

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

No. DC/Bulletin/2022/ 987

Dated: 17/6/22

All Drugs Control Officers,
Rajasthan State.


Sub:- Details of Drugs declared as Not of Standard Quality w.e.f. 01.06.2022 to 15.06.2022.

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.	Mfgd. by	Reason
1.	Etoricoxib & Thiocolchicoside Tablets (Azithoril-ET)	RR-2558	M/s Rickson Remedies, M.G. Lane, Ahmedgarh-148021 (Pb)	The sample does not conforms to the claim with respect to Assay of Etoricoxib and Thiocolchicoside. Assay: Etoricoxib: Claim-60.00mg, Found 47.58mg (i.e 79.30% of claim). Thiocolchicoside: Claim-4.00mg, Found 2.41mg (i.e 60.25% of claim).
2.	Ofloxacin & Ornidazole Tablets IP (Flagday-ON)	ADB-9549	M/s Park Pharmaceuticals, 272, Ind. Area, Phase-II, Panchkula-134113	The sample does not conforms to the claim with respect to Assay and Dissolution. Assay: Ofloxacin: Claim-200.00mg, Found 116.34mg (i.e 58.17% of claim). Ornidazole: Claim-500.00mg, Found 250.02mg (i.e 50.00% of claim). Dissolution: Ofloxacin: D=75%, Average: 50.82% Ornidazole: Average: 50.20%
3.	Enalapril Maleate Tablets IP 10mg	RJET-06	M/s Combatic Global Caplet Pvt. Ltd., M-15, D-2, D-3, Industrial Area, Sonapat-131001 (Hr.) INDIA	The sample does not conforms to the claim with respect to Assay and Dissolution. Assay: Enalapril Maleate: Claim-10.00mg, Found 4.355mg (i.e 43.55% of claim). Dissolution: D=80%, Average: 37.15%
4.	Rabeprazole Sodium (EC) & Domperidone (SR) Capsules (Racme-DSR)	G012066C	M/s Nikvin Healthcare (I) Pvt. Ltd., Baddi-Barotiwalwa Road, Behind Govt. Timber Depot, Vill. Katha, Baddi (H.P.) 173205	The sample does not conforms to the claim with respect to Assay of Rabeprazole Sodium. Assay: Rabeprazole Sodium: Claim- 20.00mg, Found 12.66mg (i.e 63.30% of claim).
5.	Enalapril Maleate Tablets I.P.	STN-190622	M/s Terrace Pharmaceuticals (P) Ltd., 3-B(a) Phase-III, Industrial Area, Sansarpur Terrace, Distt. Kangra (HP)-176501	The sample does not conforms to the claim with respect to Assay and Dissolution. Assay: Enalapril Maleate: Claim- 10.00mg, Found 2.831mg (i.e 28.31% of claim). Dissolution: D=80%, Average: 18.60%
6.	Enalapril Maleate Tablets I.P. 5mg	PRT-200801	M/s Preet Remedies Ltd., 183-186, HPSIDC, Industrial Area, Baddi-173205 (H.P.)	The sample does not conforms to the claim with respect to Assay and Dissolution. Assay: Enalapril Maleate: Claim- 5.00mg, Found 3.891mg (i.e 77.82% of claim). Dissolution: D=80%, Average: 72.66%
7.	Ibuprofen Tablets I.P. 400mg	BPT20003	M/s Vivek Pharmachem (India) Ltd., NH-8, Chimanpura, Amer, Jaipur	The sample does not conform to I.P. with respect to the test for Dissolution.
8.	Ibuprofen Tablets I.P. 400mg	BPT20005	M/s Vivek Pharmachem (India) Ltd., NH-8, Chimanpura, Amer, Jaipur	The sample does not conform to I.P. with respect to the test for Dissolution.
9.	Misoprostol Tablets I.P. 200mcg	MOT20002	M/s Vivek Pharmachem (India) Ltd., NH-8, Chimanpura, Amer, Jaipur	The sample does not conform to I.P. with respect to the test for Assay of Misoprostol. Assay: Found mcg/tab=27.53. Claim/mcg/tab=200.00, % of claim=13.76%.

It is also informed by the Deputy Drugs Controller (India), CDSCO, NZ, Ghaziabad through his letter no. 14-NZ/NSQ Alert/190/2022/411 Dated 02.06.2022 that the sample of Calcium and Vitamin D3 Tablets IP (500mg + 250IU) (Calcium 500mg and Vitamin D3 250IU), B.No. CWTY-103, D/M 02/2021, D/E 01/2023, Mfgd. By M/s Hindustan Antibiotics Ltd., at: 11, W.E.A. Faridabad-121001 (Haryana) has declared NSQ as "the sample does not conform to I.P. with respect to the test for "Dissolution" and "Assay of Vitamin D3".

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


P.T.O.

No. DC/Bulletin/2022/ 987

Date: 17/6/22

Copy forwarded for necessary action to:-

- 1- Drugs Controller General (India), FDA Bhawan, CITEB Campus, Kotla Road, New Delhi.
- 2- Mission Director, NHM, Medical & Health Services, Bq. 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./BASU/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/Eihar/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, Kailash 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 और इसे नियमन संकेतक Bulletin heading and e-mail to all above officers.
- 20- Computer Desk/Concerning files.


 Drugs Controller
 Rajasthan, Jaipur