

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

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No. DC/Bulletin/2018/ 1656

Dated: 2/8/18

All Drugs Control Officers,
Rajasthan, State.

Sub:- Details of Drugs declared as Not of Standard Quality w.e.f. 16-07-2018 to
31-07-2018.

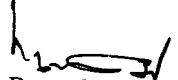
Particulars of the samples declared as not of standard quality on test /analysis are given below for ensuring that the stocks of these drugs are not consumed anymore and appropriate safe guard to the consumers is provided by withdrawing the available stock and take action as per provisions of Drugs & Cosmetics Act 1940 & Rules made there under.

S. No.	Name of Drugs	B.No./ Exp. Date	Mfgd. by	Reason
1	Pantoprazole & Domperidone Tablets (CUPAN-D)	G527/480, OCT.2018	M/s Elfin Drugs Pvt. Ltd., Vill. Berson, Nalagarh (H.P.) 174101	The sample does not conform to the claim as it does not contain Domperidone (Nil)
2	Montelukast Sodium & Levocetirizine Hydrochloride Tablets (Montair-LC)	SA65947, SEP.18	M/s Cipla Ltd., Kumrek, Rangpo, Sikkim 737132, India	The sample does not conform to the claim with respect to Assay of Levocetirizine Hydrochloride and as it does not contain Montelukast (Nil). Assay: Levocetirizine Hydrochloride found 5.94mg (i.e. 118.8% of claim)
3	Enteric Coated Pantoprazole Sodium & Domperidone SR Capsules (Pantop-DSR)	B452J037, AUG.2019	M/s Aristo Pharmaceuticals Pvt. Ltd., Village Makhnumajra, P.O. Bhud, Baddi, Dist. Solan (H.P)-173205	The sample does not conform to the claim with respect to Assay of Domperidone & it does not contain Pantoprazole (Nil) and Found Omeprazole 20.32 mg/cap. Assay: Domperidone found 11.06mg (i.e. 36.87% of claim)
4	Pantoprazole Gastro resistant Tablets IP (Pantop 40)	S171K017, Mar.2020	M/s Aristo Pharmaceuticals Pvt. Ltd., Village Makhnumajra, P.O. Bhud, Baddi, Dist. Solan (H.P)-173205	The sample does not conform to the claim as it does not contain Pantoprazole (Nil)
5	Cefpodoxime Tablets IP 200mg (Monocef-O 200),	B198H197, Jul.2019	M/s Aristo Pharmaceuticals Pvt. Ltd., Village Makhnumajra, P.O. Bhud, Baddi, Dist. Solan (H.P)-173205	The sample does not conform to the claim as it does not contain Cefpodoxime (Nil)
6	Cefpodoxime Tablets IP 200mg (Monocef-O 200)	B198J017, Aug.2019	M/s Aristo Pharmaceuticals Pvt. Ltd., Village Makhnumajra, P.O. Bhud, Baddi, Dist. Solan (H.P)-173205	The sample does not conform to the claim as it does not contain Cefpodoxime (Nil)
7	Amoxicillin And Potassium Clavulanate Tablets I.P. (CLAVAM 625)	7170784, Mar.2019	M/s Alkem Laboratories Limited (Unit-II), Village-Thana, Baddi, Distt. Solan, Himachal Pradesh-173205	The sample does not conform to the claim with respect to assay of Amoxicillin and it does not contain Clavulanic Acid (Nil).
8	Calcium Supplement with vitamin D3 Chewable Tablets (CAL D3 Tablets)	GSMT-019, 09/2018	M/s Laborate Pharmaceuticals India Ltd., Unit-2, # 31, Rajban Road, Nariwala, Paonta Sahib (H.P.)	The sample does not conform to the claim with respect to as it does not contain Vitamin D3 (Nil)
9.	Cefixime Tablets I.P. (Taxim-O 200)	7181490, 08/2019	M/s Alkem Health Science, A Unit of Alkem Laboratories Limited, Samardung, Karek Block P.O. Namthang South Sikkim-737137	The sample does not conform to the claim as it does not contain Cefixime (Nil) and found Ofloxacin 207.62mg/tab
10.	Pantoprazole Gastro Resistant Tablets IP (PAN 40),	7133275, E 04/20	M/s Alkem Laboratories Limited, Central Pendam Block, Dugailaka, Kumrek, Rangpo, East Sikkim-737132	The sample does not conform to the claim as it does not contain Pantoprazole (Nil)
11.	Enteric Coated Pantoprazole Sodium and Sustained Release Domperidone Capsules (Pantocid DSR)	EMS 2060, 06/2019	M/s Sun Pharma Laboratories Ltd., Plot No. 107/108, Namli Block. P.O. Ranipool, East Sikkim-737135	The sample does not conform to the claim with respect to Assay of Domperidone & it does not contain Pantoprazole (Nil) and Found Omeprazole 21.69 mg/cap. Assay: Domperidone found 11.12mg (i.e. 37.07% of claim)
12.	Azithromycin Tablets I.P. (AZIPRIME-250 TABLETS)	TNAP-476, 08/2018	M/s Accurate Pharmaceuticals, C-3 (A&B) Gondpur Industrial Area, Paonta Sahib (HP)-173025	The sample does not conform to the claim with respect to Assay of Azithromycin. Assay: Azithromycin Found 77.34mg (i.e. 30.94% of claim)

 P.T.O.

13.	Glimepiride & Metformin Hydrochloride Tablets (GLIMICUT-M1)	AP6334, Oct.18	M/s Affy Parenterals, Vil. Gullerwala, P.O.-Baddi, Distt.- Solan-173205 (H.P.)	The sample does not conform to the claim with respect to Assay of Glimepiride. Assay: Glimepiride Found 0.1848mg (i.e 18.48% of claim)
14.	Telmisartan Tablets IP 40mg (TEMI-40),	DVTC1672, 08/18	M/s Digital Vision, 176, Mauzaogli, Nahan Road, Kala Amb, Distt. Sirmour (H.P.) 173030	The sample does not conform to the claim with respect to Dissolution. Average 22.99%
15.	Calcium Carbonate, Magnesium Hydroxide Zinc & Cholecalciferol Suspension (CaljonD3 Suspension 200ml)	YS-7084, OCT.2018	M/s Yacca Life Sciences Pvt. Ltd., 156, Raipur, Bhagwanpur, Roorkee-247661	The sample does not conform to the claim with respect to Assay of Cholecalciferol.
16.	Diclofenac Sodium Tab. I.P. 50mg,	DFT17013, 08/19	M/s Vivek Pharmachem (I) Ltd., NH-8, Chimanpura, Amer, Jaipur	The sample does not conform to the claim as per IP 2014 with respect to test for uniformity of weight.
17.	Hydrocortisone Sodium Succinate Inj. IP 100mg	HCL16048, 07/2018	M/s Vivek Pharmachem (I) Ltd., NH-8, Chimanpura, Amer, Jaipur	The sample has been declared as Not of standard quality as it does not conform to IP standards with respect to test for Sterility.
18.	Pantoprazole & Domperidone Tab. (TOP-D)	G-177, 08/2018	M/s Care-Well Healthcare, 142, Mahagujarat Ind. Estate, Moraiya Sarkhej Bavla Road, Ahmedabad 382210	The sample does not conform to the claim with respect to Assay Pantoprazole & Domperidone. Assay: Pantoprazole Found 31.58mg (i.e 78.95% of claim) Domperidone Found 7.76mg (i.e 77.6% of claim)

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, Kailash 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.


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Rajasthan, Jaipur