

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

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

No. DC/Bulletin/2018/2046

Dated: 25/10/18

All Drugs Control Officers,
Rajasthan, State.

Sub:- Details of Drugs declared as Not of Standard Quality w.e.f. 01-10-2018 to
15-10-2018.

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	Hydroxyzine Hcl Tablets IP (Arotex-25)	NO-8984, Nov-2018	M/s Mefro Organic Ltd., Plot No. 4, Indl. Area, Tahiwal, Tehsil Haroli, Distt Una (HP) 174301	The sample does not conform to the claim with respect to Dissolution Dissolution: Average 42.24%
2	Ondansetron Hydrochloride & Omeprazole Magnesium Tablets (Omra CAP-O)	T4680, OCT.2018	M/s D.M. Pharma, NH-21A, Vill. Bhud, Baddi, Distt. Solan (H.P.) 173205	The sample does not conform to the claim with respect to Assay of Ondansetron & Omeprazole. Assay: Ondansetron Found 3.03mg (i.e 75.75% of claim) Omeprazole Found 5.75mg (i.e 57.5% of claim)
3	Rabeprazole Sodium & Domperidone (SR) Capsules (RABIROS-DSR)	MC-16029, 12/2018	M/s Sunlife Sciences, 130, Kurdi, Jhabrera Road, Manglour, Roorkee, Distt. Haridwar (U.K.)	The sample does not conform to the claim with respect to Assay of Rabeprazole Sodium & Domperidone. Assay: Rabeprazole Sodium Found 15.4mg (i.e 77% of claim). Domperidone Found 24.36mg (i.e 81.2% of claim)
4	Diclofenac Sodium Tablets I.P 50mg,	DCTT-07, 12/2018	M/s Nestorpharmaceuticals Limited, 11, Western Extension Area, Faridabad 121001, India	The sample does not conform to the claim with respect to Disintegration. Disintegration: Does not comply (All 06 tablets are disintegrate in 0.1M NCL in 30 min)
5	Dextromethorphan HBr Ammonium, Chloride Phenylephrine HCl, Chlorpheniramine Maleate & Menthol Syrup (COFURA DMR Syrup COUGH EXPECTORANT),	HL-1612045, 11/2018	M/s Helax Health Care Private Limited, Khasra No. 410, Village Karondi, Roorkee-247667, Distt. Haridwar	The sample does not conform to the claim as it contain colour Sunset Yellow
6.	Dextromethorphan HBr, Ammonium Chloride Phenylephrine HCl, Chlorpheniramine Maleate & Menthol Syrup (COFURA DMR Syrup COUGH EXPECTORANT)	HL-1701007, 12/2018	M/s Helax Health Care Private Limited, Khasra No. 410, Village Karondi, Roorkee-247667, Distt. Haridwar	The sample does not conform to the claim as it contain colour Sunset Yellow

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

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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, 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](http://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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Rajasthan, Jaipur