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GOVERNMENT OF RAJASTHAN
COMMISSIONERATE, FOOD SAFETY AND DRUGS CONTROL
SWASTHYA BHAWAN, TILAK MARG, JAIPUR (RAJASTHAN)

E-mail: drugcontroller1.mh@rajasthan.gov.in Contact no. 0141-2221760, 2221670

No. DC/Bulletin/E-00208/2024/ 1536

Dated: 04/03/24

All Drugs Control Officers,
Rajasthan State.

Sub:- Details of Drugs declared as Not of Standard Quality w.e.f. 15.02.2024
to 29.02.2024.

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.	Metformin Hydrochloride & Glimepiride Tablets IP	ATT-454 AUG.2025	M/s Alliaance Biotech, 440/3, Vill. Katha Baddi, Distt. Solan (H.P.)-1732s05	The sample does not conform to the IP with respect to Dissolution of Glimepiride.
2	Metformin Hydrochloride & Glimepiride Tablets IP	ATT-455 AUG.2025	M/s Alliaance Biotech, 440/3, Vill. Katha Baddi, Distt. Solan (H.P.)-173205	The sample does not conform to the IP with respect to Dissolution of Glimepiride.
3	Metformin Hydrochloride & Glimepiride Tablets IP	ATT-435 MAY2025	M/s Alliaance Biotech, 440/3, Vill. Katha Baddi, Distt. Solan (H.P.)-173205	The sample does not conform to the IP with respect to Dissolution of Glimepiride.
4	Metformin Hydrochloride & Glimepiride Tablets IP	ATT-457 AUG.2025	M/s Alliaance Biotech, 440/3, Vill. Katha Baddi, Distt. Solan (H.P.)-173205	The sample does not conform to the IP with respect to Dissolution of Glimepiride.
5.	Metformin Hydrochloride & Glimepiride Tablets IP	ATT-426 MAY.2025	M/s Alliaance Biotech, 440/3, Vill. Katha Baddi, Distt. Solan (H.P.)-173205	The sample does not conform to the IP with respect to Assay & Dissolution of Glimepiride.
6.	Metformin Hydrochloride (Sustained Release) & Glimepiride Tablets IP	22A-T031 03/2025	M/s Orison Pharma International, Vill. Khari, Mauza Ogli, Kala Amb-173030 (H.P.)	The sample does not conform to IP with respect to Assay of Glimepiride.
7.	Metformin Hydrochloride (Sustained Release) & Glimepiride Tablets IP	22A-T022 03/2025	M/s Orison Pharma International, Vill. Khari, Mauza Ogli, Kala Amb-173030 (H.P.)	The sample does not conform to IP with respect to Assay of Glimepiride.
8.	Metformin Hydrochloride (Sustained Release) & Glimepiride Tablets IP	22B-T186 04/2025	M/s Orison Pharma International, Vill. Khari, Mauza Ogli, Kala Amb-173030 (H.P.)	The sample does not conform to IP with respect to Assay of Glimepiride.
9.	Metformin Hydrochloride (Sustained Release) & Glimepiride Tablets IP	22B-T187 04/2025	M/s Orison Pharma International, Vill. Khari, Mauza Ogli, Kala Amb-173030 (H.P.)	The sample does not conform to IP with respect to Assay of Glimepiride.
10.	Metformin Hydrochloride (Sustained Release) & Glimepiride Tablets IP	21I-T1111 11/2024	M/s Orison Pharma International, Vill. Khari, Mauza Ogli, Kala Amb-173030 (H.P.)	The sample does not conform to the IP with respect to Assay and Dissolution of Glimepiride.
11.	Metformin Hydrochloride (Sustained Release) & Glimepiride Tablets IP	21K-T1371 JAN.2025	M/s Orison Pharma International, Vill. Khari, Mauza Ogli, Kala Amb-173030 (H.P.)	The sample does not conform to IP with respect to Assay of Glimepiride.
12.	Metformin Hydrochloride (Sustained Release) & Glimepiride Tablets IP	21J-T1234 12/2024	M/s Orison Pharma International, Vill. Khari, Mauza Ogli, Kala Amb-173030 (H.P.)	The sample does not conform to the IP with respect to Uniformity of weight, Assay and Dissolution of Glimepiride.

Signature valid

RajKaj Ref
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RajKaj Ref
5930112

Digitally signed by Ram
Sharma
Designation: Drug Controller
Date: 2024.03.04 4:04:32 IST
Reason: Approved

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13.	Metformin Hydrochloride Prolonged-release and Glimepiride Tablets IP	GT1F014 05/2024	M/s Scott-Edil Pharmacia Ltd., 56, E.P.I.P., Phase-I, Jharmajri, Baddi, Distt. Solan (H.P.)-173205, INDIA	The sample does not conform to the IP with respect to Dissolution of Glimepiride.
14.	Atorvastatin & Aspirin Tablets (Atodin ASP 75)	ST23-1802, JUN.2025	M/s Salud Care(I) Pvt. Ltd., 435, Kishanpur, Roorkee-247661	The sample does not conform to the claim with respect to Assay of Atorvastatin.
15.	Ofloxacin & Ornidazole Tablets IP (ORNIFIC-OX)	ZT22252A, 05/2024	M/s Prince Prolific, Survey No. 343/P, Bavia Sanand Highway, Modasar, Ahmedabad-382220, Gujarat (India)	The sample does not conform to the IP with respect to Assay of Ofloxacin.
16.	Pantoprazole Gastro resistant & Domperidone Sustained release Capsules IP (Antidom DSR)	00623326, 03/2025	M/s Scout Lifescience Pvt. Ltd., Plot No. 353, Sector 2, Industrial Growth Centre, HSIIDC Saha Ambala Haryana India- 133104	The sample does not conform to the IP with respect to Assay.
17.	CHLORAMPHENICOL EYE DROPS IP	CML-090, 05/2025	M/s Agron Remedies Pvt. Ltd., Sarverkhera, Moradabad Road, Kashipur-244713 (Uttarakhand)	The sample does not conform to the IP with respect to pH.
18.	Olmesartan Medoxomil & Hydrochlorothiazide Tablets IP (Meg-OL H)	RT22113, MAR.2024	M/s RACHIL PHARMA, 18-19, Phase-I, Ind. Area, Sansarpur Terrace, Distt. Kangra (H.P.) 176501	The sample does not conform to the IP with respect to Assay of Olmesartan Medoxomil.
19.	Cefpodoxime & Potassium Clavulanate Tablets (CefEntod-CV)	MNYAB31, 08/2024	M/s Malik Lifesciences Pvt. Ltd., Plot No. 16, Vardhman Indl. Estate, N.H.58, Haridwar-247667 (Uttarakhand)	The sample does not conform to the claim with respect to Assay of Clavulanic Acid.
20.	Cefpodoxime Dispersible Tablets 200mg (Podomin-200)	MBT-0206, MAY.2025	M/s MS Remedies, Khasra No. 285-290, Village-Sisona, Bhagwanpur, Roorkee-247661, Distt. Haridwar UK	The sample does not conform to the IP with respect to Assay of Cefpodoxime.
21.	Betamethasone Sodium Phosphate Tablet I.P. 0.5mg (Betameg)	PNTC-003, 03/2025	M/s PFINEXT LIFESCIENCES, Plot No. 172, Phase-I, HSIIDC, Barhi, Sonapat-131001 (Haryana)	The sample does not conform to the IP with respect to Assay of Betamethasone.
22.	Liquid Paraffin IP 100ml.	R23L003, MAR.2025	Repacked by : M/s SAMKEM, 15-B, A.K.V.N. Industrial Area, Rangwasa Rao Indore-453331 INDIA	The sample does not conform to the claim with respect to Viscosity and Weight per ml.
23.	Telmisartan & Amlodipine Tablets I.P. (Telmiron-AM 40)	R23D160, 03/25	M/s Rhombus Pharma Private Limited, 816/1, Rakanpur, Kalol-382721 (Gujarat)	The sample does not conform to the IP with respect to Assay and Dissolution of Amlodipine.
24.	Metoprolol Succinate Extended Release Tablets IP (METCARD-50)	AF-22T773, 08/2025	M/s Affine Formulations Ltd., 1947/3, Vill. Bhatia, Tehsil Nalagarh, Distt. Solan 174101 (H.P.)	The sample does not conform to the IP with respect to Assay.
25.	Heparin Sodium Injection IP 25000IU/5ml	22HE16, SEP.2024	M/s SAI Parenterals Ltd., D1 & D4, Suvey No. 280, Phase-V, IDA, Jeedimetla, Hyderabad-500055, Telangana, India	The sample does not conform to IP with respect to test for "Extractable Volume", "Particulate Matter" and "Assay" and is also not of Standard Quality for the reason stated under "Description".
26.	Temozolomide Capsules IP 250mg	23BTZ05, 01/2025	M/s SPAL Private Limited, Plot No. 12, Biotech Park, Phase-II, Lalgadi, Malakpet (V), Shamirpet (M) Medchal- Malkajgiri (Dist), Telangana (State), 500101, India	The sample does not conform to the IP with respect to Assay of Temozolomide.
27.	Cefixime with Lactic Acid Bacillus Dispersible Tablets (Cefumay-O 200 LB)	DB230070, 02/2025	M/s Daxin Pharmaceuticals Pvt. Ltd., Plot No 121-122, EPIP, Jharmajri, Phase 1, Teh. Baddi, Distt. Solan (H.P.)-174103	The sample does not conform to the claim with respect to Assay of Anhydrous Cefixime.
28.	Cefixime, Azithromycin & Lactic Acid Bacillus Tablets (MEXIM-AZ LB)	BT-235023F, 04/2025	M/s A.N.D. HEALTHCAE LTD., Plot No. C-42, Focal Point Kurdi Mohali-140103.	The sample does not conform to the claim with respect to Assay of anhydrous Azithromycin.

Signature validRajKaj Ref
5906969Digitally signed by Raj Ram
Sharma
Designation : Deputy Controller
Date: 2024.03.25 14:04:32 ISTRajKaj Ref Reason: Approved
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29	Calcium Carbonate & Vitamin D3 Suspension	CAH-2222, 04/2024	M/s Apple Formulations Pvt. Ltd., Plot No. 208, Kishanpur, Roorkee-247667 (U.K.)	The sample does not conform to the claim with respect to Assay of Vitamin D3.
30	Chlorpheniramine Maleate, Ammonium Chloride, Sodium Citrate and Menthol Syrup	KL-22/357, FEB.2024	M/s KAYSONS PHARMA, 1, Vigyan Nagar, Sarna Dungar, Industrial Area, Jaipur-302012 (RAJ.)	The sample does not conform to the IP with respect to Assay of Menthol.

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-00208/2024/ 1536

Dated: 04/03/24

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. Director, 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, Beaver.
- 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
5906969

Digitally signed by Ram Sharma
Designation : Drug Controller
Date: 2024.03.04 14:04:32 IST

RajKaj RefReason: Approved
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Document certified by Ajay Phatak
<DRUGCONTROLLER1.MH@RAJASTHAN.GOV.IN>

Digitally Signed by AJAY PHATAK
Designation : Drug Controller
Date :04-03-2024 02:19:46