

GOVERNMENT OF RAJASTHAN  
Drugs Control Organization, Room No. 305, Swasthya Bhawan,  
Tilak Marg, Jaipur (Rajasthan)

E-mail: [drugcontrolraj@gmail.com](mailto:drugcontrolraj@gmail.com)  
Contact no. 0141-2221760, 2221670

No. DC/Bulletin/2017/ 1554

Dated: 04/09/2017

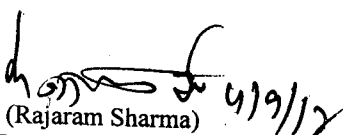
All Drugs Control Officers,  
Rajasthan, State.


Sub:- Details of Drugs declared as Not of Standard Quality w.e.f. 01.08.2017 to 31.08.2017.

Particulars of the samples declared as not of standard quality on test /analysis are given below for ensuring that the stocks of these drugs are not consumed anymore and appropriate safe guard to the consumers is provided by withdrawing the available stock and take action as per provisions of Drugs & Cosmetics Act 1940 & Rules made there under.

S. No.	Name of Drugs	B.No./ Exp. Date	Mfgd. by	Reason
1.	Betamethasone Tablets I.P. (WALACORT)	WTL-5011, DEC.17	M/s Wallace Laboratories Pvt. Ltd., Plot No. 231P-240P, K.I.A.D.B., Belur Ind. Area, Belur, Dharwad, Karnataka-580011	The sample does not conform to the claim with respect to Assay. Assay: Betamethasone found 0.1424mg (i.e. 28.48% of claim)
2.	Enteric Coated Rabepazole Sodium & Domperidone SR Capsules (RABJON-DSR Capsule)	C-161229, NOV.2018	M/s Pharma Linkers, Plot No. 26, S.G. Industrial Estate Bhagwanpur, Roorkee-247667 UK	The sample does not conform to the claim with respect to Assay of Rabepazole Sodium and Domperidone. Assay: Rabepazole Sodium Found 10.06mg (i.e 50.3% of claim) Domperidone Found 14.84mg (i.e 49.47% of claim)
3.	Pantoprazole Sodium and Domperidone SR Capsules (JONPAN-DSR Capsules)	C-161228, NOV.2018	M/s Pharma Linkers, Plot No. 26, S.G. Industrial Estate, Bhagwanpur, Roorkee-247667 UK	The sample does not conform to the claim with respect to Assay of Pantoprazole and Domperidone. Assay: Pantoprazole Found 21.3mg (i.e 53.25% of claim) Domperidone Found 16.21mg (i.e 54.03% of claim)
4.	Amoxycillin Trihydrate & Potassium Clavulanate Oral Suspension IP (CATMOX-CV DRY SYRUP)	SD-701017, 06/2018	M/s Sunniva Drugs & Formulation Ltd., Kh. No. 396, Nanhera Anantpur, Roorkee, Utrakhand-247667	The sample does not conform to the claim with respect to Assay of Amoxycillin and Clavulanic Acid. Assay: Amoxycillin Found 148.09mg (i.e 74.05% of claim) Clavulanic Acid Found 18.85mg (i.e 66.14% of claim)
5.	Ofloxacin & Ornidazole Tablets (OFLOJON-OZ)	.HOO-1602/C, 09/2018	M/s Helax Health Care Private Limited, Khasra No. 410, Village Karondi, Roorkee-247667, Distt. Haridwar	The sample does not conform to the claim with respect to Disintegration. Disintegration: 89 minutes against 30 minutes prescribed for Filmcoated tablets
6.	Tramadol Hydrochloride & Paracetamol Tablets (Contragesic)	UCT-15004, 09/2017	M/s Deccan Healthcare Pvt. Ltd., Plot No. 13, Sec-3 SIDCUL I.I.E. Pantnagar, Distt.-U.S. Nagar (U.K.) 263153	The sample does not conform to the claim with respect to Assay of Paracetamol and Tramadol HCL. Assay: Paracetamol Found 233mg (i.e 71.69% of claim) Tramadol HCL Found 18.77mg (i.e 50.05% of claim)
7.	Betamethasone Sodium Phosphate Tablets I.P. (BETASAL TABLETS)	ZRT-016, SEP.2017	M/s Zenith Remedies Pvt. Ltd., Kh. No.-242, Bahadarpur, Khadar, Roorkee Road, Laksar, Distt. Haridwar (UK)	The sample does not conform to the claim with respect to Assay of Betamethasone. Assay: Betamethasone Found 0.2939mg (i.e 58.78% of claim)
8.	Amlodipine & Atenolol Tablets (ATO PIN-A)	GAD-15737, NOV 2017	M/s elfin Drugs Pvt. Ltd., Vill-Barson Nalagarh (H.P.) 174101	The sample does not conform to the claim with respect to Assay of Amlodipine. Assay: Amlodipine Found 2.221mg (i.e 44.42% of claim)
9.	Ofloxacin Tablet IP (Opilox-200 Tablets)	T-1848C, SEP.2018	M/s Orison Pharma International Khari, Mauza Ogli, Kala Amb-173030 (H.P.)	The sample does not conform to the claim with respect to Dissolution. Average: 40.10%
10.	Rabepazole Sodium Tablets I.P. (Gaszol-20)	GTN-151925, 10/2017	M/s GMH Laboratories, Plot No. 13, Industrial Township, Bhatoli Kalan, Baddi, Distt. Solan (H.P.)	The sample does not conform to the claim with respect to Dissolution. Average: 37.98%
11.	Betamethasone Sodium Phosphate Tablets I.P. 0.5mg (BETASON)	BS1504, SEP.2017	M/s Danish Healthcare (P) Ltd., Regd. Office: 76/27-28, Industrial Estate, Maxi Road, Ujjain-456010 India	The sample does not conform to the claim with respect to Assay of Betamethasone. Assay: Betamethasone Found 0.397mg (i.e 79.4% of claim)
12.	Tobramycin Ophthalmic Solution USP	TNE1602, 05/2018	M/s Modern Laboratories, 45-47, Sector D-2, Sanwer Road, Indore (MP)-452015	The sample does not conform to the claim with respect to Assay and Sterility. Assay: Tobramycin Found 0.2428% w/v (i.e 80.93% of claim)
13.	Amikacin Sulphate Injection IP 100mg	AK1620, 07/2019	M/s Nandani Medical Laboratories Pvt. Ltd., 221/5, Bicholi Hapsi, Kanadia Road, Indore.	The sample does not conform to the claim with respect to Sterility.

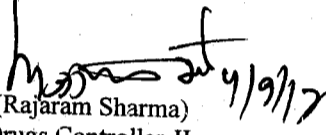
Please ensure about the quality of other batches and drugs of said manufacturers available in the market from time to time.

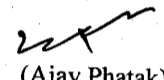
  
(Rajaram Sharma)  
Drugs Controller-II,  
Rajasthan, Jaipur

  
(Ajay Phatak)  
Drugs Controller-I,  
Rajasthan, Jaipur

Copy forwarded for necessary action to:-

- 1- Drugs Controller General (India), FDA Bhawan, CHER Campus, Kotla Road, New Delhi.
- 2- Mission Director, NHM, Medical & Health Services, Hq. Jaipur.
- 3- Managing Director, R.M.S.C.L., Swasthya Bhawan, Jaipur.
- 4- Dy. Secretary, Medical & Health Department (Gr.II), Rajasthan, Jaipur.
- 5- Director, Medical & Health Services (P.H./F.W./MSU/ESI/AIDS), Jaipur.
- 6- Director, Public Relation Directorate, Rajasthan, Jaipur for publicity.
- 7- Director, Animal Husbandry, Rajasthan, Jaipur.
- 8- The Drugs Controllers" Andrapradesh/Gujarat/Himachal Pradesh/Pondicherry/Madhya Pradesh/ Uttrakhand/ Assam/Arunachal Pradesh/Andaman Nicobar/Bihar/Chattisgarh/Daman/Delhi/Dadar & Nagar Haveli/ Maharashtra/Goa/Haryana/Jammu & Kashmir/Jharkhand/Kerala/Lakshadweep/ Manipur/ Meghalaya/ Mizoram/ Nagaland/Orissa/Punjab/Sikkim/Tripura/UttarPradesh/West Bengal/ Karnataka.
- 9- All Suptt, Associated Group of Hospitals,/All Principals, Medical Colleges, Rajasthan.
- 10- Jt. Drugs Controller (India), North Zone, Kamla Nehru Nagar, Ghaziabad.
- 11- Asst. Drirector, Public Relation, Swasthya Bhawan, Jaipur.
- 12- All CM&HO, Rajasthan/All P.M.O's/All Asst. Drugs Controllers, Rajasthan.
- 13- President, Rajasthan Chemist Association, Dawa Bazar, Jaipur.
- 14- Dawa Charcha, Kirana Bhawan Marg, Hanumangarh Town-335513.
- 15- Health View, 170/3, Ram Gali, Rajapark, Jaipur./Medicare News, Outside Chhawani Railway Crossing, Dungari Road, Kailas h Colony, Beawer.
- 16- Medical Times 382 Rani Sati Nagar Nirman Nagar E, Ajmer Road, Jaipur./ "Lok Ujala" Ujala Marg, Chotina Kuwa, Bikaner/ Health Topics, 2049, Pitaliyon Ka Chowk, Zohari Bazar, Jaipur.
- 17- J.J. Health Times, 2 KHA-16, J.J. House, Vaishali Nagar, Ajmer.
- 18- Officer I/c, Server room to please provide the page under www. Rajswasthya.nic.in औषधि नियंत्रण संगठन Bulletin heading and e-mail to all above officers.
- 19- Computer Desk/ concerning files.

  
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