, उपभोग किए गए विलायक के 3% से अधिक नहीं होना चाहिए।	
		घ. थोक दवा और निर्माण उद्योग में शोधित बहिस्राव में एंटोबायोटिक अवशिष्ट और थोक दवा और निर्माण इकाइयों की सदस्यता सहित सीईटीपी। पृथक एंटीबायोटिक अवशिष्ट नीचे तालिका में दिए गए मानों के बराबर या उससे कम होंगे।	
		पैरामीटर	**सांद्रण के लिए सीमित मान) u/g / l)**
		i. एमिकासिन	6.40

		ii. एमोक्सिसिलिन	0.10
		iii. एम्फोटेरिसिन बी	0.01
		iv. एम्पीसिलीन	0.10
		v. एनीड्यूलाफंगिन	0.01
		vi. एविलामाईसिन	3.20
		vii. एजिथ्रोमाईसिन	0.01
		viii. एजट्रियोनाम	0.20
		ix. बेसिट्रेसिन	3.20
		x. बेडाक्विलिन	0.03
		xi. बेन्ज़ाइलपेन्सिलीन	0.10
		xii. केप्रियोमाईसिन	0.80
		xiii. सेफेकलोर	0.20
		xiv. सेफाड्रोक्सिल	0.80
		xv. सेफालोनियम	8.40
		xvi. सेफालोरिडीन	1.60
		xvii. सेफालोथिन	0.80
		xviii. सेफाजोलिन	0.40
		xix. सेफडिनिर	0.10
		xx. सेफेपाईम	0.20
		xxi. सेफीजाईम	0.02
		xxii. सेफोपेराजोन	0.20
		xxiii. सेफोटेक्सिम	0.04
		xxiv. सेफोऐक्सिटिन	3.20
		xxv. सेफपिरोम	0.02
		xxvi. सेफपोडोक्सिन	0.10
		xxvii. सेफक्विनोम	0.64
		xxviii. सेफटेरोलिन	0.02
		xxix. सेफटाजिडिम	0.20
		xxx. सेफटीब्यूटेन	0.10
		xxxi. सेफटीओफर	0.02
		xxxii. सेफटोबिप्रोल	0.09
		xxxiii. सेफटोलोजेन	0.76
		xxxiv. सेफाट्रियोक्सन	0.01
		xxxv. सेफुरोक्सिम	0.20
		xxxvi. सेफालेक्सिन	0.03
		xxxvii. क्लोरामफेनिकोल	3.20
		xxxviii. सिपरोफ्लोक्सासिंन	0.02
		xxxix. क्लेरिथ्रोमाईसिन	0.03
		xl. क्लेब्युलेनिक एसिड	22.40

		xli. क्लिनाफ्लोक्सासिन	0.20
		xlii. क्लिन्डामाईसिन	0.04
		xliii. क्लोक्सासिलीन	0.05
		xliv. कोलिस्टिन	0.80
		xlv. डेपटोमाईसिन	0.40
		xlvi. डेलमानिड	0.02
		xlvii. डोरीपेनेम	0.04
		xlviii. डॉक्सीसाइक्लिन	0.80
		xlix. एनरामाईसिन	1.92
		l. एनरोफ्लोक्ससिन	0.02
		li. एरटापेनेम	0.05
		lii. एरिथ्रोमाईसिन	0.20
		liii. एथामब्युटोल	0.80
		liv. फेरोपेनेम	0.01
		lv. फिडाएक्सोमाईसिन	0.01
		lvi. फ्लोरफेनिकोल	0.80
		lvii. फ्लूकोनेज़ोल	0.10
		lviii. फ्लुमेक्विन	0.10
		lix. फॉस्फोमाईसिन	0.80
		lx. फ्युसीडिक एसिड	0.20
		lxi. सेटीफ्लोक्सासिन	0.05
		lxii. जेमीफलोक्सासिन	0.02
		lxiii. जेंटामाईसिन	0.08
		lxiv. इनीपेनेम	0.05
		lxv. आइसोनियाजिड	0.05
		lxvi. इट्राकोनेजोल	0.004
		lxvii. कानामाईसिन	0.44
		lxviii. लेवोफ्लोक्सासिन	0.10
		lxix. लिंकोमाईसिन	0.72
		lxx. लाईनज़ोलिड	2.68
		lxxi. लोराकारबेफ	0.80
		lxxii. मेसिलिनेम	0.40
		lxxiii. मेरोपेनेम	0.02
		lxxiv. मेट्रोनिडेजोल	0.05
		lxxv. माइनोसाइक्लिन	0.40
		lxxvi. मॉक्सीफ्लोक्सिन	0.05
		lxxvii. म्युरीरोसिन	0.10
		lxxviii. नेलीडिक्सिक एसिड	6.40
		lxxix. नारासिन	0.20

		lxxx. नियोमाईसिन	0.01
		lxxxi. नेटीलमिसिन	0.20
		lxxxii. निट्रोफ्यूरेनटोएन	25.60
		lxxxiii. नॉरफ्लोक्सिन	0.20
		lxxxiv. ऑफ्लोक्सिन	0.20
		lxxxv. ऑक्सासिलिन	0.40
		lxxxvi. ऑक्सीटेट्रासाइक्लिन	0.20
		lxxxvii. पेफक्लोसिन	3.20
		lxxxviii. फेनक्सीमेथिलपेनसिलिन	0.02
		lxxxix. पिपेरासिलिन	0.20
		xc. पॉलीमिक्सिन	0.80
		xci. रेटापाम्युलिन	0.02
		xcii. रिफाम्पसिन	0.02
		xciii. रॉक्सीथ्रोमाईसिन	0.40
		xciv. सेक्नीडेजोल	0.40
		xcv. स्पाराफ्लोक्सिन	0.02
		xcvi. स्पेक्टीनोमाईसिन	12.80
		xcvii. स्पिरामाईसिन	0.20
		xcviii. स्ट्रेप्टोमाइसिन	6.40
		xcix. सल्बेक्टम	6.40
		c. सल्फाडियाजिन	288.00
		ci. सल्फाडिमिथियोजिन	20.00
		cii. सल्फाडॉक्सिन	0.24
		ciii. सल्फामेथोक्साजोल	0.24
		civ. टेजोबेक्टम	17.60
		cv. टेडीजोलिड	3.92
		cvi. टेईकोप्लानिन	0.20
		cvii. टेलीथ्रोमाईसिन	0.02
		cviii. टेट्रासाइक्लिन	0.40
		cix. थियाम्फेनीकोल	0.40
		cx. टियाम्युलिन	0.40
		cxi. टिकार्सिलिन	3.20
		cxii. टिगेसाइक्लिन	0.40
		cxiii. टिल्डीपीरोसिन	0.17
		cxiv. टिल्मीकोसिन	0.40
		cxv. टोबरामाईसिन	0.40
		cxvi. ट्रिमेथोप्रिम	0.20
		cxvii. ट्रोवाफ्लोक्सासिन	0.01
		cxviii. टाइलोसिन	0.33

		cxix. बेंकोमाईसिन	3.20
		cxx. वियोमाईसिन	0.80
		cxxi. विर्जिनियामाईसिन	0.80. ".

टिप्पणी: - एंटीबायोटिक अवशिष्ट युक्त गाद को जलाकर राख किया जाएगा और साझा खतरनाक अपशिष्ट भस्मक अथवा उद्योग विशिष्ट भस्मक के लिए अधिसूचित किए गए भस्मक का मानक लागू होगा।

[फा.सं.क्यू.-15017/12/2018-सीपीडब्ल्यू]

जिगमेत टक्पा, संयुक्त सचिव

टिप्पणी: मूल नियम भारत के राजपत्र असाधारण, भाग- II, खंड 3, उप-खंड (i) में दिनांक 19 नवम्बर, 1986 को संख्या का.आ. 844 (अ) द्वारा प्रकाशित किए गए थे और उन्हें अंतिम बार दिनांक 26 दिसम्बर, 2019 को सा.का.नि. 952 (अ) की अधिसूचना द्वारा संशोधित किया गया था।

MINISTRY OF ENVIRONMENT, FOREST AND CLIMATE CHANGE

NOTIFICATION

New Delhi, the 23rd January, 2020

G.S.R. 44(E).— The following draft of the notification, which the Central Government proposes to issue in exercise of the powers conferred by sections 6 and 25 of the Environment (Protection) Act, 1986 (29 of 1986) is hereby published, as required under sub-rule (3) of 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 taken 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-110003, or send it to Member Secretary, CPCB and Scientist 'E' Ministry at the e-mail address i.e. mscb.cpcb@nic.in and h.kharkwal@nic.in.

Draft Notification

The Central Government hereby makes the following rules further to amend the Environment (Protection) Rules, 1986, namely:-

1. **Short title and commencement-** (1) These rules may be called the Environment (Protection) Amendment Rules, 2019.

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

2. In the Environment (Protection) Rules, 1986, in Schedule-l, for serial number 73 and the entries relating thereto, the following serial number and entries shall be substituted, namely:-

Sl. No.	Industry	Parameters	Standard
1	2	3	4
"73	Bulk Drug and Formulation (Pharmaceutical)	**A. EFFLUENT STANDARDS**	
			For final outlet of ETP Limiting value for concentration (in mg/l except for pH and Bio assay)
		i) Compulsory Parameters	
		pH	6.0 -8.5

		BOD (3 days 27°C)	30
		COD	250
		TSS	100
		TDS	2100
		Oil & Grease	10
		Bio - Assay Test**	90% Survival of Fish after first 96 hours in 100% effluent
		ii) Additional Parameters	
		Ammonical Nitrogen	50
		Nitrate Nitrogen	10
		****Benzene*	*0.05*
		****Toluene*	*0.05*
		****Xylene*	*0.06*
		****Methylene Chloride*	*0.9*
		Phosphates as P	5
		Chlorides	1000
		Sulphates as SO_4	1000
		Fluoride	2
		Sulphides as S	2
		Phenolic Compounds	1
		Total Residual Chlorine	1
		Zinc	5
		Iron	3
		Copper	3
		Total Chromium	2
		Hexavalent Chromium (Cr^{6+})	0.1
		Cyanide	0.1
		Arsenic	0.2
		Mercury	0.01
		Lead	0.1
		****Active Pharmaceutical Ingredient (API)	*0.05*
		iii) for final outlet of Industries discharging to CETP	
		For each Common Effluent Treatment Plant(CETP), the state Board will prescribe inlet quality Standards for general parameters, Ammonical Nitrogen and Heavy Metals as per the design of the Common Effluent Treatment Plant(CETP) and local needs and conditions. As per notification S.O. 4 (E) dated 1st January, 2016	
		Note: **ZLD** = Zero Liquid Discharge system in *Bulk Drug and formulation* industry is considered when treated effluent meeting the limits prescribed for compulsory parameters shall be used in Process or Utilities (boiler/ Cooling tower etc.). The reuse of treated effluent in gardening/ horticulture shall not be considered as ZLD in Bulk Drug and formulation industries. **** The Bio assay test** shall be conducted as per IS : 6582-1971 Parameters listed as **"Additional Parameters"** shall be prescribed depending upon the process and product. *** *Limits shall be applicable to industries those are using Benzene,* Toluene, Xylene, Methylene Chloride, Chlorobenzene. ****API limits shall be applicable for units manufacturing API other than antibiotics.	
		B. EMISSION STANDARDS from Process Reactor Vents/ Tank farm Vents	
		Parameter	**Limiting value for concentration (mg/Nm^3)**
		Chlorine	15
		Hydrochloric acid vapour	35
		Ammonia	30
		Benzene	5
		Toluene	100
		Acetonitrile	1000
		Dichloromethane	200

		Xylene	100
		Acetone	2000
		C. The total losses of solvent should not be more than 3% of the solvent consumed.	
		D. Antibiotic Residues in the treated effluent of Bulk Drug and Formulation Industry and CETP with membership of *Bulk Drug and formulation* Units Individual antibiotic residues will be equal to or less than the values given in the below table.	
		Parameter	**Limiting value for concentration (µg/l)**
		i. Amikacin	6.40
		ii. Amoxicillin	0.10
		iii. Amphotericin B	0.01
		iv. Ampicillin	0.10
		v. Anidulafungin	0.01
		vi. Avilamycin	3.20
		vii. Azithromycin	0.01
		viii. Aztreonam	0.20
		ix. Bacitracin	3.20
		x. Bedaquiline	0.03
		xi. Benzylpenicillin	0.10
		xii. Capreomycin	0.80
		xiii. Cefaclor	0.20
		xiv. Cefadroxil	0.80
		xv. Cefalonium	8.40
		xvi. Cefaloridine	1.60
		xvii. Cefalothin	0.80
		xviii. Cefazolin	0.40
		xix. Cefdinir	0.10
		xx. Cefepime	0.20
		xxi. Cefixime	0.02
		xxii. Cefoperazone	0.20
		xxiii. Cefotaxime	0.04
		xxiv. Cefoxitin	3.20
		xxv. Cefpirome	0.02
		xxvi. Cefpodoxime	0.10
		xxvii. Cefquinome	0.64
		xxviii. Ceftaroline	0.02
		xxix. Ceftazidime	0.20
		xxx. Ceftibuten	0.10
		xxxi. Ceftiofur	0.02
		xxxii. Ceftobiprole	0.09
		xxxiii. Ceftolozane	0.76
		xxxiv. Ceftriaxone	0.01
		xxxv. Cefuroxime	0.20
		xxxvi. Cephalexin	0.03
		xxxvii. Chloramphenicol	3.20
		xxxviii. Ciprofloxacin	0.02
		xxxix. Clarithromycin	0.03
		xl. Clavulanic Acid	22.40
		xli. Clinafloxacin	0.20
		xlii. Clindamycin	0.04
		xliii. Cloxacillin	0.05
		xliv. Colistin	0.80
		xlv. Daptomycin	0.40
		xlvi. Delamanid	0.02
		xlvii. Doripenem	0.04
		xlviii. Doxycycline	0.80
		xlix. Enramycin	1.92
		l. Enrofloxacin	0.02

		li.	Ertapenem	0.05
		lii.	Erythromycin	0.20
		liii.	Ethambutol	0.80
		liv.	Faropenem	0.01
		lv.	Fidaxomicin	0.01
		lvi.	Florfenicol	0.80
		lvii.	Fluconazole	0.10
		lviii.	Flumequine	0.10
		lix.	Fosfomycin	0.80
		lx.	Fusidic acid	0.20
		lxi.	Gatifloxacin	0.05
		lxii.	Gemifloxacin	0.02
		lxiii.	Gentamicin	0.08
		lxiv.	Imipenem	0.05
		lxv.	Isoniazid	0.05
		lxvi.	Itraconazole	0.004
		lxvii.	Kanamycin	0.44
		lxviii.	Levofloxacin	0.10
		lxix.	Lincomycin	0.72
		lxx.	Linezolid	2.68
		lxxi.	Loracarbef	0.80
		lxxii.	Mecillinam	0.40
		lxxiii.	Meropenem	0.02
		lxxiv.	Metronidazole	0.05
		lxxv.	Minocycline	0.40
		lxxvi.	Moxifloxacin	0.05
		lxxvii.	Mupirocin	0.10
		lxxviii.	Nalidixic acid	6.40
		lxxix.	Narasin	0.20
		lxxx.	Neomycin	0.01
		lxxxi.	Netilmicin	0.20
		lxxxii.	Nitrofurantoin	25.60
		lxxxiii.	Norfloxacin	0.20
		lxxxiv.	Ofloxacin	0.20
		lxxxv.	Oxacillin	0.40
		lxxxvi.	Oxytetracycline	0.20
		lxxxvii.	Pefloxacin	3.20
		lxxxviii.	Phenoxymethylpenicillin	0.02
		lxxxix.	Piperacillin	0.20
		xc.	Polymixin	0.80
		xci.	Retapamulin	0.02
		xcii.	Rifampicin	0.02
		xciii.	Roxithromycin	0.40
		xciv.	Secnidazole	0.40
		xcv.	Sparfloxacin	0.02
		xcvi.	Spectinomycin	12.80
		xcvii.	Spiramycin	0.20
		xcviii.	Streptomycin	6.40
		xcix.	Sulbactam	6.40
		c.	Sulfadiazine	288.00
		ci.	Sulfadimethoxine	20.00
		cii.	Sulfadoxine	0.24
		ciii.	Sulfamethoxazole	0.24
		civ.	Tazobactam	17.60
		cv.	Tedizolid	3.92
		cvi.	Teicoplanin	0.20
		cvii.	Telithromycin	0.02

		cviii.	Tetracycline	0.40
		cix.	Thiamphenicol	0.40
		cx.	Tiamulin	0.40
		cxi.	Ticarcillin	3.20
		cxii.	Tigecycline	0.40
		cxiii.	Tildipirosin	0.17
		cxiv.	Tilmicosin	0.40
		cxv.	Tobramycin	0.40
		cxvi.	Trimethoprim	0.20
		cxvii.	Trovafloxacin	0.01
		cxviii.	Tylosin	0.33
		cxix.	Vancomycin	3.20
		cxx.	Viomycin	0.80
		cxxi.	Virginiamycin	0.80.”.

Note:- The sludge containing antibiotic residues shall be incinerated and the standard of incinerator notified for common hazardous waste incinerator or industry specific incinerator shall be applicable.

[F.No. Q-15017/12/2018-CPW]

JIGMET TAKPA, Jt. Secy.

Note: The principal 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 last amended vide notification number G.S.R. 952(E), dated the 26th December, 2019.

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