

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

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No. DC/Bulletin/2018/ 181

Dated: 11/2/2018


All Drugs Control Officers,  
Rajasthan, State.

Sub:- Details of Drugs declared as Not of Standard Quality w.e.f. 16-01-2018 to 31-01-2018.

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.	Amlodipine & Atenolol Tablets (Biopress-AM)	AKT-8519, 02/2018	M/s Allkind Healthcare Ltd., Plot No. 88-B. Export Promotion Industrial Park, Phase-II, Vill. Thana Baddi Distt. Solan 173205 (H.P.)	The sample does not conform to the claim with respect to Assay of Amlodipine. Assay: Amlodipine Found 2.249mg (i.e 44.98% of claim)
2.	Ciprofloxacin Eye Drops I.P.	ED6147. 11-19	M/s Scott Edil Pharmacia Ltd., 56, E.P.I.P. Phase-I, Jharmajri-173205	The sample does not conform to the claim with respect to description as it show physical instability in the form of particulate matter
3.	Ondansetron Oral Solution (PONDEM)	FRS-089, 04/2018	M/s Francis Remedies (India) Pvt. Ltd., Vill. Mandawali, Roorkee Distt. Haridwar (U.K.)	The sample does not conform to the claim as it does not contain Ondansetron (Nil).
4.	Ondansetron Oral Solution IP (NITRON).	L-5423, 02/2018	M/s Saibliss Drugs & Pharmaceuticals, 66-67, Gondpur Industrial Area, Paonta Sahib-173025 (H.P)	The sample does not conform to the claim as it does not contain Anhydrous Ondansetron (Nil).
5.	Betamethasone Sodium Phosphate Tablets IP (Beetasol)	BT-03, 02/2018	M/s Oshino Drug (P) Ltd., B-23/8, B.S. Road. Indl. Area, Ghaziabad-201009 (U.P)	The sample does not conform to the claim with respect to Assay. Assay: Betamethasone Found 0.39mg (i.e 78% of claim)
6.	New Rama Handloom Rolled Cloth	RC 17, D/M JAN.17, D/E Exp. Date after 5 Years	M/s Fab India Surgicals, Prithvi Ganj, Kanth-244501 (MBD)	The sample does not conform to the claim with respect to Dimension (Length & width), Threads per dm (warp no and weft no), weight per unit area, fluorescence and description as cloth is not good white
7.	Betamethasone Sodium Phosphate Tablets I.P. (BETASOP TABLETS)	NHT-401, MAR.2018	M/s Neutec Healthcare Pvt. Ltd., E-698, DSIDC Narela, Industrial Area, Delhi-110040	The sample does not conform to the claim with respect to Assay. Assay: Betamethasone Found 0.395mg (i.e 79% of claim)
8.	A Handloom Product Rolled Bandage as per Schedule F(II) (Non Sterile)	636, D/M JULY 2017. D/E After 2 years from Mfg. Month,	M/s Bhansali Udhog, 1, Indra Gandhi Udyogpuri, Main Ajmer Road, Beawar	The sample does not conform to the claim with respect to dimension (length), Threads per dm (Warp no. and weft no.) weight per unit area fluorescence.
9.	Budesonide Nebuliser Suspension BP	ABT1048 03/2019	M/s Cadila Healthcare Limited, Shree shyam singh nursery, Phase-II, Indl. Area, Bhiwandi, Mfg at SP-918, Phase-III, Indl Area, Bhiwandi, Dist. Alwar 301019.	The sample does not comply the requirements of preparations for inhalation with respect to description as per BP monograph for inhaled products/ Ph Eur monograph 0671.
10.	Betamethasone Sodium Phosphate Tablets I.P. 0.5MG (Betachem)	B-1009, MAR.18	M/s Nikem Drugs Pvt. Ltd., 245, Sector-F, Ind. Area, Sanwer Road, Indore-452015.	The sample does not conform to the claim with respect to Assay. Assay: Betamethasone Found 0.379mg (i.e 75.8% of claim)
11.	Tobramycin Ophthalmic Solution USP	TNE1606, 08/2018	M/s Modern Laboratories, 45, Sector D-2, Sanwer Road, Indore (M.P.)	The sample does not conform to the claim with respect to Sterility.

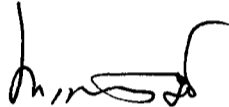
Please ensure about the quality of other batches and drugs of said manufacturers available in the market from time to time.

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

P.T.O.

Copy forwarded for necessary action to:-

- 1- Drugs Controller General (India), FDA Bhawan, CHEB 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.

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