

GOVERNMENT OF RAJASTHAN
FOOD SAFETY AND DRUGS CONTROL COMMISSIONERATE,
 SWASTHYA BHAWAN, TILAK MARG, JAIPUR (RAJASTHAN)
 E-mail: drugcontroller1.mh@rajasthan.gov.in Contact no. 0141-2221760, 2221670

No. DC/Bulletin/E-00208/2023/ 4999

Dated: 18/12/23

All Drugs Control Officers,
Rajasthan State.

Sub:- Details of Drugs declared as Not of Standard Quality w.e.f. 16.11.2023 to 30.11.2023.

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 & Copsmetics Act 1940 & Rules made there under.

S. No.	Name of Drugs	B.No./ Exp. Date	Mfgd. by	Reason
1.	Ferrous Sulphate & Folic Acid Syrup IP (Iron & Folic Acid Syrup IP)	L22/277A, NOV.2023	M/s SAMKEM, 15-B, A.K.V.N. Industrial Area, Rangwasa, Rao Indore-453331 (M.P.)	The sample does not conform to the IP with respect to Assay of Folic Acid and pH.
2.	Betamethasone Sodium Phosphate Tablets IP 0.5 mg (Betasin)	BTN-09, 02/2025	M/s Oshino Drugs Private Limited (Unit I), B-23/8, B.S. Road Industrial Area, Ghaziabad- 201009 UTTAR PRADESH	The sample does not conforms to the IP with respect to Assay of Betamethasone.
3.	Fluconazole Tablets IP 150 mg	GT2L024, 11/2024	M/s Scott-Edil Pharmacia Ltd., 56, E.P.I.P., Phase-I, Jharmajri, Baddi, Distt. Solan-173205 (HP), INDIA	The sample does not conform to the IP with respect to Dissolution (33.91%).
4.	Domperidone Dispersible Tablets 10 mg (DOM-DT RAPITAB)	E3B0177, Jan.2025	M/s MOREPEN LABORATORIES LIMITED, Plot No. 12-B, Sector-2, Parwanoo, Distt. Solan (H.P.)- 173220	The sample does not conforms to the claim with respect to assay.
5.	Rabeprazole Sodium (EC) & Domperidone (SR) Capsules (SOLRAB-DSR)	TC22-0991, 06/2024	M/s Tanishka Pharmaceuticals Pvt. Ltd., Vill. Nandpur, Kharuni-Lodhi Majra Road, Baddi, Teh. Nalagarh (H.P.)	The sample does not conform to the claim with respect to Assay of Rabeprazole Sodium.
6.	Ambroxol Hydrochloride, Terbutaline Sulphate, Guaiphenesin & Menthol Syrup	AMT-79, APR-2024	M/s Agron Remedies Pvt. Ltd., Sarverkhera, Moradabad Road, Kashipur-244713 (Uttarakhand)	The sample does not conform to the claim with respect to Assay of Menthol.
7.	Ambroxol Hydrochloride, Terbutaline Sulphate, Guaiphenesin & Menthol Syrup	AMT-77, APR-2024	M/s Agron Remedies Pvt. Ltd., Sarverkhera, Moradabad Road, Kashipur-244713 (Uttarakhand)	The sample does not conform to the claim with respect to Assay of Menthol.
8.	Rabeprazole Sodium (EC) & Domperidone (SR) Capsules (RIAZOLE-DSR)	LGL11/389J01, MAR.2024	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 of Rabeprazole Sodium.
9.	Domperidone Oral Drops IP 10mg/ml	DPD-018, 09/2024	M/s Medipol Pharmaceutical India Pvt. Ltd., 1199/3, Bhud, Baddi, Distt. Solan. H.P., INDIA	The sample does not conforms to the claim with respect to Assay of Domperidone, Description as it shows Physical Instability form of pink coloured mass.

Signature valid

RajKaj Ref
5197896

Digitally signed by Ram
Sharma
Designation: Drug Controller
Date: 2023.12.18:40:09 IST
Reason: Approved

E-mail

10.	Amoxicillin Trihydrate Capsules I.P. (A MOXY-250)	APC-0090, 03/2025	M/s Alentia Pharma, At : Medicine Market Faldi Charasta, Ahmedabad-380007	The sample does not conform to the IP with respect to Assay and Dissolution (14.37%)
11	Betamethasone Sodium Phosphate Tablets IP	BMS-42, 03/2025	M/s Oshino Drugs Private Limited (Unit I), B-23/8, B.S. Road Industrial Area, Ghaziabad- 201009 UTTAR PRADESH	The sample does not conform to the IP with respect to Assay of Betamethasone.
12.	Betamethasone Sodium Phosphate Tablets IP 0.5mg (BETAPRO)	OT-2210011 SEP.-2025	M/s OSHIN LABORATORIES PVT. LTD., Aggarwal Industrial Area, Piou Maniyari Narela Road, Kundli-131028 (HR)	The sample does not conform to the IP with respect to Assay of Betamethasone (As Betamethasone Sodium Phosphate I.P.).

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

Drugs Controller-I
Rajasthan, Jaipur

Drugs Controller-II
Rajasthan, Jaipur

No. DC/Bulletin/E-00208/2023/ 4999

Dated: 18/12/23

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- Commissioner, Food Safety & Drug Control, Swasthya Bhawan, Tilak Marg, Jaipur (Raj.)
- 4- Managing Director, R.M.S.C.L., Swasthya Bhawan, Jaipur.
- 5- Jt. Secretary, Medical & Health Department (Gr.II), Rajasthan, Jaipur.
- 6- Director, Medical & Health Services (P.H./F.W./MSU/ESI/AIDS), Jaipur.
- 7- Director, Public Relation Directorate, Rajasthan, Jaipur for publicity.
- 8- Director, Animal Husbandry, Rajasthan, Jaipur.
- 9- The Drugs Controller's, 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.
- 10- All Suptt, Associated Group of Hospitals/All Principals, Medical Colleges, Rajasthan.
- 11- Jt. Drugs Controller (India), North Zone, Kamla Nehru Nagar, Ghaziabad.
- 12- Asst. Drirector, Public Relation, Swasthya Bhawan, Jaipur.
- 13- All CM&HO, Rajasthan/All P.M.O's/All Asst. Drugs Controllers, Rajasthan.
- 14- President, Rajasthan Chemist Association, Dawa Bazar, Jaipur.
- 15- Dawa Charcha, Kirana Bhawan Marg, Hanumangarh Town-335513.
- 16- Health View, 170/3, Ram Gali, Rajapark, Jaipur/Medicare News, Outside Chhawani Railway Crossing, Dungari Road, Kailas h Colony, Beawer.
- 17- 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.
- 18- J.J. Health Times, 2 KHA-16, J.J. House, Vaishali Nagar, Ajmer.
- 19- Officer I/c, Server room to please provide the page under www. Rajswasthya.nic.in औषधि नियंत्रण Bulletin heading and e-mail to all above officers.
- 20- Computer Desk/Concerning files.

Drugs Controller-I
Rajasthan, Jaipur

Drugs Controller-II
Rajasthan, Jaipur

Signature valid

RajKaj Ref
5197898

Digitally signed by R. Ram
Sharma
Designation: Drug Controller
Date: 2023.12.18:40:51 IST
Reason: Digitally signed by AJAY
PHATAK
Designation: Drug Controller
Date :15-12-2023 06:07:52