

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

No. DC/Bulletin/2023/ 2906

Dated: 18/7/23

All Drugs Control Officers,
 Rajasthan State.

Sub:- Details of Drugs declared as Not of Standard Quality w.e.f. 01.07.2023
 to 15.07.2023.

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 & Cosmetics Act 1940 & Rules made there under.

| S. No | Name of Drugs | B.No./ Exp. Date | Mfgd. by | Reason |
|-------|--|---------------------|---|---|
| 1. | Diclofenac Sodium Tablet I.P. (DicloCure) | DCR-1006, NOV.2023 | M/s Harvey India Pharmaceutical Division, 8, Sarvodaya Colony, Barkat Nagar, Jaipur (Raj.). | The sample does not conform to the claim as it contain Tartrazine Colour. |
| 2. | Ciprofloxacin Tablets IP 500mg | CPT22014, 04/2024 | M/s Vivek Pharmachem (India) Ltd., NH-8, Chimanpura, Amer, Jaipur-303102 (Raj.). | The sample does not conform to IP specification for Ciprofloxacin Tablets with respect to Dissolution. |
| 3. | Pantoprazole for Injection BP 40mg (Pandostar-IV) | PLI-112102, 10/2023 | M/s Galpha Laboratories Limited, At: 1, Pharmacy, Selaqui, Dehradun- 248011 (U.K.) India. | The sample does not conforms to the B.P. with respect to Assay, uniformity of Dosage units and uniformity of weight (Mass). |
| 4. | Pregabalin Capsules IP 300 mg (NEWRO-300) | DGCD03039, FEB.2025 | M/s Digital Vision, 176, Mauza Ogli, Nahan Road, Kala-Amb, Distt. Sirmour (H.P. 173030 | The sample does not conforms to the IP with respect to Dissolution (31.03%). |
| 5. | Calcium & Vitamin D3 Tablets I.P. (Calrio) | SVT-B0018, SEP.2023 | M/s SIDDHI VINAYAK INDUSTRIES, Kh. No. 339/183/46, Vill: Mauza Johron, Industrial Area, Trilokpur Road, Kala-amb, Tehsil-Nahan, Distt.: Sirmour (H.P.) 173030 | The sample does not conforms to the IP with respect to Assay of Vitamin D3. |
| 6. | Norfloxacin Tablets IP 400 mg. | RJNL-11, AUG.2023 | M/s Combitic Global Caplet Pvt. Ltd., M-15, D-2, D-3, Ind. Area, Sonepat-131001, Hr. (India) | The sample does not conform to the IP with respect to Dissolution (45.79%). |
| 7. | Norfloxacin Tablets IP 400 mg. | RJNL-13, AUG.2023 | M/s Combitic Global Caplet Pvt. Ltd., M-15, D-2, D-3, Ind. Area, Sonepat-131001, Hr. (India) | The sample does not conform to the IP with respect to Dissolution (64.22%). |
| 8. | Ramipril Tablets I.P. 2.5 mg (Rugen-2.5) | STN-220975, 08/2024 | M/s Terrace Pharmaceuticals (P) Ltd., 3-B(a) Phase III Industrial Area, Sansarpur Terrace, Distt. Kangra (H.P.)- 176501. | The sample does not conform to the IP with respect to Assay and Dissolution (60.21%). |
| 9. | Metoprolol Succinate (ER) & Ramipril Tablets (Metwon-R5) | SA-9699, FEB.2024 | M/s Sano-Cito Therapeutics Inc. Vill. Loharan, P.O. Gharti. Solan- 173211 (H.P.) | The sample does not conform to the claim with respect Assay of Ramipril. |

Signature valid

Digitally signed by A. Phatak
 Designation: Drug Controller
 Date: 2023.07.17 15:22 IST
 Reason: Approved

RajKaj Ref No. : 4298698

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Signature valid

Digitally signed by F. Ram
 Sharma
 Designation: Drug Controller
 Date: 2023.07.17 14:27 IST
 Reason: Approved

RajKaj Ref No. : 4307887



E-mail

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|-----|--|-----------------------|--|---|
| 10. | Calcium & Vitamin D3 Tablets IP (Cadcal) | GCH0435, DEC.2023 | M/s Cotec Healthcare Pvt. Ltd., NH No. 74, Roorkee-Dehradun Highway Kishanpur, Roorkee 247667 (Uttarakhand) | The sample does not conform to the IP with respect to Assay of Vitamin D3. |
| 11. | Ramipril 2.5 mg Tablets (Ramspin 2.5) | MDG219C, FEB.2025 | M/s M.R. Healthcare Pvt. Ltd., Vill. Tanda Mallu, Kashipur Road, Ramnagar-244715, Dist. Nainital (Uttarakhand) | The sample does not conform to the IP with respect to Assay and Dissolution (28.22%). |
| 12 | Pregabalin Capsules IP (NEURO-300) | NBC-62, 08/2024 | M/s A.N.D HEALTHCARE LTD., Plot No. : C-42, Focal Point Chanallon, Kurali, Mohali-140103 | The sample does not conform to the I.P. with respect to Dissolution test. |
| 13 | Pregabalin Capsules IP (GIO PG-DS) | NBC-81, 08/2024 | M/s A.N.D HEALTHCARE LTD., Plot No. : C-42, Focal Point Chanallon, Kurali, Mohali-140103 | The sample does not conform to the I.P. with respect to Dissolution test. |
| 14 | Methylprednisolone Tablets I.P. 16 mg (V-SOLON-16) | MLS-20201316, 07/2023 | M/s MASKON LIFE SCIENCES PVT. LTD., Kh. No. 69/70, Khatakeri, Bhagwanpur, Roorkee (U.K) India | The sample does not conform to the IP with respect to Assay and Dissolution test. |

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

No. DC/Bulletin/2023/ 2906

Dated: 18/7/23

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, SwasthyaBhawan, Tilak Marg, Jaipur (Raj.)
- 4- Managing Director, R.M.S.C.L., SwasthyaBhawan, 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 Supt, Associated Group of Hospitals/All Principals, Medical Colleges, Rajasthan.
- 11- Jt. Drugs Controller (India), North Zone, Kamla Nehru Nagar, Ghaziabad.
- 12- Asst. Director, Public Relation, SwasthyaBhawan, 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- DawaCharcha, KiranaBhawan 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./ "LokUjala" Ujala Marg, ChotinaKuwa, Bikaner/ Health Topics, 2049, PitaliyonKaChowk, 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-II
Rajasthan, Jaipur

Drugs Controller-I
Rajasthan, Jaipur

Signature valid

Digitally signed by A. Phatak
Designation: Drug Controller
Date: 2023.07.17 11:15:22 IST
Reason: Approved

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RajKaj Ref No. : 4298698



RajKaj Ref No. : 4307887

Signature valid

Digitally signed by P. Ram
Sharma
Designation: Drug Controller
Date: 2023.07.17 11:14:27 IST
Reason: Approved

