## GOVERNMENT OF RAJASTHAN FOOD SAFETY AND DRUGS CONTROL COMMISSIONERATE, (DRUG CONTROL WING),

SWASTHYA BHAWAN, TILAK MARG, JAIPUR (RAJASTHAN) E-mail: <a href="mailto:drugcontroller1.mh@rajasthan.gov.in">drugcontroller1.mh@rajasthan.gov.in</a> Contact no. 0141-2221760, 2221670

No. DC/Bulletin/2022/ 216

Dated: 05/4/2022

All Drugs Control Officers, Rajasthan State.

Sub:- Details of Drugs declared as Not of Standard Quality w.e.f. 16.03.2022 to 31.03.2022.

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./ Exp. Date	Mfgd. by	Reason
1	Chlorpheniramine Maleate, Ammonium Chloride, Sodium Citrate & Menthol cough syrup	LH0008A 07-2022	M/s Navkar Lifesciences, Plot No. 76, Lodhi Majra, Industrial Area, Baddi, Distt. Solan (H.P.)	The sample does not conform to the claim with respect to Assay of Menthol.  Assay:- Menthol Claim 0.5mg, Found 0.0312mg (i.e 6.24% of claim).  NOTE:- Contents in form of white powder accumulated around the "SEALCAP" on the bottle. Its resultantly that deteriorate and damage of aluminium cap.
2	Chlorpheniramine Maleate, Ammonium Chloride, Sodium Citrate & Menthol cough syrup	LH0006A 07-2022	M/s Navkar Lifesciences, Plot No. 76, Lodhi Majra, Industrial Area, Baddi, Distt. Solan (H.P.)	The sample does not conform to the claim with respect to Assay of Menthol.  Assay:- Menthol Claim 0.5mg, Found 0.0353mg (i.e 7.06% of claim).  NOTE:- Contents in form of white powder accumulated around the "SEALCAP" on the bottle. Its resultantly that deteriorate and damage of aluminium cap.
3	Chlorpheniramine Maleate, Ammonium Chloride, Sodium Citrate & Menthol cough syrup	LH0004A 07-2022	M/s Navkar Lifesciences, Plot No. 76, Lodhi Majra, Industrial Area, Baddi, Distt. Solan (H.P.)	The sample does not conform to the claim with respect to Assay of Menthol. Assay:- Menthol Claim 0.5mg, Found 0.0883mg (i.e 17.66% of claim). NOTE:- Contents in form of white powder accumulated around the "SEALCAP" on the bottle. Its resultantly that deteriorate and damage of aluminium cap.
4	Chlorpheniramine Maleate, Ammonium Chloride, Sodium Citrate & Menthol cough syrup	LH0005A 07-2022	M/s Navkar Lifesciences, Plot No. 76, Lodhi Majra, Industrial Area, Baddi, Distt. Solan (H.P.)	The sample does not conform to the claim with respect to Assay of Menthol. Assay:- Menthol Claim 0.5mg, Found 0.1048mg (i.e 20.96% of claim). NOTE:- Contents in form of white powder accumulated around the "SEALCAP" on the bottle. Its resultantly that deteriorate and damage of aluminium cap.
5	Chlorpheniramine Maleate, Ammonium Chloride, Sodium Citrate & Menthol cough syrup	LH00013A 07-2022	M/s Navkar Lifesciences, Plot No. 76, Lodhi Majra, Industrial Area, Baddi, Distt. Solan (H.P.)	The sample does not conform to the claim with respect to Assay of Menthol. Assay:- Menthol Claim 0.5mg, Found 0.0555mg (i.e 11.10% of claim). NOTE:- Contents in form of white powder accumulated around the "SEALCAP" on the bottle. Its resultantly that deteriorate and damage of aluminium cap.
6	Chlorpheniramine Maleate, Ammonium Chloride, Sodium Citrate & Menthol cough syrup	LH0003A 07-2022	M/s Navkar Lifesciences, Plot No. 76, Lodhi Majra, Industrial Area, Baddi, Distt. Solan (H.P.)	The sample does not conform to the claim with respect to Assay of Menthol. Assay:- Menthol Claim 0.5mg, Found 0.0774mg (i.e 15.48% of claim). NOTE:- Contents in form of white powder accumulated around the "SEALCAP" on the bottle. Its resultantly that deteriorate and damage of aluminium cap.
7	Chlorpheniramine Maleate, Ammonium Chloride, Sodium Citrate & Menthol cough syrup	LH0080A 11-2022	M/s Navkar Lifesciences, Plot No. 76, Lodhi Majra, Industrial Area, Baddi, Distt. Solan (H.P.)	The sample does not conform to the claim with respect to Assay of Menthol. Assay:- Menthol Claim 0.5mg, Found 0.1274mg (i.e 25.48% of claim).
8	Chlorpheniramine Maleate, Ammonium Chloride, Sodium Citrate & Menthol cough syrup	LH0015A 07-2022	M/s Navkar Lifesciences, Plot No. 76, Lodhi Majra, Industrial Area, Baddi, Distt. Solan (H.P.)	The sample does not conform to the claim with respect to Assay of Menthol.  Assay:- Menthol Claim 0.5mg, Found 0.0538mg (i.e 10.76% of claim).  NOTE:- Contents in form of white powder accumulated around the "SEALCAP" on the bottle. Its resultantly that deteriorate and damage of aluminium cap.

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9	Chlorpheniramine Maleate, Ammonium Chloride, Sodium Citrate & Menthol cough syrup	LH0014A 07-2022	M/s Navkar Lifesciences, Plot No. 76, Lodhi Majra, Industrial Area, Baddi, Distt. Solan (H.P.)	The sample does not conform to the claim with respect to Assay of Menthol.  Assay:- Menthol Claim 0.5mg, Found 0.0456mg (i.e 9.12% of claim).  NOTE:- Contents in form of white powder accumulated around the "SEALCAP" on the bottle. Its resultantly that deteriorate and damage of aluminium cap.
10	Chlorpheniramine Maleate, Ammonium Chloride, Sodium Citrate & Menthol cough syrup	LH00012A 07-2022	M/s Navkar Lifesciences, Plot No. 76, Lodhi Majra, Industrial Area, Baddi, Distt. Solan (H.P.)	The sample does not conform to the claim with respect to Assay of Menthol.  Assay:- Menthol Claim 0.5mg, Found 0.0326mg (i.e 6.52% of claim).  NOTE:- Contents in form of white powder accumulated around the "SEALCAP" on the bottle. Its resultantly that deteriorate and damage of aluminium cap.
11	Chlorpheniramine Maleate, Ammonium Chloride, Sodium Citrate & Menthol cough syrup	LH0010A 07-2022	M/s Navkar Lifesciences, Plot No. 76, Lodhi Majra, Industrial Area, Baddi, Distt. Solan (H.P.)	The sample does not conform to the claim with respect to Assay of Menthol.  Assay:- Menthol Claim 0.5mg, Found 0.0380mg (i.e 7.6% of claim).  NOTE:- Contents in form of white powder accumulated around the "SEALCAP" on the bottle. Its resultantly that deteriorate and damage of aluminium cap.
12	Chlorpheniramine Maleate, Ammonium Chloride, Sodium Citrate & Menthol cough syrup	LH0009A 07-2022	M/s Navkar Lifesciences, Plot No. 76, Lodhi Majra, Industrial Area, Baddi, Distt. Solan (H.P.)	The sample does not conform to the claim with respect to Assay of Menthol. Assay:- Menthol Claim 0.5mg, Found 0.0448mg (i.e 8.96% of claim). NOTE:- Contents in form of white powder accumulated around the "SEALCAP" on the bottle. Its resultantly that deteriorate and damage of aluminium cap.
13	Chlorpheniramine Maleate, Ammonium Chloride, Sodium Citrate & Menthol cough syrup	LH0011A 07-2022	M/s Navkar Lifesciences, Plot No. 76, Lodhi Majra, Industrial Area, Baddi, Distt. Solan (H.P.)	The sample does not conform to the claim with respect to Assay of Menthol. Assay:- Menthol Claim 0.5mg, Found 0.0534mg (i.e 10.68% of claim). NOTE:- Contents in form of white powder accumulated around the "SEALCAP" on the bottle. Its resultantly that deteriorate and damage of aluminium cap.
14	Atorvastatin Tablets I.P.	ATT-302 JUL.2022	M/s Alliaance Biotech, 440/3, Vill. Katha Baddi DisttSolan (H.P.)-173205	The sample does not conforms to the claim with respect to Dissolution.
15	Atorvastatin Tablets I.P.	ATT-314 OCT.2022	M/s Alliaance Biotech, 440/3, Vill. Katha Baddi DisttSolan (H.P.)-173205	The sample does not conforms to the claim with respect to Dissolution.
16	Atorvastatin Tablets I.P.	ATT-313 OCT.2022	M/s Alliaance Biotech, 440/3, Vill. Katha Baddi DisttSolan (H.P.)-173205	The sample does not conforms to the claim with respect to Dissolution.
17	Atorvastatin Tablets I.P.	ATT-305 AUG.2022	M/s Alliaance Biotech, 440/3, Vill. Katha Baddi DisttSolan (H.P.)-173205	The sample does not conforms to the claim with respect to Dissolution.
18	Drotaverine Hydrochloride & Mefenamic Acid Tablets (DROPAS-M)	LTA-11962 OCT/22	M/s Life Vision Healthcare, Plot No. 140-141, E.P.I.P., Phase-I, Jharmajri, Baddi, Distt. Solan (H.P.) 174103	The sample does not conforms to the claim with respect to Assay of Drotaverine Hydrochloride. <u>Assay:</u> Drotaverine Hydrochloride: Claim-80.00mg, Found 65.01mg (i.e 81.26% of claim)
19	Drotaverine Hydrochloride & Mefenamic Acid Tablets (Spasrot-M)	AF-T2547 06/22	M/s Affine Formulations Ltd., 1947/3, Vill. Bhatian, Tehsil Nalagarh, Dist. Solan 174101 (H.P.)	The sample does not conforms to the claim with respect to Assay of Drotaverine Hydrochloride.  Assay: Drotaverine Hydrochloride: Claim-80.00mg, Found 65.16mg (i.e 81.45% of claim)
20	Drotaverine Hydrochloride & Mefenamic Acid Tablets (Taver-M)	UD2T- 2357F 05/2022	M/s Ultra Drugs Pvt. Ltd., (Unit-II), HS No. 211, K.No. 77/1, 78/1, Vill Katha, Baddi, Distt. Solan (H.P.)	The sample does not conforms to the claim with respect to Assay of Drotaverine Hydrochloride.  Assay: Drotaverine Hydrochloride: Claim-80.00mg, Found 64.35mg (i.e 80.43% of claim)
21	Calcium and Vitamin D3 Tablets IP	BVCT-198 10/22	M/s Ind-Swift Limited, (Unit- III), Village-Malkumajra, Tehsil-Nalagarh, Distt. Solan- 173205 (H.P.) INDIA	The sample does not conforms to the claim with respect to Assay of Vitamin D3.  Assay: Vitamin D3: Claim-250.00IU, Found 69.65IU (i.e 27.86% of claim)
22	Calcium and Vitamin D3 Tablets IP	BVCT-116 05/22	M/s Ind-Swift Limited, (Unit- III), Village-Malkumajra, Tehsil-Nalagarh, Distt. Solan- 173205 (H.P.) INDIA	The sample does not conforms to the claim with respect to Assay of Vitamin D3.  Assay: Vitamin D3: Claim-250.00IU, Found 167.71IU (i.e 67.08% of claim)

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23	Alprazolam Tablets I.P. (Alprazolam 0.5mg)	GAM20001 JUN.2023	M/s Sanctus Global Formulations Limited, Khasra No. 587/588, Village: Kunjhal, Backside Jharmajri, Tehsil Baddi, Distt. Solan, HP Pin-174103	The sample does not conforms to the claim with respect to Dissolution. Average: 54.82%
24	Alprazolam Tablets I.P. (Alprazolam 0.5mg)	GAM20002 JUN.2023	M/s Sanctus Global Formulations Limited, Khasra No. 587/588, Village: Kunjhal, Backside Jharmajri, Tehsil Baddi, Distt. Solan, HP Pin-174103	The sample does not conforms to the claim with respect to Dissolution.  Average: 33.79%
25	Alprazolam Tablets I.P. (Alprazolam 0.5mg)	GAM20003 AUG.2023	M/s Sanctus Global Formulations Limited, Khasra No. 587/588, Village: Kunjhal, Backside Jharmajri, Tehsil Baddi, Distt. Solan, HP Pin-174103	The sample does not conforms to the claim with respect to Dissolution.  Average: 35.24%
26	Alprazolam Tablets I.P. (Alprazolam 0.5mg)	GAM20003 AUG.2023	M/s Sanctus Global Formulations Limited, Khasra No. 587/588, Village: Kunjhal, Backside Jharmajri, Tehsil Baddi, Distt. Solan, HP Pin-174103	The sample does not conforms to the claim with respect to Dissolution. Average: 31.36%
27	Calcium & Vitamin D3, Tablets I.P. (MEGCAL-500)	SP-2040 12/2022	M/s Sritech Pharma, F-19, UPSIDC, Industrial Area, Gajraula, J.P. Nagar (UP) 244235	The sample does not conforms to the claim with respect to Assay of Vitamin D3.  Assay: Vitamin D3 found 173.97IU (i.e 69.58% of claim), Claim: 250.00IU.
28	Rosuvastatin Calcium & Aspirin Enteric Coated Capsules (Rosusen-A)	RC2005- 22A 04/2022	M/s Regent Ajanta Biotech, 86-87, Village Makhiyali Dundi, Peerpura Road, Roorkee-247667 (UK)	The sample does not conforms to the claim with respect to Assay of Rosuvastatin and Aspirin.  Assay: Rosuvastatin found 4.141mg (i.e 41.41% of claim), Claim: 10.00mg.  Assay: Aspirin found 42.49mg (i.e 56.65% of claim), Claim: 75.00mg.
29	Chlorpheniramine Maleate, Ammonium Chloride, Sodium Citrate and Menthol Syrup	KL-20/504 May.2022	M/s Kaysons Pharma, 1, Vigyan Nagar, Sarna Dungar, Industrial Arca, Jaipur- 302012 (Raj.)	The sample does not conform to the claim with respect to Assay of Menthol. Assay: Menthol Claim 0.5mg, Found 0.0736mg (i.e. 14.72% of claim).
30	Chlorpheniramine Maleate, Ammonium Chloride, Sodium Citrate and Menthol Syrup	KL-21/050 Dec.2022	M/s Kaysons Pharma, 1, Vigyan Nagar, Sarna Dungar, Industrial Area, Jaipur- 302012 (Raj.)	The sample does not conform to the claim with respect to Assay of Menthol. Assay: Menthol Claim 0.5mg, Found 0.1421mg (i.e 28.42% of claim).
31	Chlorpheniramine Maleate, Ammonium Chloride, Sodium Citrate and Menthol Syrup	KL-20/908 Nov.2022	M/s Kaysons Pharma, 1, Vigyan Nagar, Sarna Dungar, Industrial Area, Jaipur- 302012 (Raj.)	The sample does not conform to the claim with respect to Assay of Menthol. Assay: Menthol Claim 0.5mg, Found 0.1131mg (i.e 22.62% of claim).
32	Chlorpheniramine Maleate, Ammonium Chloride, Sodium Citrate and Menthol Syrup	KL-20/938 Nov.2022	M/s Kaysons Pharma, 1, Vigyan Nagar, Sarna Dungar, Industrial Area, Jaipur- 302012 (Raj.)	The sample does not conform to the claim with respect to Assay of Menthol. Assay: Menthol Claim 0.5mg, Found 0.0754mg (i.e. 15.08% of claim).
33	Chlorpheniramine Maleate, Ammonium Chloride, Sodium Citrate and Menthol Syrup	KL-20/923 Nov.2022	M/s Kaysons Pharma, 1, Vigyan Nagar, Sarna Dungar, Industrial Area, Jaipur- 302012 (Raj.)	The sample does not conform to the claim with respect to Assay of Menthol. Assay: Menthol Claim 0.5mg, Found 0.0725mg (i.e. 14.50% of claim).
34	Chlorpheniramine Maleate, Ammonium Chloride, Sodium Citrate and Menthol Syrup	KL-20/501 May.2022	M/s Kaysons Pharma, 1, Vigyan Nagar, Sarna Dungar, Industrial Area, Jaipur- 302012 (Raj.)	The sample does not conform to the claim with respect to Assay of Menthol. Assay: Menthol Claim 0.5mg, Found 0.0591mg (i.e 11.82% of claim).
35	Chlorpheniramine Maleate, Ammonium Chloride, Sodium Citrate and Menthol Syrup	KL-20/500 Apr.2022	M/s Kaysons Pharma, 1, Vigyan Nagar, Sarna Dungar, Industrial Area, Jaipur- 302012 (Raj.)	The sample does not conform to the claim with respect to Assay of Menthol. Assay: Menthol Claim 0.5mg, Found 0.0390mg (i.e 7.80% of claim).
36	Chlorpheniramine Maleate, Ammonium Chloride, Sodium Citrate and Menthol Syrup	KL-20/498 Apr.2022	M/s Kaysons Pharma, 1, Vigyan Nagar, Sarna Dungar, Industrial Arca, Jaipur-	The sample does not conform to the claim with respect to Assay of Menthol. Assay: Menthol Claim 0.5mg, Found 0.0479mg (i.e.
37	Chlorpheniramine Maleate, Ammonium Chloride, Sodium Citrate and Menthol Syrup	KL-20/496 Apr.2022	Dungar, Industrial Area, Jaipur-	9.58% of claim).  The sample does not conform to the claim with respect to Assay of Menthol.  Assay:  Menthol Claim 0.5mg, Found 0.0460mg (i.e 9.2% of claim).

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38	Chlorpheniramine Maleate, Ammonium Chloride, Sodium Citrate and Menthol Syrup	KL-20/492 Apr.2022	M/s Kaysons Pharma, 1, Vigyan Nagar, Sarna Dungar, Industrial Area, Jaipur- 302012 (Raj.)	The sample does not conform to the claim with respect to Assay of Menthol. Assay: Menthol Claim 0.5mg, Found 0.0826mg (i.e 16.52% of claim).
39	Chlorpheniramine Maleate, Ammonium Chloride, Sodium Citrate and Menthol Syrup	KL-20/489 Apr.2022	M/s Kaysons Pharma, 1, Vigyan Nagar, Sarna Dungar, Industrial Area, Jaipur- 302012 (Raj.)	The sample does not conform to the claim with respect to Assay of Menthol. Assay: Menthol Claim 0.5mg, Found 0.0813mg (i.e 16.26% of claim).
40	Chlorpheniramine Maleate, Ammonium Chloride, Sodium Citrate and Menthol Syrup	KL-20/487 Apr.2022	M/s Kaysons Pharma, 1, Vigyan Nagar, Sarna Dungar, Industrial Area, Jaipur- 302012 (Raj.)	The sample does not conform to the claim with respect to Assay of Menthol. Assay: Menthol Claim 0.5mg, Found 0.0718mg (i.e. 14.36% of claim).
41	Chlorpheniramine Maleate, Ammonium Chloride, Sodium Citrate and Menthol Syrup	KL-20/482 Apr.2022	M/s Kaysons Pharma, 1, Vigyan Nagar, Sarna Dungar, Industrial Area, Jaipur- 302012 (Raj.)	The sample does not conform to the claim with respect to Assay of Menthol. Assay: Menthol Claim 0.5mg, Found 0.0755mg (i.e. 15.10% of claim).
42	Chlorpheniramine Maleate, Ammonium Chloride, Sodium Citrate and Menthol Syrup	KL-20/462 Apr.2022	M/s Kaysons Pharma, 1, Vigyan Nagar, Sarna Dungar, Industrial Area, Jaipur- 302012 (Raj.)	The sample does not conform to the claim with respect to Assay of Menthol. Assay: Menthol Claim 0.5mg, Found 0.0731mg (i.e. 14.62% of claim).
43	Chlorpheniramine Maleate, Ammonium Chloride, Sodium Citrate and Menthol Syrup	KL-20/486 Apr.2022	M/s Kaysons Pharma, 1, Vigyan Nagar, Sarna Dungar, Industrial Area, Jaipur- 302012 (Raj.)	The sample does not conform to the claim with respect to Assay of Menthol. Assay: Menthol Claim 0.5mg, Found 0.1096mg (1221.92% of claim).
44	Chlorpheniramine Maleate, Ammonium Chloride, Sodium Citrate and Menthol Syrup	KL-20/939 Nov.2022	M/s Kaysons Pharma, 1, Vigyan Nagar, Sarna Dungar, Industrial Area, Jaipur- 302012 (Raj.)	The sample does not conform to the claim with respect to Assay of Menthol. Assay: Menthol Claim 0.5mg, Found 0.0946mg (i.e. 18.92% of claim).

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

Dated: 574/2022

## No. DC/Bulletin/2022/216

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 संगठन Bulletin heading and e-mail to all above officers.
- 20- Computer Desk/Concerning files.

Drugs Controller Rajasthan, Jaipur