

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

E-mail: drugcontrolraj@gmail.com
Contact no. 0141-2221760, 2221670

No. DC/Bulletin/2017/ 567

Dated: 3/4/17


All Drugs Control Officers,
Rajasthan, State.


Sub:- Details of Drugs declared as Not of Standard Quality w.e.f. 16.03.2017 to
31.03.2017.

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.	Levocetirizine Dihydrochloride Tablets I.P. (AMBOLEV-5)	LE09/108/08, Aug.2017	M/s Logos Pharma, Village, Maissa Tibba, Tehsil Nalagarh, District Solan (H.P.) 174101.	The sample does not conform to the claim with respect to assay & dissolution
2.	Cefixime Tablets I.P. 200mg (ZIFI 200)	CKM0161001, 02/2018	M/s FDC Limited, Village Khol-Bhud, Tehsil-Nalagarh, Baddi-173205, Dist-Solan H.P.	The sample does not conform to the claim with respect to Assay
3.	Cefixime Tablets I.P. (Taxim-O 200)	6181782, 08/2018	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 with respect to Assay and Dissolution.
4.	Pantoprazole Gastro Resistant Tablets IP (PAN*40)	6131847, 12/18	M/s Alkem Laboratories Ltd., Central Pendam Block, Dugailaka, Kumrek, Rangpo, East Sikkim-717332	The sample does not conform to the claim with respect to Assay and Dissolution. (A&B)
5.	Vildagliptin and Metformin HCL Tablets (Galvas Met 50mg/500mg)	WJ485, 09.2017	M/s Novartis Singapore Pharmaceutical Pte.Ltd., 10 Tuas Bay Lane 637461 Singapore, Imported in India By: Novartis Healthcare Pvt. Ltd., Gala No. 1-A&2-A Bldg. No. 28, Arihant Compound, Kopar, Purna, Bhiwandi 421302.	The sample does not conform to the claim with respect to Assay of Vildagliptin (Nil) and Metformin HCL.
6.	Vildagliptin and Metformin HCL Tablets (Jalra-M 50mg/ 500mg)	WJ835, 07.2017	M/s Novartis Pharma Stein AG. Schffhauserstrasse 4332, Stein Switzerland. Imported in India By: Novartis Healthcare Pvt. Ltd., Gala No. 1-A& 2-A Bldg. No. 28, Arihant Compound, Kopar, Purna, Bhiwandi 421302.	The sample does not conform to the claim with respect to Assay of Vildagliptin (Nil) and Metformin HCL.
7.	Vildagliptin and Metformin HCL Tablets (Jalra-M 50mg/ 500mg)	WL153, 11.2017	M/s Novartis Pharma Stein AG. Schffhauserstrasse 4332, Stein Switzerland. Imported in India By: Novartis Healthcare Pvt. Ltd., Gala No. 1-A & 2-A Bldg. No. 28, Arihant Compound, Kopar, Purne, Bhiwandi 421302.	The sample does not conform to the claim with respect to Assay of Vildagliptin (Nil) and Metformin HCL.
8.	Vildagliptin Tablets (Jalra 50mg)	BD 832, 01/2019	M/s Novartis Farmaceutica S.A. Ronda de Santa Maria 158, E-08210 Barbera del Valles, Barcelona Spain Imported in India By: Novartis Healthcare Pvt. Ltd., Gala No. 1-A & 2-A Bldg. No. 28, Arihant Compound, Kopar, Purna, Bhiwandi 421302.	The sample does not conform to the claim as it does not contain Vildagliptin and found Metformin HCL (139.73mg/Tab).

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


Drugs Controller-II,
Rajasthan, Jaipur


Drugs Controller-I,
Rajasthan, Jaipur

P.T.O.

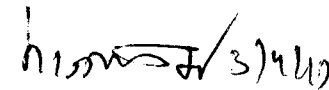
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Copy forwarded for necessary action to:-

- 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- Public Relation Officer, Swasthya Bhawan, Jaipur.
- 12- All CM&HO, Rajasthan/All P.M.O's, 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](http://www.Rajswasthya.nic.in) औषधि नियंत्रण संगठन Bulletin heading and e-mail to all above officers.
- 19- Computer Desk/ concerning files.


Drugs Controller-II,
Rajasthan, Jaipur


Drugs Controller-I,
Rajasthan, Jaipur