

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/2019/1576

Dated: 19/9/2019

All Drugs Control Officers,
Rajasthan, State.

Sub.- Details of Drugs declared as Not of Standard Quality w.e.f. 01-09-19 to 15-09-19


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	Calcium with Vitamin D3 Tablet USP (Calzac-500)	LAS 0004, SEP 2019	M/s Acme Formulation Pvt. Ltd, Ropar Road, Nalagarh, Dist. Solan, Himachal Pradesh, 174101,	The sample does not conform to the claim with respect to Assay of Vitamin D3. Assay Claim 250.00mg, found 80.07mg (ie 32.03% of claim)
2	Ramipril Tablets IP (Ramilet 2 5mg)	RM2T-003, 09/2019	M/s IOSIS REMEDIES, Rajpura Road, Village-Khera Nihla, Teh. Nalagarh, Distt. Solan, Himachal Pradesh-174101	The sample does not conform to the claim with respect to Assay and Dissolution. Assay: Claim 2.50 mg, found 1.02mg (ie 40.8% of claim) Dissolution. Average 29.05%
3	DOMPERIDONE SUSPENSION IP	RJ 329, 09/20	M/s Saar Biotech, NH-21A, Bhud, Baddi, Distt. Solan(HP) 173205	The sample does not conform to the claim with respect to Microbial Contamination
4	DOMPERIDONE SUSPENSION IP	RJ 330 09/20	M/s Saar Biotech, NH-21A, Bhud, Baddi, Distt. Solan(HP) 173205	The sample does not conform to the claim with respect to Assay and Microbial Contamination. Assay Claim 5.00 mg, found 2.96mg (ie 59.2% of claim)
5	DOMPERIDONE SUSPENSION IP	RJ 332 09/20	M/s Saar Biotech, NH-21A, Bhud, Baddi, Distt. Solan(HP) 173205	The sample does not conform to the claim with respect to Assay and Microbial Contamination. Assay: Claim 5.00 mg, found 3.39 mg (ie 67.8% of claim)
6	DOMPERIDONE SUSPENSION IP	RJ 334 09/20	M/s Saar Biotech, NH-21A, Bhud, Baddi, Distt. Solan(HP) 173205	The sample does not conform to the claim with respect to Microbial Contamination.
7	Iron & Folic Acid Oral Suspension	5058-BRJ34 Apr. 2020	M/s Biogenetic Drugs Pvt. Ltd., Vill- Jharmajari, Baddi -174103 Distt. Solan(HP)	The sample does not conform to the claim with respect to Assay of elemental Iron and Folic Acid elemental Iron Claim 100.00 mg, found 33.47 mg (ie 33.47% of claim) Folic Acid Claim 500.00 mcg, found 147.9mcg mg (ie 29.58% of claim)
8	Iron & Folic Acid Oral Suspension	07078-BRJ34, Jun 2020	M/s Biogenetic Drugs Pvt. Ltd., Vill- Jharmajari, Baddi -174103 Distt. Solan(HP) 173205	The sample does not conform to the claim with respect to Assay of elemental Iron and Folic Acid elemental Iron Claim 100.00 mg, found 36.25 mg (ie 36.25% of claim) Folic Acid Claim 500.00 mcg, found 182.05mcg mg (ie 36.41% of claim)

9	Doxorubicin Injection IP	HB118063 May 2020,	M/s Health Biotech Ltd., Unit-II, Nalagarh Road, Baddi -173205 Distt. Solani(HP)	The sample does not conform to the claim with respect to Assay Assay: Claim 2.00 mg, found 0.878 mg (ie 43.9% of claim)
10	Doxorubicin Injection IP	HB118044 Mar. 2020,	M/s Health Biotech Ltd., Unit-II, Nalagarh Road, Baddi -173205 Distt. Solani(HP)	The sample does not conform to the claim with respect to Assay Assay: Claim 2.00 mg, found 0.9 mg (ie 45% of claim)
11	Doxorubicin Injection IP	B.No. ADC8002DRB, D/M 05/2018, D/E 04/2020,	M/s Adley Formulation, Kotla, Barotiwala 174103	The sample does not conform to the claim with respect to Assay Assay: Claim 2.00 mg, found 1.61 mg (ie 80.5% of claim)
12	Paracetamol Paediatric Syrup IP	PCS17242 09/2019	M/s Vivek Pharmachem (India) Ltd., N.H.-08, Chimnapura, Amer-303102	The sample does not conform to the claim with respect to Microbial Contamination.
13	Iron & Folic Acid Suspension	MS-18187 03/2020	M/s Max Chem Pharmaceuticals Pvt Ltd., Plot No. 22, Sector-3, Sidcul-IIIE, Rudrapur, Distt- US Nagar (Uttarakhand) 263153	The sample does not conform to the claim with respect to Assay of elemental Iron and Folic Acid elemental Iron Claim 100.00 mg, found 41.83 mg (ie 41.83% of claim) Folic Acid Claim 500.00 mcg, found 182.19mcg mg (ie 36.44% of claim)
14	Iron & Folic Acid Suspension	MS-18188 03/2020	M/s Max Chem Pharmaceuticals Pvt. Ltd., Plot No. 22, Sector-3, Sidcul-IIIE, Rudrapur, Distt- US Nagar (Uttarakhand) 263153	The sample does not conform to the claim with respect to Assay of elemental Iron and Folic Acid elemental Iron Claim 100.00 mg, found 39.04 mg (ie 39.04% of claim) Folic Acid Claim 500.00 mcg, found 217.5mcg mg (ie 43.5% of claim)
15	Iron & Folic Acid Suspension	MS-18191 03/2020	M/s Max Chem Pharmaceuticals Pvt. Ltd., Plot No. 22, Sector-3, Sidcul-IIIE, Rudrapur, Distt- US Nagar (Uttarakhand) 263153	The sample does not conform to the claim with respect to Assay of elemental Iron and Folic Acid elemental Iron Claim 100.00 mg, found 40.16 mg (ie 40.16% of claim) Folic Acid Claim 500.00 mcg, found 227.51mcg mg (ie 45.5% of claim)
16	Iron & Folic Acid Suspension	MS-18194 03/2020	M/s Max Chem Pharmaceuticals Pvt. Ltd., Plot No. 22, Sector-3, Sidcul-IIIE, Rudrapur, Distt- US Nagar (Uttarakhand) 263153	The sample does not conform to the claim with respect to Assay of elemental Iron and Folic Acid elemental Iron Claim 100.00 mg, found 30.68 mg (ie 30.68% of claim) Folic Acid Claim 500.00 mcg, found 122.61mcg mg (ie 24.52% of claim)
17	Ferrous Sulphate & Folic Acid Syrup IP	FLS/8013 03/2020	M/s Maan Pharmaceuticals Ltd., Plot No. 1, GIDC, Phase II, Modhera Road, Mehsana Gujrat INDIA	The sample does not conform to the claim with respect to Assay of Folic Acid Folic Acid Claim 0.50 mg, found 0.1127 mg (ie 22.54% of claim)

18	Ferrous Sulphate & Folic Acid Syrup IP	FLS/8003 02/2020	M/s Maan Pharmaceuticals Ltd., Plot No. 1, GIDC, Phase II, Modhera Road, Mehsana Gujrat INDIA	The sample does not conform to the claim with respect to Assay of Folic Acid Folic Acid Claim 0 50 mg, found 0 0956 mg (ie 19 12% of claim)
19	Ferrous Sulphate & Folic Acid Syrup IP	FLS/8010 03/2020	M/s Maan Pharmaceuticals Ltd., Plot No. 1, GIDC, Phase II, Modhera Road, Mehsana Gujrat INDIA	The sample does not conform to the claim with respect to Assay of Folic Acid Folic Acid Claim 0 50 mg, found 0 191 mg (ie 38 2% of claim)
20	Prednisolone Tablets IP	A2-220 Sep.2019	M/s Anchor Pharma Pvt. Ltd., B-6, O.I.D.C, Ringawada 396210 Daman.	The sample does not conform to the claim with respect to Dissolution Dissolution. Average 47.77%
21	Prednisolone Tablets IP 5 mg (Prednee-5)	PRN-05 10/2019	M/s Askon Health Care, 11-B, Industrial Area, Maxi Road, Ujjain-456010 (MP)	The sample does not conform to the claim with respect to Dissolution. Dissolution: Average 38.26%

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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Dated 19/9/2019

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, 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 ओषधि नियंत्रण समठन Bulletin heading and e-mail to all above officers
- 19- Computer Desk/Concerning files.


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