

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

E-mail: rajdrugcontroller200@gmail.com
drugcontrolraj@gmail.com
Contact no. 0141-2221760, 2221670

No. DC/Bulletin/2018/ 818
All Drugs Control Officers,
Rajasthan, State.

Dated: 17/4/18

Sub:- Details of Drugs declared as Not of Standard Quality w.e.f. 01-04-2018 to 15-04-2018.

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-	Drotaverine Hydrochloride & Mefenamic Acid Tablets	TDMA-005, 04/2018,	M/s Medipol Pharmaceutia India Pvt. Ltd., 1199/3, Bhud, Baddi, Distt-Solan, H.P. INDIA	The sample does not conform to the claim with respect to Description as tablets shows physical instability in form of powder and granules.
2	Paracetamol, Phenylephrine HCl, Guaiphenesin Cetirizine Dihydrochloride, Ambroxol HCl Tablets (BROXINE)	BPLT-2366, 10/2019,	M/s Bennet Pharmaceuticals Ltd., Village-Chanal Majra, Nr. Manpura, BADDI, Ta: Nalagarh, Distt.-Solar, (H.P.)- 173205	The sample does not conform to the claim with respect to Assay of Cetirizine Dihydrochloride. Assay: Cetirizine Dihydrochloride Found 11.09mg (i.e 221.8% of claim)
3	Levofloxacin Tablets IP (GLV-500)	GPT-160720, 04/2018	M/s GNOSIS Pharmaceuticals Pvt. Ltd., Nahan Road, Village: Moginand, Kala-Amb, Distt. Sirmour, H.P-173030	The sample does not conform to the claim with respect to Dissolution. Dissolution: Average: 21.09%
4	Ciprofloxacin Eye Drops I.P.	ED6146, 11-19	M/s Scott-Edil Pharmacia Ltd., 56, E.P.I.P. Phase-I, Jharajri-173205	The sample does not conforms to the claim with respect to Description as it show the physical instability in the form of particulate matter.
5	Paracetamol Tablets IP (TIFMOL-650)	T1445, MAR.2019	M/s D M Pharma, NH-21 A, Bhud, Baddi, Distt. Solan (H.P.) 173205	The sample does not conform to the claim with respect to Dissolution. Dissolution: Average: 68.11%
6	Paracetamol Tablets I.P (PACKER-650 TABLETS)	415-3856, 11/2018	M/s Zee Laboratories Ltd., Behind 47, Industrial Area, Paonta Sahib-173025	The sample does not conform to the claim with respect to Dissolution. Dissolution: Average: 20.10%
7	Paracetamol Tablets I.P. 650 mg (Thermol 650)	ST-60255 Aug.2018	M/s Sunvij Drugs Limited. 511, G.I.D.C., Waghodia, Vadodara Gujrat 391760	The sample does not conform to the claim with respect to Dissolution Dissolution: Average: 33.33%

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

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

(Raja Ram Sharma)
Drugs Controller-I,
Rajasthan, Jaipur

No. DC/Bulletin/2018/ 818

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, Animai Husbandry, Rajasthan, Jaipur.
- 8- The Drugs Controllers" Andrapradesh/Gujarat/Himachal Pradesh/Pondicherry/Madhya Pradesh/Uttarakhand/ 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, Dungalari 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.

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

(Raja Ram Sharma)
Drugs Controller-I,
Rajasthan, Jaipur