

No. DC/Bulletin/2018/ 687

Dated: 3/4/18

All Drugs Control Officers,
Rajasthan, State.

Sub:- Details of Drugs declared as Not of Standard Quality w.e.f. 16-03-2018 to 31-03-2018.

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.	Amoxicillin and Potassium Clavulanate Oral Suspension IP (CLAV Dry Syrup)	CP-0430E, 04-2018	M/s Curehealth Pharmaceuticals Pvt. Ltd., Village: Raipur P.O. Deothi Tehsil & District Solan HP 173211	The sample does not conform to the claim with respect to Assay and Storage Stability of Clavulanic Acid. Assay: Clavulanic Acid Found 17.94mg (i.e 62.95% of claim)
2.	Enteric Coated Rabeprazole Sodium & Sustained Release Domperidone Capsules (Rabil-DSR)	MCAS-1505, APR.2018	M/s Maxtar Bio-Genics, K.No. 705, Nalagarh Road, Malku Majra, Baddi, 173205 (H.P)	The sample does not conform to the claim with respect to Assay of Rabeprazole Sodium. Assay: Rabeprazole Sodium Found 10.6mg (i.e 53% of claim)
3.	Rabeprazole Sodium Tablet IP 20mg (Y RAB-20)	DLT-2146, Apr.2018	M/s Daffohils Laboratories Pvt. Ltd., F-109-110, UPSIDC Industrial Area, Selaqui, Dehradun, U.K.-248011, (INDIA)	The sample does not conform to the claim with respect to Assay. Assay: Rabeprazole Sodium Found 12.68mg (i.e 63.4% of claim)
4.	Cetirizine Hydrochloride Tablets I.P. 10mg	CTR01, 02/2020	M/s Lark Laboratories (I) Ltd., SP-1192E, Phase-IV Indl. Area, Bhiwadi-301019, Dist. Alwar (Raj.)	The sample does not conform to I.P. with respect to uniformity of content.
5.	Amoxicillin 200mg and Clavulanic Acid 28.5mg/5ml oral suspension I.P.	ACO-01, 04/2018	M/s Lark Laboratories (I) Ltd., SP-1192E, Phase-IV Indl. Area, Bhiwadi-301019, Dist. Alwar (Raj.)	The sample has been declared as Not of Standard Quality as it does not conform to I.P. standards with respect to Assay for Clavulanic Acid. Assay: Found 19.03mg/5ml

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

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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/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.

(Ajay Phatak)
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Rajasthan, Jaipur

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