

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

No. DC/Bulletin/E-00208/2023/ 3717

Dated: 4/9/23

All Drugs Control Officers,
 Rajasthan State

Sub:- Details of Drugs/Cosmetic declared as Not of Standard Quality w.e.f.
 16.08.2023 to 31.08.2023.

Particulars of the samples declared as not of standard quality on test /analysis are given below for ensuring that the stocks of these drugs/cosmetic 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/Cosmetic	B.No./ Exp. Date	Mfgd. by	Reason
1.	Amlodipine Besylate & Atenolol Tablets (Amlofit-AT)	AFA2201, 03/2024	M/s Apple Formulations Pvt. Ltd., Plot No. 208, Kishanpur, Roorkee- 247667 (U.K.)	The sample does not conform to the IP with respect to assay of Amlodipine Besylate eqv. to Amlodipine.
2.	Jasmin MEHANDI CONE	06.23.JH, June 2023, Best use before 6 Months	M/s Sankhala Mehandi Udyog, H-115, G-116(A), Industrial Area, Phase-III, Sojat City, Dist. Pali (Rajasthan)	The sample does not conform to the claim made on the label as to the nature and quality of cosmetic with respect to Picramic Acid (Found 0.2155%) and Lawsone.
3.	Jasmin MEHANDI CONE	JM-23, MAY 2023, Best use before 6 Months	M/s Sankhala Mehandi Udyog, H-115, G-116(A), Industrial Area, Phase-III, Sojat City, Dist. Pali (Rajasthan)	The sample does not conform to the claim made on the label as to the nature and quality of cosmetic with respect to Picramic Acid (Found 0.5701%) and Lawsone.
4.	Jasmin MEHANDI CONE	07.23.JH July 2023, Best use before 6 Months	M/s Sankhala Mehandi Udyog, H-115, G-116(A), Industrial Area, Phase-III, Sojat City, Dist. Pali (Rajasthan)	The sample does not conform to the claim made on the label as to the nature and quality of cosmetic with respect to Picramic Acid (Found 0.7114%) and Lawsone.
5.	Compound Benzoin Tincture IP 1x100ml	TB081, 09/2024	M/s Apex Healthcare, H1-510, RIICO Industrial Area, Bhamashah Kaladwas, Udaipur (Raj.).	The sample does not conform to IP specification for Compound Benzoin Tincture with respect to Total Solids, Ethanol Content and to the content of Cinnamic Acid (Total balsamic acid).
6.	Norfloxacin Tablets IP 400mg	NRT22006, 07/2024	M/s Vivek Pharmachem (India) Ltd., NH-8, Chimanpura, Amer, Jaipur-303102 (Raj.).	The sample does not conform to IP specification for Norfloxacin Tablets with respect to Dissolution.
7.	Norfloxacin Tablets IP 400mg	NRT23009, Dec-2024	M/s Vivek Pharmachem (India) Ltd., NH-8, Chimanpura, Amer, Jaipur-303102 (Raj.).	The sample received does not conform to IP standard with respect to test for Dissolution.

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

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RajKaj Ref No. : 4633339

Signature valid
 Drugs Controller-I
 Digitally signed by Ashish Phatak
 Designation: Drug Controller
 Date: 2023.09.11 11:43:14 IST
 Reason: Approved



RajKaj Ref No. : 4638624

Signature valid
 Digitally signed by Ram
 Sharma
 Designation: Drug Controller
 Date: 2023.09.11 11:35:10 IST
 Reason: Approved



No. DC/Bulletin/E-00208/2023/ 3717

Dated: 4/9/23

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. 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 Chhwani 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 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

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RajKaj Ref No. : 4633339



RajKaj Ref No. : 4638624



Signature valid

Digitally signed by A. Phatak
Designation: Drug Controller
Date: 2023.09.11 11:43:14 IST
Reason: Approved

Signature valid

Digitally signed by R. Ram
Sharma
Designation: Drug Controller
Date: 2023.09.11 11:35:10 IST
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