

**GOVERNMENT OF INDIA  
MINISTRY OF CHEMICALS AND FERTILIZERS  
DEPARTMENT OF PHARMACEUTICALS**

LOK SABHA  
STARRED QUESTION No. 210  
TO BE ANSWERED ON THE 3<sup>rd</sup> December, 2019

**Quality Test of Medicines**

**†\*210. SHRI AJAY KUMAR MISRA TENI:  
SHRI KHAGEN MURMU:**

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

- (a) whether the Central Drugs Standard Control Organisation (CDSCO) has given its report mentioning that samples of several medicines taken in the month of August-September, 2019 including the medicines for heart and kidney problems, high blood pressure, thyroid, malaria, antibiotics and medicines for fever and pain have failed the quality test; and
- (b) if so, the details of the said medicines along with the details of action being taken by the Government against these companies, company-wise?

**ANSWER**

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

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(a) to (b): A statement is laid on the Table of the House.

**STATEMENT REFERRED TO IN REPLY TO PARTS (a) TO (b) OF LOK SABHA  
STARRED QUESTION NO. 210 FOR REPLY ON 03.12.2019**

(a): Details of drugs declared as spurious/ substandard/ adulterated/ misbranded by Central Drug Testing Laboratories are regularly uploaded on CDSCO website ([www.cdsc.nic.in](http://www.cdsc.nic.in)) under the heading "Drug Alert". Details of such cases of Not of Standard Quality for the months of August-September 2019 is enclosed as Annexure-A. These cases include drugs for kidney problems, Thyroid and Malaria apart from antibiotics and also medicines for fever and pain, etc.

(b): Licence for manufacturing, sale & distribution of drugs are granted by the State Licensing Authorities appointed by respective State Governments. State Governments are empowered to take action on violations of any of the provisions of Drugs & Cosmetics Act, 1940 and Rules made thereunder. In all above cases, the State Drugs Controllers of the concerned State where the drugs were manufactured have been informed accordingly.

List of Drugs declared as Not of Standard, for the Month of August 2019

S. No.	Name of Drugs/medical device/cosmetics	Batch No./Date of Manufacture/Date of Expiry/Manufactured By
1.	Cefixime Oral Suspension I.P.	B. No.: MCS-17039, Mfg dt: 09/2017, Exp dt: 08/2019, Mfd by: M/s. Maxmed Lifesciences Pvt. Ltd. Plot No. 54, Sector IIDC SIDCUL Rudrapur, Uttarakhand.
2.	Norfloxacin Tablets I.P. 400 mg	B. No.: NT606, Mfg dt: 02/2019, Exp dt: 01/2021, Mfd by: M/s. Unicure India Ltd. C-21, 22 & 23, Sector-3, Noida, Gautam Budh Nagar, Uttar Pradesh-201301.
3.	Norfloxacin Tablets I.P. 400 mg (NORTEC-400)	B. No.: NTK-18004, Mfg dt: 03/2019, Exp dt: 02/2022, Mfd by: M/s. Neutec Healthcare Pvt. Ltd. E-698, DSIIDC Narela, Industrial Area Delhi-110040.
4.	PGAB-MB 75 (Pregabalin and Mecobalamin Capsules 75 mg)	B. No.: WGC1828, Mfg dt: 06/2018, Exp dt: 05/2021, Mfd by: M/s. West Coast Pharmaceuticals Works Limited, FP-17 & 16/5 Meldi Mata Temple Near Gota railway Station Crossing, Gota, Ahmedabad – 382481, Gujarat.
5.	Levocetirizine tablets I.P. 5mg	B. No.: 9704418, Mfg dt: 12/2018, Exp dt: 11/2021, Mfd by: M/s. Karnataka Antibiotics & Pharmaceuticals Limited )A Govt. of India Enterprise), Plot No. 14, II Phase, Peenya, Bengaluru – 560058.
6.	Alprazolam tablets I.P.	B. No.: TAZP-001, Mfg dt: 11/2018, Exp dt: 10/2020, Mfd by: M/s. Medipol Pharmaceuticals India Pvt. Limited, 1199/3, Bhud, Baddi, distt. Solan. Himachal Pradesh.
7.	Eryfast-250 (Erythromycin Stearate Tablets B.P. 250 mg)	B. No.: MD926, Mfg dt: 04/2019, Exp dt: 02/2022, Mfd by: M/s. Mihika Pharmaceuticals, 506, Parmeshwari Centre, 18, Dalmia estate, Mulund (W), Mumbai – 400 080.

8.	Thyrocare-100 (Thyroxine Tablets I.P. 100 mcg)	B. No.: THDT611, Mfg dt: 12/2018, Exp dt: 05/2020, Mfd by: M/s. Unicure India Ltd., C-21, 22 & 23, Sector-3, Noida – 201 301, Distt. Gautam Budh Nagar (Uttar Pradesh).
9.	Eufox-O (Ofloxacin and Ornidazole Tablets)	B. No.: CJM711031, Mfg dt: 11/2017, Exp dt: 10/2020, Mfd by: M/s. Celebrity Biopharma Ltd., Vill: Panga Hill Top Estate, Via-Jharmajri, Barotiwala, Distt. Solan, Himachal Pradesh.
10.	Ornizole (Ornidazole Tablets I.P. 500 mg)	B. No.: T-1710151, Mfg dt: 10/2017, Exp dt: 09/2019, Mfd by: M/s. Aagya Biotech Pvt. Ltd., 1.5 KM, Manglour-Saharanpur Road, Manglour-247656, Roorkee, Distt. Haridwar, (Uttarakhand).
11.	ZEPARA –XT 650 mg (Paracetamol Tablets 650 mg)	B. No.: 418-955, Mfg dt: 10/2018, Exp dt: 09/2020, Mfd by: M/s. Zee Laboratories, Industrial Area, Paonta Sahib-173025. (Himachal Pradesh).
12.	Ticomox CV (Amoxicillin & Potassium Clavulanate Tablets I.P.)	B. No.: EBT-18L1588, Mfg dt: 12/2018, Exp dt: 02/2020, Mfd by: M/s. Edwin Biotech, Plot No. 184, Indl. Area, Phase IX, SAS, 160059 (Punjab).
13.	MOXCON-CV 625 (Amoxicillin & Potassium Clavulanate Tablets I.P.)	B. No.: SRDTB-1233, Mfg dt: 06/2019, Exp dt: 11/2020, Mfd by: M/s. Spas Remedise, Vill. Bersan, P.O. - Lodhi Majra, Teh. Baddi, Distt. Solan – 173 205 (Himachal Pradesh).
14.	Framycetin Skin Cream (Soframycin Skin Cream)	B. No.: N8080, Mfg dt: 04/2018, Exp dt: 09/2020, Mfd by: M/s. Sanofi India Limited, Plot No. C-1, Madkaim Ind. Estate, Ponda, Goa – 403 404.
15.	Monozin 50 (Cefpodoxime Proxetil Oral Suspension I.P.)	B. No.: SRDS-1031 , Mfg dt: 03/2019, Exp dt: 02/2021, Mfd by: M/s. Spas Remedies, Vill. Bersan, P.O. Lodhi Majra, Teh. Baddi, Distt. Solan – 173 205. (Himachal Pradesh).
16.	Clopidogrel & Aspirin Tablets	B. No.: T8202, Mfg dt: 07/2018, Exp dt: 06/2020,

		Mfd by: M/s. Bharat Parenterals Ltd., Vill. Haripura, Ta. Savli, Dist. Vadodara -391 520,Gujrat.
17.	Frusemide Injection I.P. 2 ml	B. No.: AI18064, Mfg dt: 07/2018, Exp dt: 06/2020, Mfd by: M/s. Alves Healthcare Pvt. Ltd., Nangal Uperia, Swarghat Road, Nalagarh, Dist. Solan, Himachal Pradesh – 174 101.
18.	Dermacur Cream 20g (Clobetasol Propionate Cream)	B. No.: E19009, Mfg dt: 01/2019, Exp dt: 36 months from date of mfg, Mfd by: M/s. Curis Lifesciences Pvt. Ltd., PF-23, Sanand GIDC - II, Sanand, Ahmedabad – 382110.
19.	FLI Drops Eye Drops 5 ml (Fluorometholone Acetate Ophthalmic Suspension 0.1% w/v)	B. No.: FLD904021, Mfg dt: 04/2019, Exp dt: 03/2021, Mfd by: M/s. Senses Phamaceuticals Ltd., No. 77, 3rd Road, Bommasandra Industrial Area, Bommasandra 4th Phase, Bangalore – 560 099.
20.	Dulcoflex (Biscodyl Tablets I.P. 5 mg)	B. No.: DLA18146, Mfg dt: 12/2018, Exp dt: 11/2021, Mfd by: M/s. Recipharm Pharmservices Pvt. Ltd., Khatha No. 845/713 & 1108/970/1, 34th KM, Tumkur Road, T-Begur, Nelamangala, Bangalore, Rural – 562123.
21.	Ciprofloxacin Tablets I.P. 500mg	B. No.: RCTW-06, Mfg dt: 01/2019, Exp dt: 12/2021, Mfd by: M/s. Nestor Pharmaceuticals Limited, 11, Westrn Extension Area Faridabad – 121001, India.
22.	Climox 1.2g (Amoxycillin & Potassium Clavulanate Injection I.P.)	B. No.: I-17225, Mfg dt: 06/2018, Exp dt: 05/2020, Mfd by: M/s. Jackson Laboratories Pvt. Ltd., 22-24, Majitha Road, Bye Pass, Amritsar 143001 (India) Punjab.
23.	Abiraterone Acetate	B. No.: 20180303, Mfg dt: 03/2018, Exp dt: 03/2020, Mfd by: M/s. Shijiazhuang Dingmin Pharmaceuticals Sciences Co. Ltd., No. 41 Zhaiyng South Street, Shijiazhuang, Hebei, China
24.	Calcium-Vitamins Tonic (CALCINOL SYRUP)	B. No.: T18016, Mfg dt: 07/2018, Exp dt: 12/2019, Mfd by: M/s. Raptakos, Brett & Co. Ltd. 1st Pokhran Road,

		Thane-400606.
25.	(RANITIDINE INJECTION IP)	B. No.: HLI849K, Mfg dt: 10/2018, Exp dt: 09/2020, Mfd by: M/s. Himalaya Meditek Pvt. Ltd. Plot No. 35 & 36 Pharmacy Selaqui, Industrial Area Dehradun-248197 (Uttarakhand).
26.	Allopurinol Tablets IP 300 mg (AURINOL-300 TABLETS)	B. No.: AT/5515, Mfg dt: 11/2018, Exp dt: 10/2020, Mfd by: M/s. Apple Biotech Vill.Deep Nagar, Teh Payal, Ludhiana-141421 (Punjab) India.
27.	Lactic Acid Bacillus Capsules (VIZYLAC CAPSULES)	B. No.: G2AD219010, Mfg dt: 02/2019, Exp dt: 07/2020, Mfd by: M/s. Uni Medicolabs Plot No. 25 & 26, Pharma City, Selaqui, Dehradun (Uttarakhand).
28.	Gabapentin 400 mg and Nortriptyline 10 mg Tablets (DOLENEURON NT TABLETS )	B. No.: DNT1099D, Mfg dt: 04/2019, Exp dt: 01/2021, Mfd by: M/s. Pulse Pharmaceuticals Pvt. Ltd. Khasra No:- 400,407 and 409, Karondi, Roorkee, Uttarakhand-247667.

**List of Drugs declared as Not of Standard, for the Month of September 2019**

<b>S. N.</b>	<b>Name of Drugs/medical device/cosmetics</b>	<b>Batch No./Date of Manufacture/Date of Expiry/Manufactured By</b>
1.	Ciprofloxacin Tablets IP 500 Mg	B. No.: 05028-BTN21, Mfg dt: 02/2018 Exp dt: 01/2020, Mfd by: M/s. Biogenetic Drugs Pvt. Ltd., Vill.-Jharmazri, Baddi-174103, Dist. Solan, Himachal Pradesh.
2.	Pantoprazole Sodium Tablets IP 40 mg	B. No.: GSM-18557, Mfg dt: 04/2018, Exp dt: 03/2020, Mfd by: M/s. Chem Pharmaceuticals Pvt. Ltd., plot No. 22, Sector-3, SIDCUL-IIIE, Kudrapur, Dist. US Nagar (Uttarakhand) 263153.
3.	Norfloxacin Tablet I.P. 400 mg.	B. No.: NT603, Mfg dt: 02/2019, Exp dt: 01/2021, Mfd by: M/s. Unicure India Ltd. C-21, 22 & 23 Sector-3, Noida-201301 Dist-Gautam Budh Nagar (UttarPradesh).
4.	Chloramphenicol Capsules I.P. 250 mg. (Starphenicol 250)	B. No.: JK18002, Mfg dt: 03/2019, Exp dt: 02/2020, Mfd by: M/s. Cadila Pharmaceuticals Ltd. Indst. Growth Centre, Samba (Jammu & Kashmir)-184121.
5.	Thyrocare-50 (Thyroxine Tablets I.P. 50 mcg)	B. No.: THAT616, Mfg dt: 12/2018, Exp dt: 05/2020, Mfd by: M/s. Unicure India Ltd., C-21, 22 & 23, Sector-3, Noida – 201301, Distt. Gautam Budh Nagar (Uttar Pradesh).
6.	Dispersible Paracetamol Tablets B.P. 250 mg	B. No.: T-17517, Mfg dt: 07/2018, Exp dt: 06/2020, Mfd by: M/s. Jackson Laboratories Pvt. Ltd., 22-24, Majitha Road, Bye Pass, Amristar – 143001 (Punjab).
7.	Primaquine Tablets IP 2.5mg	B. No.: PJVT-01, Mfg dt: 02/2018, Exp dt: 01/2020, Mfd by: M/s. Nestor Pharmaceuticals Limited, 11, Western, Extension Area, Faridabad-121001 (Haryana)
8.	Primaquine Tablets I.P.,	B. No.: PRD1801, Mfg dt: 03/2018, Exp dt: 02/2020, Mfd by: M/s. La-Chemico Private Limited, Taki Road, Kadambagachi, Barasat, North 24-Parganas, Kolkata- 700125.

9.	Ranitidine Injection I.P.	B. No.: I-17347, Mfg dt: 07/2018, Exp dt: 06/2020, Mfd by: M/s. Jackson Laboratories Pvt. Ltd., 22-24, Majitha Road, Bye Pass, Amritsar-143 001 (Punjab).
10.	Amiject 500 (Amikacin Sulphate Injection I.P.)	B. No.: L079018, Mfg dt: 04/2019, Exp dt: 03/2021, Mfd by: M/s. Abaris Healthcare Pvt. Ltd., Survey No.1407-11, Village-Rajpur, Taluka-Kadi, Distt. Mehsana (Gujarat).
11.	PQ-7.5 (Primaquine Phosphate Tablets I.P.)	B. No.: PRM-1001B, Mfg dt: 01/2017, Exp dt: 12/2019, Mfd by: M/s. Ridley Life Sciences Pvt. Ltd., D-1651, DSIDC Indl. Complex, Nbarela, Delhi- 110 040.
12.	Cetfast (Cetirizine Hydrochloride Tablets I.P.)	B. No.: MT-17533, Mfg dt: 03/2018, Exp dt: 02/2020, Mfd by: M/s. Medimark Drugs &Pharmaceuticals, Plot No. 39, Sector - 6A, IIE, Sidcul Haridwar - 249403 (Uttarakhand).
13.	Okacet-L (Levocetirizine Tablets I.P. 5 mg)	B. No.: AFB8D36, Mfg dt: 09/2018, Exp dt: 08/2020, Mfd by: M/s. Pure & Cure Healthcare Pvt. Ltd., Plot No. 26A-30, Sector-8A, I.I.E. SIDCUL, Haridwar-249403 (Uttarakhand).
14.	Zylocef-S 375 (Ceftriaxone & Sulbactam for Injection)	B. No.: 14718/A, Mfg dt: 03/2019, Exp dt: 02/2021, Mfd by: M/s. Osper Formulations Pvt. Ltd., Plot No. 134-B, Export Promotion Industrial Park, Phase- 1, Jharmajri Baddi, Dist. Solan (Himachal Pradesh).
15.	Atorvastatin Tablets IP 20mg	B. No.: 968-01, Mfg dt: 01/2019, Exp dt: 12/2020, Mfd by: M/s. Hab Pharmaceuticals & Research Limited., 10, Pharmacy, SIDCUL, Selaqui, Dehradun – 248011 (Uttarakhand).
16.	Calcium Carbonate Tablets I.P.	B. No.: T190324, Mfg dt: 03/2019, Exp dt: 02/2021, Mfd by: M/s. Micron Pharmaceuticals, 2117, A-2, Phase-III, G.I.D.C., Vapi – 396195 (Gujarat).
17.	Cetirizine Hydrochloride Tablets IP 10mg	B. No.: SHT9114, Mfg dt: 01/2019, Exp dt: 12/2021, Mfd by: M/s. Syncom Healthcare Limited., D-42, IIE SIDCUL., Selaqui, Dehradun – 248197 (Uttarakhand).



18.	Mycophenolate Sodium Tablets USP 720 mg (Mycophaz-720 Tablets )	B. No.: AT/7822, Mfg dt: 02/2019, Exp dt: 01/2021, Mfd by: M/s. Apple Biotech Vill.Deep Nagar, Tehsil Payal, Ludhiana (Punjab )-141421.
19.	Ofloxacin Tablets 400 mg (Ofloz-400 Tablets)	B. No.: AHT-1133, Mfg dt: 01/2019, Exp dt: 12/2020, Mfd by: M/s. Algen Healthcare Limited 134/2. Vill. Khara Khari, Sadhaura Road, Kala Amb, Distt. Sirmour (Himachal Pradesh).
20.	Sucralfate with Oxetacaine Oral Suspension (Sucrazed-O Suspension )	B. No.: SL-416, Mfg dt: 06/2019, Exp dt: 05/2021, Mfd by: M/s. Sridhara Lifesciences Pvt. Ltd. Khasra No. 28, Sisona, Bhagwanpur, Roorkee, Distt. Haridwar (Uttarakhand).
21.	Sucralfate with Oxetacaine Oral Suspension (Sucrazed-O Suspension )	B. No.: ULL-1855, Mfg dt: 09/2018, Exp dt: 08/2020, Mfd by: M/s. Ultramed Life Sciences Khasra No. 26, Shiv Ganga Indi. Estate, Lakeshwari Bhagwanpur, Roorkee-247667 (Uttarakhand).

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