

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

E-mail: [drugcontroller1.mh@rajasthan.gov.in](mailto:drugcontroller1.mh@rajasthan.gov.in)  
Contact no. 0141-2221760, 2221670

No DC/Bulletin/2019/ 562

Dated: 11/5/19


All Drugs Control Officers,  
Rajasthan, State.

Sub:- Details of Drugs declared as Not of Standard Quality w.e.f. 16.04.19 to 30.04.19.

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	Diclofenac Sodium Tablets IP 50mg	DFT 18010, 06/2020	M/s Vivek Pharmachem (India) Ltd , NH-8, Chimanpura, Amer, Jaipur-303102 INDIA	Sample does not conform to IP standards This batch fails the test disintegration hence declared as Not of Standard Quality Medicine
2	Esomeprazole & Domperidone Capsules (PEPTILCER-DSR)	BE17053, 05/2019	M/s Skymap Pharmaceuticals Pvt Ltd , B-3, Dev Bhoomi Industrial Estate, Pohana Iqbalpur Road, Roorkee-247667	The sample does not conform to the claim with respect to Assay of Domperidone. Assay- Esomeprazole Sodium Found 37.88mg (i.e 94.7% of claim) Domperidone Found 25.36mg (i.e 84.53% of claim)
3	Enteric Coated Rabeprazole Sodium and Domperidone (SR) Capsules (Colofresh-D)	NC-17138, May-2019	M/s H.L. Healthcare Pvt Ltd , Plot No 25, Ind Area, Phase II, Garget-177201(H P)	The sample does not conform to the claim with respect to Assay of Rabeprazole Sodium and Domperidone Assay Rabeprazole Sodium Found 10.72mg (i.e 53.6% of claim) Domperidone Found 22.82mg (i.e 76.07% of claim)
4	Rabeprazole Sodium (EC) & Domperidone (SR) Capsules (Raph-D)	C-003, 07/2019	M/s Merit Healthcare, Plot No 74C(II), HPSIDC Ind Area, Baddi, Distt-Solan (HP)-173205	The sample does not conform to the claim with respect to Assay of Rabeprazole Sodium and Domperidone Assay Rabeprazole Found 12.12mg (i.e 60.6% of claim) Domperidone Found 23.1mg (i.e 77% of claim)
5	Rabeprazole Sodium (EC) & Domperidone (SR) Capsules (Rabedit)	GCN-170086, 05/2019	M/s GMH Laboratories, Plot No 13, Industrial Township, Bhatoli Kalan, Baddi, Distt Solan (H P)	The sample does not conform to the claim with respect to Assay of Rabeprazole Sodium Assay Rabeprazole Sodium Found 9.84mg (i.e 49.2% of claim) Domperidone Found 29.82mg (i.e 99.4% of claim)
6	Enteric Coated Rabeprazole Sodium and Domperidone Sustained Release Capsules (Rabesec-D SR)	GL7348, JUN 19	M/s Tirupati Medicare Limited, Nahar Road, Paonta Sahib, Dist Sirmour 173025 (H P)	The sample does not conform to the claim with respect to Assay of Rabeprazole Sodium Assay Rabeprazole Sodium Found 15.6mg (i.e 78% of claim)

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  
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- It 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/Asst. Drugs Controllers, Rajasthan.
- 13- President, Rajasthan Chemist Association, Dawa Bazar, Jaipur.
- 14- Dawa Charcha, Kiran 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 Ram 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 सगठन Bulletin heading and e-mail to all above officers.
- 19- Computer Desk/Concerning files.

  
(Raja Ram Sharma)  
Drugs Controller  
Rajasthan, Jaipur