

GOVERNMENT OF RAJASTHAN
Drugs Control Organization, Room No. 315, Swasthya Bhawan,
Tilak Marg, Jaipur (Rajasthan)

E-mail: drugcontroller1.mh@rajasthan.gov.in
Contact no. 0141-2221760, 2221670

No. DC/Bulletin/2019/259

Dated: 18/2/19


All Drugs Control Officers,
Rajasthan, State.

Sub:- Details of Drugs declared as Not of Standard Quality w.e.f. 01-02-19 to 15-02-19.

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	Ciprofloxacin Hydrochloride Tablets IP 500mg (DIOCIN-500 TABLETS)	DL17020, FEB.19	M/s IBN Herbals (A Unit of Curetech Formulations (P) Ltd.), Khasra No. 63, Vill. Juddi Kalan, Baddi, Distt. Solan (H.P.)	The sample does not conform to the claim with respect to Dissolution. Dissolution: Average: 35.96%
2	Montelukast Sodium Tablets IP (Montelar-10)	MLT-05, 11/2019	M/s Lark Laboratories (I) Ltd., SP-1192E, RIICO Industrial Area, Phase-IV, Bhiwadi, Dist. Alwar (Raj.)	The sample does not conform to IP this particular batch of sample fails the test dissolution.
3	Amoxicillin & Potassium Clavulanate Tablets IP (Clavpen-625)	18A073, Aug.2019	M/s Astam Healthcare Pvt. Ltd., Vill Theda Teh. Nalagarh Dist Solan-174101 (HP).	The sample does not conform to the claim with respect to Assay of Clavulanic Acid. Assay: Clavulanic Acid Found 97.89 mg (i.e 78.31% of claim)
4	Drotaverine Hydrochloride Injection 2ml	BIO17002, 12/2019	M/s Heaith Biotech Ltd., Unit-II Nalagarh Road, Baddi 173205 Distt. Solan (H.P.)	The sample does not conform to the claim with respect to Particulate Matter and Description as it shows the physical instability in form of particles
5	Ofloxacin Tablets IP (Ormixa-200)	17B-T168A, 04/19	M/s Orison Pharma International, Khari Mauza-Ogli, Kala Amb 173030 (HP)	The sample does not conform to the claim with respect to Dissolution. Dissolution: Average: 16.58%
6	Betamethasone Sodium Phosphate Tablets I.P. (BETASOP TABLETS)	NHT-501, MAR/2019	M/s Neutec Healthcare Pvt. Ltd., E-698, DSIDC, Nerala Industrial Area, Delhi-110040.	The sample does not conform to the claim with respect to Assay. Assay- Betamethasone Found 0.345% (i.e. 69% of claim)

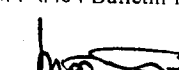
Please ensure about the quality of other batches and drugs of said manufacturers available in the market from time to time.


Drugs Controller
Rajasthan, Jaipur
Dated: 18/2/19

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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. Director, 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, Kailash 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 अधि नियंत्रण संगठन Bulletin heading and e-mail to all above officers.
- 19- Computer Desk/ concerning files.


Drugs Controller
Rajasthan, Jaipur