## GOVERNMENT OF RAJASTHAN

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

> E-mail: <u>drugcontrolraj@gmail.com</u> Contact no. 0141-2221760, 2221670

No. DC/Bulletin/2017/ 47/

All Drugs Control Officers, Rajasthan, State.

Dated: 16/3/2017

Sub:- Details of Drugs declared as Not of Standard Quality w.e.f. 01.03.2017 to 15.03.2017.

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.	Name of Drugs	B.No./	Mfgd. by	Reason
No.		Exp. Date		
1.	Levocetirizine Dihydrochloride Tablets I.P. (Varcet-LV)	ZT1081501, Apr.2017	M/s Progressive Lifesciences Pvt. Ltd., Latherdevahoon, P.O. Jhabrera, Roorkee, Distt. Haridwar-247665 (U.K.)	The sample does not conform to the claim with respect to Assay
2.	Ciprofloxacin Hydrochloride Tablets I.P. 500mg (Ofran-500)	RT-375, May.2017	M/s Rachil Pharma, 18-19 Phase-I, Ind. Area Sansarpur, Terrace (HP)	The sample does not conform to the claim with respect to Dissolution test
3.	Alprazolam Tablets I.P. 0.25mg	414-1338, 07/2017	M/s Zee Laboratories, 47, Industrial Area, Paonta Sahib 173025 (H.P.)	The sample does not conform to the claim with respect to Dissolution test.
4.	Ofloxacin Tablet I.P. (Oflokem-200)	OFCT-15063, MAY.2017	M/s Sri Ram Healthcare Pvt. Ltd., 81- C/2, EPIP-I, Jharmajri, Baddi, Distt. Solan HP-173205	The sample does not conform to the claim with respect to Dissolution.
5.	Ofloxacin & Ornidazole Tablets (Ofloxur-OZ)	150685, 05/2017	M/s Alive Healthcare, 123, HPSIDC, Baddi, Dist. Solan-173205 (H.P)	The sample does not conform to the claim with respect to Disintegration.
6.	Ofloxacin Tablet I.P. (Oflokem-200)	OFCT15062, MAY 2017	M/s Sri Ram Healthcare Pvt. Ltd., 81-C/2, EPIP-I, Jharmajri, Baddi, Distt. Solan HP-173205	The sample does not conform to the claim with respect to Dissolution.
7.	Ofloxacin & Ornidazole Tablets (Careflox-OZ)	A-10346, 04/2017	M/s Regent Ajanta Biotech, 86-87, Village: Makhiyali Dundi Peerpura Road, Roorkee-247667 (UK)	The sample does not conform to the claim with respect to Disintegration
8.	Clonazepam with Escitalopram Tablets (Empinex-D)	M-1045, Oct.2017	M/s Santo Formulations, Deonghat, P.O. Saproon, Distt. Solan 173211 (H.P.)	The sample does not conform to the claim with respect to Assay of Clonazepam
9.	Ofloxacin & Ornidazole Tablets (Pentaflox-oz)	PT15-130A, JUN 2017	M/s Pentachem Pharmaceuticals, Chunari Road. Kishanpura, Nalagarh- Baddi Highway, NH-21-A, P.O. Gurumajra, Solan (HP)-174101	The sample does not conform to the claim with respect to Disintegration.
10.	Ofloxacin & Ornidazole Tablets (Orane-OZ)	E51181, 04/2017	M/s Arion Healthcare, Vill-Kishapura, Baddi, Distt. Solan 174101 (H.P.)	The sample does not conform to the claim with respect to Disintegration
11.	Rabeprazole & Domperidone Tablets (RABY-D)	DLT-1637, Apr.2017	M/s Daffohils Laboratories Pvt. Ltd., F-109-110, UPSIDC Industrial Area, Selaqui, Dehradun, U.K248011 (India)	The sample does not conform to the claim with respect to Disintegration
12.	Prednisolone Tablets I.P. (Pretox-10)	IGTB15- 2301, Jul.2017	M/s I.G. Pharma Ltd., 12.4Km., Merrut Road, Roorkee, Distt. Haridwar (U.K.)	The sample does not conform to the claim with respect to Dissolution.
13.	Ramipril Tablets I.P. 2.5mg	LT50993, 02/2018	M/s Omega Biotech Ltd., 7th Mile Stone, Dehradun Road, Roorkee 247667 (Uttarakhand)	The sample does not conform to the claim with respect to Assay and Dissolution.
14.	Ramipril Tablets I.P (Mapril 5)	AT-44001, Feb.18	M/s Abaris Health Care, Plot No. 131 & Part of 130 Phase III, Inds. Area, Sansarpur Terrace, Dist. Kangra, Himachal Pradesh 176501	The sample does not conform to the claim with respect to Assay & Dissolution.
15.	Montelukast Sodium & Levocetirizine Hydrochloride Tablets (Arkast-L)	SWT-45615, 08/2017	M/s Staywell Formulation Pvt. Ltd., 162/1, Nalhera, Anantpura, Roorkee 247667, Uttarakhand	The sample does not conform to the claim with respect to Assay of Levocetirizine Hydrochloride.
16.	Pantoprazole & Domperidone Tablets (PENT-AV-D)	TP50280, 12/2017	M/s Taurus Parentrals Pvt. Ltd., Plot No. 46-A, Sector IIDC, Sidcul IIE Pantnagar, Rudrapur, Dist. U.S. Nagar, Uttaranchal	The sample does not conform to the claim with respect to Assay of Domperidone and Disintegration

17.	Doxylamine Succinate & Pyridoxine Hydrochloride Tablets (EMESTAT-OD)	OEDT-504, 06/2017	M/s Unicure India Ltd., (Unit II) 46(B)/49/B, Village Raipur, Bhagwanpur, Roorkee 247661 (Uttarakhand)	The sample does not conform to the claim with respect to Disintegration
18.	Nimesulide & Paracetamol Tablets (Thermex)	RT-150966, 08/2017	M/s Relief Biotech Pvt. Ltd., 6th Mile Stone, Opp. Oberai Hyundai, Peerpura Road, Delhi-Road, Roorkee-247667	The sample does not conform as it contains sunset yellow colour and Disintegration.
19.	Omeprazole Magnesium & Domperidone Tablets (Ranidom)	A5AFO107, 06/2017	M/s Mediforce Healthcare Pvt. Ltd., 46, Industrial Area, Gondpur, Paonta Sahib, Distt. Sirmour, H.P173025	The sample does not conform to the claim with respect to Assay of Omeprazole.
20.	Nimesulide & Paracetamol Tablets (Elelide-P)	415-298, 09/2017	M/s Zee Laboratories Limited, Behind 47, Industrial Area, Paonta Sahib 173025	The sample does not conform as it contains Sunset yellow colour and bilayered not found as claimed on label.
21.	Paracetamol Tablets I.P 650mg (Peragesic 650)	T-310F, 08/2017	M/s Go-ish Remedies Limited, Baddi, Nalagarh Road, 174101, Dist. Solan (H.P)	The sample does not conform to the claim with respect to Dissolution.
22.	Montelukast Sodium & Levocetirizine Hydrochloride Tablets (Mancet M Tablets)	DET-1901, 08/2017	M/s Dr. Edwin Lab, Plot No. 517, Indl Area, Phase IX, SAS Nagar 160059 (Pb).	The sample does not conform to the claim with respect to Assay of Montelukast.
23.	Sativol (100ml)	JL16034, 05/2021	M/s SBL Pvt. Ltd., 533, Sitapura Indl. Area, Jaipur-302022.	It attracts Drugs & Cosmetics Rules Schedule M.I(6.4)
24.	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 & Dissolution.
25.	Pantoprazole & Domperidone Tablets (TOPRA-D)	2043, 06/17	M/s View Laboratories, Plot No. 4710, 11 & 12, Phase IV, GIDC Vatva, Ahmedabad.	The sample does not conform to the claim with respect to Disintegration.

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: 16/3/2017

No. DC/Bulletin/2017/47-1

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- All Suptt, Associated Group of Hospitals,/All Principals, Medical Colleges, Rajasthan.
- 9- Jt. Drugs Controller (India), North Zone, Kamla Nehru Nagar, Ghaziabad.
- 10- Public Relation Officer, Swasthya Bhawan, Jaipur.
- 11- All CM&HO, Rajasthan/All P.M.O.'s Rajasthan.
- 12- President, Rajasthan Chemist Association, Dawa Bazar, Jaipur.
- 13- Dawa Charcha, Kirana Bhawan Marg, Hanumangarh Town-335513.
- Health View, 170/3, Ram Gali, Rajapark, Jaipur./Medicare News, Outside Chhawani Railway Crossing, Dungari Road, Kailas h Colony, Beawer.
- 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.
- 16- J.J. Health Times, 2 KHA-16, J.J. House, Vaishali Nagar, Ajmer.
- 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.

18- Computer Desk/ concerning files.

Drugs Controller, Rajasthan, Jaipur