

By Register Post

The Drug Controller

GOVERNMENT OF TAMIL NADU - 1001

DIRECTORATE OF DRUGS CONTROL 25/8/17

From

Thiru. K. Sivabalan, B.Pharm.,
Director of Drugs Control i/c,
Tamil Nadu,
359 - Anna Salai,
Chennai - 6.

To

The Drugs Controller General of India,
CHEB Campus,
Kotla Road,
Opp. Mata Sundari Hostel,
New Delhi - 110 001.

Ref. No. 7171/IW3/2017, Dated. 08.08.2017

Sir,

Sub: Drugs - Drugs & Cosmetics Act 1940 and Rules made thereunder
- List of Not of Standard Quality Drugs - Reported Month of
JULY 2017 - Communicated - Reg.

List of Drugs reported as Not of Standard Quality by Government Analyst, Tamil Nadu during the Month of **JULY 2017** is enclosed herewith for your kind information and further necessary action.

Thanking you,

Yours faithfully,

DIRECTOR OF DRUGS CONTROL (i/c)

TAMIL NADU.

Copy forwarded with compliments for information to:

- 1) The Deputy Drugs Controller (India) 4th Floor, FDA Bhawan, GMSD Compound, Bellasis Road, Mumbai Central, Mumbai - 400 008.
- 2) The Deputy Drugs Controller (East Zone), Central Drugs Standard Control Organization, C.G.O. Building, 234/4, Lower Circle Road, Kolkata - 700 020.
- 3) The Joint Drugs Controller (North Zone), Central Drugs Standard Control Organization C.G.O. Building, Kamala Nehru Nagar, Segment Wing, 'A' 1st Floor, Hapur Chungi, Ghaziabad - 201 002 (UP).
- 4) The Deputy Drugs Controller (South Zone), Central Drugs Standard Control Organization, 2nd Floor, Shastri Bhawan, Haddows Road, Chennai - 600 006.
- 5) The President, Pharmaceutical Manufacture Association, Block D-1, Baid Mehta Complex, New No. 16, Old No. 183, Anna Salai, Little Mount, Saidapet, Chennai - 15.

YEAR 2017-2018 (JULY 2017)

date: 08.2017

11/03/2017

Ref. No.	SAMPLE NAME	B.NO.	M/D	E/D	M/S	Reason for Failure	RANGE	ZONE	Report No / Dated
11371	Vitamin B Complex Tablets NFI	GSM-16136	09/2016	08/2018	Max Chem Pharmaceuticals Pvt. Ltd. Plot No. 22, Sector - 3, Sidcul IIE, Rudrapur, U.S. Nagar District, Uttarakhand - 263 153	sample does not conform to Label claim with respect to the content of Vitamin B1 and Vitamin B6	Coax	Zone II	01185-D/2017-18/ 06.07.2017
11374	Vitamin B Complex Tablets NFI	GSM-16137	09/2016	08/2018	Max Chem Pharmaceuticals Pvt. Ltd. Plot No. 22, Sector - 3, Sidcul IIE, Rudrapur, U.S. Nagar District, Uttarakhand - 263 153	sample does not conform to Label claim with respect to the content of Vitamin B1 and Vitamin B6	Ambattur I	Zone IV	01021-D/2017-18/ 06.07.2017
11376	Ramipril 1.25 (Ramipril Tablets IP)	SPGT-7517	01/2016	12/2017	Sucram Pharmaceuticals Pvt. Ltd. Hudbast No. 165/1, Village Theda, Lodhi Majra Road, Tehsil - Nalagarh, Solan District - 174 101 H.P.	sample does not conform to IP specification for Ramipril Tablets with respect to the content of Ramipril 0.48mg (38.4% - 25mg)	Udumalpet	Coimbatore	02752-D/2016-17 06.07.2017
11378	Lincal (Calcium Carbonate with Vitamin D3 Tablets)	NJT-1249	08/2016	07/2018	New Jersey Life Care Pharma, R.S.No.81, Singirikudi Road, Abhishegapakkam, Puducherry - 605 007	sample does not conform to Label claim with respect to the content of Vitamin D3 and to IP specification for Film coated tablets with respect to Disintegration	Trichy I	Trichy	05443-D/2016-17/ 06.07.2017
11380	Panzo 40 (Pantoprazole Sodium Tablets IP)	BPF-003	04/2016	03/2018	Biopharm Formulations, No 24, Krish Complex, 2nd Floor, Senthil Industrial Estate, Diraviyam Nagar, Lakshmi Nagar Extension, Porur, Chennai - 600 116	sample does not conform to IP specification for Pantoprazole Sodium Tablets with respect to Dissolution in Buffer Medium	Arakkonam	Vellore	00835-D/2017-18/ 06.07.2017
11501	Single use Syringes with Needle (Dora one)	BX 029	12/2016	11/2019	Keshava Medi Devices Pvt. Ltd. Plot No.31&36, Industrial Estate, Settippalli(Post), Renigunta Road, Tirupati - 517 508 A.P	sample does not conform to requirements for Sterility	Coimbatore I	Coimbatore	124/ Laboratory No 66518-17 05.07.2017
11823	Diclofenac Sodium Tablets IP 50mg	B61013	11/2016	10/2018	Bochem Healthcare Pvt. Ltd. 83-84, Industrial Area, Dewas Road, Nagziri, Ujjain 466 010, M.P.	sample does not conform to IP specification for Enteric Coated tablets with respect to Disintegration in Acid Medium	Tirupur	Coimbatore	01208-D/2017-18/ 11.07.2017
11824	Metovin-AM (Metoprolol Succinate & Amlodipine Tablets)	MHPL17018	03/2017	02/2019	Medinok Healthcare Pvt. Ltd. R/S.No.16/7, Regavendra Kovil Street, Kurumbapet, Puducherry - 605 009	sample does not conform to label claim with respect to the content of Amlodipine in Amlodipine Besylate	Metur	Salem	00908-D/2017-18/ 10.07.2017
11825	Cough Syrup	1511010	11/2015	10/2017	S.M. Pharmaceuticals, No.37/A2, Piliagumpe Industrial Area, Hoskote, Bangalore - 562 114	sample does not conform to label claim with respect to the content of Chlorpheniramine Maleate	Vasavevakkam	Zone IV	02687-D/2016-17/ 10.07.2017
11826	Bevon Suspension (Multivitamin, Multimineral & Antioxidant Suspension)	16A16083	08/2016	01/2018	Emcure Pharmaceuticals Ltd. Lane No.3, Phase - II, Sidco, Bari-Brahmana, Jammu - 181 133	sample does not conform to label claim with respect to the content of b-Caroten Dispersion 2.5%	Ambattur II	Zone IV	06760-D/2016-17/ 11.07.2017
11827	I-Rose XT (Ferrous Ascorbate, Folic Acid & Zinc Tablets)	16066	11/2016	04/2018	G.K. Labs, No. 15, Koil Lane Street, Achrapakkam, Kancheepuram - 603 301	sample does not conform to Label claim with respect to the content of Elemental Zinc in Zinc Sulphate Monohydrate	Arumbakkam	Zone II	07473-D/2016-17/ 11.07.2017

		Shree Sandal Pack	SRHSP-002	03/2016	2 Years from Mfg	Shree Herbal, 130/135, Jogaraj Building, Bedford, Coonoor, Nilgiris - 643 101	sample does not conform to BIS specification for Cosmetics (Face Pack) with respect to Microbial limit - Total Viable count	-	Coimbatore	03504-D/2016-17/26.07.2017
		Shree Rose Pack	SRHSP-001	03/2016	2 Years from Mfg	Shree Herbal, 130/135, Jogaraj Building, Bedford, Coonoor, Nilgiris - 643 101	sample does not conform to BIS specification for Cosmetics (Face Pack) with respect to Microbial limit - Total Viable count	-	Coimbatore	03501-D/2016-17/26.07.2017
	12733	Shree Sandal Pack	SRHSP-001	06/2016	2 Years from Mfg	Shree Herbal Nilgiris Pvt Ltd, 130/135, Jogaraj Building, Bedford, Coonoor, Nilgiris - 643 101	sample does not conform to BIS specification for Cosmetics (Face Pack) with respect to Microbial limit - Total Viable count	Nilgiris	Coimbatore	03455-D/2016-17/26.07.2017
91	12736	Shree Sandal Pack	SRHSP-001	07/2016	2 Years from Mfg	Shree Herbal Nilgiris Pvt Ltd, 130/135, Jogaraj Building, Bedford, Coonoor, Nilgiris - 643 101	sample does not conform to BIS specification for Cosmetics (Face Pack) with respect to Microbial limit - Total Viable count	Nilgiris	Coimbatore	03451-D/2016-17/26.07.2017
92	12737	Shree Herbal Face Pack	SRHHFP-001	04/2016	2 Years from Mfg	Shree Herbal, 130/135, Jogaraj Building, Bedford, Coonoor, Nilgiris - 643 101	sample does not conform to BIS specification for Cosmetics (Face Pack) with respect to Microbial limit - Total Viable count	Nilgiris	Coimbatore	03452-D/2016-17/26.07.2017
93	12740	Zen-Rabiz (Rabeprazole Sodium Tablets IP)	KR-03	02/2016	01/2018	Kaizen Research Labs India Pvt Ltd, 705/5B, Old Thiruthani Salai, Melpudup Ettai, Annthalai Panchayat, Walajapet (TK), Vellore District - 632 513	sample does not conform to IP specification for Rabeprazole Sodium Tablets with respect to Dissolution in Acid Medium	Chennai	Vellore	00144-D/2016-17/26.07.2017
94	12743	Amikacin Sulphate Injection I.P. 100mg	AK1647	05/2017	09/2018	Nandani Medical Laboratories Pvt. Ltd., 221/15, Bicholi Hapsi, Kanadia Road, Indore, M.P.	sample does not conform to the requirements for BET as per Indian Pharmacopoeia 2014	Maduraiyam	Coimbatore	154/ Laboratory No 652/16-17 26.07.2017
95	12745	Nihal Single use Disposable Syringe	348027NB1	10/2016	11/2021	Nihal Health Care, 33, Export Promotion Industrial Park, Phase - I, Jharmajri Baddi, Dist - Solan (HP)	sample does not conform to the requirements for Sterility	Coimbatore - I	Coimbatore	153/ Laboratory No 640/16-17 26.07.2017

DIRECTOR OF DRUGS CONTROL (i/c)

for
8/5/17
2/8/17

From

Drugs Inspector
Chandigarh Administration
Chandigarh

To

President
Chandigarh Chemist Association
SCF No. 16, Sector-19-C,
Chandigarh

Memo No. DIS-2017/1448

Dated, Chandigarh the: - 25.8.2017

Subject:- Drugs Reported to be " **Not of Standard Quality**"--regarding.

In reference to the letter received from Drugs Controller General (India) CHEB Campus, Kotla Road, Opp. Mata Sundari Hostel, New Delhi Ref No. Ref. No. 7171/IW3/2017 Dt. 08.08.2017 regarding List of "**Not of Standard Quality**" Drugs-Reported communicated. (Copy enclosed herewith).

You are hereby directed to further inform the retail & whole sale chemists to not to carryout purchase/ sale of these particular batches of these drugs & if any drugs stock is available with them, then immediately inform to this office.


Drugs Inspector
Chandigarh Administration
Chandigarh