

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

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Contact no. 0141-2221760, 2221670

No. DC/Bulletin/2019/ 1284

Dated: 5/8/19

All Drugs Control Officers,
Rajasthan, State.

Sub:- Details of Drugs declared as Not of Standard Quality w.e.f. 16-07-19 to 31-07-19

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 Potassium, Paracetamol & Serratiopeptidase Tablets (Sevfen-SP)	GT-205 10/2019	M/s Globin Pharmaceuticals Pvt. Ltd., Puhana, Chowk-Dehradun Rd. Roorkee (UK)	The sample does not conform to the claim as it does not contain Diclofenac Potassium (NIL) and found Acaclofenac 80.49 mg/Tablets..
2	Acaclofenac, Paracetamol & Serratiopeptidase Tablets (Acclor-SP)	T-2042 Aug. 2019	M/s Betamax Remedies Pvt. Ltd., Plot No. 24-25, Ind. Area, Phase-I & II, Vill. Tahliwal, Distt. Una, HP (India)	The sample does not conform to the claim with respect to assay of Acaclofenac & Paracetamol. Assay: Acaclofenac found 74.4%of claim, Paracetamol found 85.49% of claim
3	Enteric Coated Rabeprazole Sodium and Domperidone SR Capsules (Rabee-D)	4177005 08/2019	M/s Innova CapTab, 81-B, EPIP, Phase-I, Jharmajri, Baddi (HP)	The sample does not conform to the claim with respect to assay of Rabeprazole Sodium. Assay: Rabeprazole found 67.95%of claim
4	Hysfloxx-200 (Ofloxacin Tablets IP)	EH 17021 Jul.19	M/s Elcon Drugs & Formulation Ltd., F-59, Riico, Ind. Area, Bindaayaka, Jaipur 302012	As it does not conform to IP standards with respect to the test for uniformity of weight of tablets.
5	Enteric Coated Rabeprazole Sodium & sustained release Domperidone Capsules (Rubaz- DSR Capsules)	RCD-440, 08/2019	M/s Regent Ajanta Biotech, 86-87, Village: Makhiyali Dundi, Peerpura Road, Roorkee (UK) 247667	The sample does not conform to the claim with respect to Assay of Rabeprazole Sodium Assay: Rabeprazole found 82.9% of claim
6-	Pantoprazole Enteric Coated & Domperidone Sustained Release Capsules (Punch-DSR Capsules)	SMD-17K169 Oct.2019	M/s SMD Chemi Pharma Pvt. Ltd., Kumar Hatti, Distt. Solan (HP) 173229	The sample does not conform to the claim with respect to Assay of Pantoprazole and Domperidone. Assay: Pantoprazole found 54.9%of claim Domperidone found 78.67% of claim.
7-	Ciprofloxacin Tablets IP 500mg (CIPROWIN-500)	CY6611013 09/2019	M/s Alembic Pharmaceutical Ltd., Kh No. 1328-1330, Vill. Manpura, The. Baddi, Distt. Solan (HP)	The sample does not conform to the claim with respect to Dissolution. Dissolution : 49.98%
8-	Ciprofloxacin Tablets IP 250 mg (CIPRO PLUS 250)	AT-126916 10/2019	M/s Pinnacle Life sciences Pvt. Ltd., Kh No. 1328-1330, Vill. Manpura, Teh. Baddi, Distt. Solan (HP)	The sample does not conform to the claim with respect to Dissolution. Dissolution : 57.62%
9	Ciprofloxacin Tablets IP 500 mg (CIPROCIN-500)	AT-103516 09/2019	M/s Pinnacle Life sciences Pvt. Ltd., Kh No. 1328-1330, Vill. Manpura, The. Baddi, Distt. Solan (HP)	The sample does not conform to the claim with respect to Dissolution. Dissolution : 63.96%
10	Ciprofloxacin Tablets I.P (Cipropil-500 Tablets)	16T-0684 08/2019	M/s Psychotropics India Ltd., Plot No. 12 & 12A Industrial Park-2, Phase-1, Salempur Mehdood-2, Haridwar-249403 (Uttarakhand)	The sample does not conform to the claim with respect to Dissolution Dissolution : 62.02%

11	Ceftriaxone Injection IP 250mg	DC-7072 11-19	M/s Scott-Edil Pharmacia Ltd., 56, EPIP, Phase-I, Jharmajri- 173205	The sample does not conform to the claim with respect to Appearance of Solution, Clarity of Solution and Particulate Matter
12	Calcium Carbonate with Vitamin D3 Suspension	V098074 Aug. 2020	M/s Vivimed Labs Ltd., Plot No. 25, Kundeshwari Village Kashipur 244713, Uttrakhand	The sample doesnot conform to the claim with respect to microbial contamination.
13	Salbutamol Sulphate Syrup IP	L-174 Nov. 2020	M/s Daffodills Pharmaceuticals Ltd., Jawahar Nagar. Rohta Road, Meerut 250001	The sample doesnot conform to the claim with respect to microbial contamination.
14	Salbutamol Sulphate Syrup i?	L-175 Nov. 2020	M/s Daffodills Pharmaceuticals Ltd., Jawahar Nagar. Rohta Road, Meerut 250001	The sample doesnot conform to the claim with respect to microbial contamination.
15	Salbutamol Sulphate Syrup IP	L-140 Sep. 2020	M/s Daffodills Pharmaceuticals Ltd., Jawahar Nagar. Rohta Road, Meerut 250001	The sample doesnot conform to the claim with respect to microbial contamination.
16	Salbutamol Sulphate Syrup IP	L-138 Sep. 2020	M/s Daffodills Pharmaceuticals Ltd., Jawahar Nagar. Rohta Road, Meerut 250001	The sample doesnot conform to the claim with respect to microbial contamination.
17	Vitamin D3 Oral Solution 60000 IU	GRV 18005 Apr.2020	M/s Tirupati Medicare Ltd, Nahan Road, Paonta Sahib, Dist. Sirmour (H P)	The sample doesnot conform to the claim with respect to microbial contamination
18	Ciprofloxacin Tablets IP 250mg	CA 8010 May 21	M/s Halewood Laboratories Pvt Ltd., 319, Phase II, GIDC Vatva, Ahmedabad 382445 Gujrat	The sample does not conform to the claim with respect to Dissolution. Dissolution : 59.71%
19	Ciprofloxacin Tablets IP 250mg	CA 8009 May 21	M/s Halewood Laboratories Pvt. Ltd., 319, Phase II, GIDC-Vatva, Ahmedabad 382445 Gujrat	The sample does not conform to the claim with respect to Dissolution. Dissolution : 60.12%
20	Ciprofloxacin Tablets IP 250mg	CA 8008 May 21	M/s Halewood Laboratories Pvt. Ltd., 319, Phase II, GIDC Vatva, Ahmedabad 382445 Gujrat	The sample does not conform to the claim with respect to Dissolution. Dissolution : 49.08%

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: 5/8/19

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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/ Arunacha 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 सगठन Bulletin heading and e-mail to all above officers.
- 19- Computer Desk/Concerning files.

Drugs Controller
Rajasthan, Jaipur