

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

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No. DC/Bulletin/2018/ **476**

Dated: **6/3/18**


All Drugs Control Officers,
Rajasthan, State.

Sub:- Details of Drugs declared as Not of Standard Quality w.e.f. 16-02-2018 to 28-02-2018.

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.	Dextromethorphan HBr. Ammonium Chloride, Phenylephrine HCl, Chlorpheniramine Maleate Syrup (COFURA DMR Syrup)	SL-704008, 03/2019	M/s Sunniva Drugs & Formulation, Khasra No. 396, Nanhera Anantpur, Roorkee, Uttrakhand 247667	The sample does not conform to the claim as it contain colour Ponceau 4R.
2.	Dextromethorphan HBr. Ammonium Chloride, Phenylephrine HCl, Chlorpheniramine Maleate Syrup (COFURA DMR Syrup)	SL-704009, 03/2019	M/s Sunniva Drugs & Formulation, Khasra No. 396, Nanhera Anantpur, Roorkee, Uttrakhand 247667	The sample does not conform to the claim as it contain colour Ponceau 4R.
3.	Dextromethorphan HBr, Chlorpheniramine Maleate, Ammonium Chloride, Sodium Citrate & Menthol Syrup (COFURA DMR-DS Syrup)	SL-701004, Dec.2018	M/s Sunniva Drugs & Formulation, Kh. No. 396, Nanhera Anantpur, Roorkee, Uttrakhand-247667	The sample does not conform to the claim as it contain colour Sunset Yellow.
4.	Dextromethorphan HBr. Ammonium Chloride, Phenylephrine HCl, Chlorpheniramine Maleate & Menthol Syrup (COFURA DMR Syrup)	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. The label does not state the amount of menthol where as mentioned in generic name
5.	Tobramycin & Dexamethasone Ophthalmic Suspension USP	BC6091, FEB. 18	M/s Axa Parenterals Ltd., Plot No. 936,937 & 939, Kishanpur, Jamalpur, Roorkee-247667 Uttarakhand INDIA	The sample does not conform to the claim with respect to Description as found pale yellow coloured solution in place of suspension as claimed. Description: Clear, pale yellow coloured solution found in PVC vial.
6.	Amoxicillin Trihydrate & Potassium Clavulanate Tablets I.P (Catmax-CV 625)	T-16052 03/2018	M/s Saniva Formulations, 96, Nanhera Anantpur, Bhagwanpur U.K.	The sample does not conform to the claim as it does not contains Amoxicillin (Nil) and Clavulanic Acid (Nil).
7.	Amoxicillin & Potassium Clavulanate Dispersible Tablets (Zacova-CV DT Kid Tablets)	BT16-692, 03/2018	M/s Athens Labs. Ltd., Plot No. 258/197/4/6, Mauza Rampur Jattan, Near Kalaamb, Teh-Nahan Distt. Sirmour-HP-173030	The sample does not conform to the claim with respect to Assay of Clavulanic Acid (Nil). Dispersible Amoxicillin and Potassium Clavulanate Tablets are official in B.P. it should be claimed accordingly.

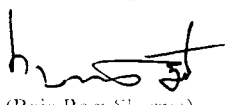
Please ensure about the quality of other batches and drugs of said manufacturers available in the market from time to time.


(Raja Ram Sharma)
Drugs Controller-I,
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/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/Uttar Pradesh/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, Kishan Colony, Beawer.
- 16- Medical Times 382 Rani Sati Nagar Nirman Nagar E, Ajmer Road, Jaipur./ "Lok Ujala" Ujala Marg, Chotina Kuwa, Durgam/ 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.


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