



कर्मचारी राज्य बीमा निगम
(श्रम एवं रोजगार मंत्रालय, भारत सरकार)
EMPLOYEES' STATE INSURANCE CORPORATION
(Ministry of Labour & Employment, Govt. of India)



मुख्यालय/HEADQUARTERS
पंचदीप भवन, सी.आई.डी. मार्ग, नई दिल्ली - 110 002
Panchdeep Bhawan, C.I.G. Marg, New Delhi-110002
www.esic.gov.in ☎011-23804773, ✉dmrc@esic.nic.in

U-25/12/NSQ/2023-Med V (E-178406) /356 Dated:

To,
Director (Medical) Delhi/ Director (Medical) Noida
Deans/Medical Superintendents -All ESIC Medical College & Hospitals
Directors, ESI Scheme, All State

NSQ/2024

Subject: Declaration of Drug "Not of Standard Quality" on Testing - reg

Sir/Madam

It is hereby informed that the Drug as detailed below has been reported as "Not of Standard Quality", It is directed to stop use of the said batch of the following said item immediately (copy enclosed)

NSQ reported by Institution	Name of the Firm	Item Name/ Brand Name	RC No/ Item No/ Page No	Batch No./ DOM/ DOE	Name of the Laboratory/Report No. & Date	Reason of NSQ
ESIC Model Hospital, Beltola, Guwahati, Assam	M/s Signature Phytochemical Industries 122,MI,Selaqui Industrial Area, Dehradun-248011	Fexofenadine Tab - Each tab to contain: 120mg	146C 1145 48	658-021 Nov-2023/Oct-2025	Regional Drug Testing Laboratory (RDTL)- Guwahati GUV/LS/2024-25/863, Dated.- 26.02.2024	The sample does not conform to I.P. with respect to the test for "Dissolution" Category 'B'

It is also directed that action may be taken as per clause for "Testing of Drugs-Quality Control" of Terms & Conditions of respective DG-ESIC RC. Replacement of supplies or cost of the material is to be recovered along with testing charges, if any, from the firm.

Action taken is to be maintained as record in respective user units.

This issues with the approval of Medical Commissioner (Procurement).

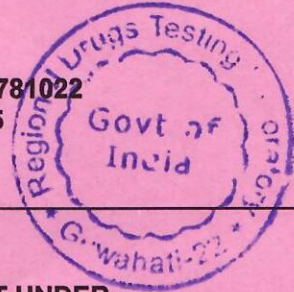
Yours Faithfully,

Enclosures: As above

Signed by Neeta Garbiyal
Date: 09-10-2024 15:11:51
Dy. Medical Commissioner(RC)

Copy to:

1. The Drug Controller General of India, CDSCO, CIG Road, New Delhi 110002(dci@nic.in).
2. Office of Commissioner, Food & Drug Administration, Assam Secretariat, Block-A, Dispur, Guwahati-781006, with the request to take appropriate action on NSQ reported for the above said batch under information to this office (foodsafety.assam@gmail.com).
3. State Drug Controller , Office of Drugs Controller(Uttarakhand) ,Director General of Medical, Health & Family Welfare, Sahastradhara Road, Dehradun, Uttarakhand with the request to take appropriate action on NSQ reported for the above said batch under information to this office (drugcontroluk@gmail.com).
4. The State Drug Controller, Food & Drug Administration, Survey No.341,2nd Floor, Bandra Kurla Complex , Opposite RBI , Kala Nagar , Bandra East,Mumbai-400051,with the request to take appropriate action on NSQ reported for the above said batch under information to this office(whogmp.mahafda@gmail.com).
5. M/s Signature Phytochemical Industries,310, 3rd Floor T.V Industrial Estate, S.K Ahire Marg Worli, Mumbai 30 ,Maharashtra (marketing@signaturepi.in).
6. Website Content Manager with request for uploading on ESIC website.
7. Guard file.



FORM 13
(See rule 46)

CERTIFICATE OF TEST OR ANALYSIS BY GOVERNMENT ANALYST UNDER
SECTION 25(1) OF THE DRUGS AND COSMETICS ACT, 1940

1. Name of Inspector from whom received : Mr. Baljeet Singh,
(Inspector)
SZ GUWAHATI
Regional Drugs Testing Laboratory Campus,
Six Mile, Panjabari Road, Guwahati- 781022
2. Serial No. and date of Inspector's memorandum : CDSO-Guwahati/sampling/BSS/2024/0161 ,
Date: 23-FEB-2024
3. Number of Sample : LS/GHY/BSS/2024/29
4. Date of receipt : 26-FEB-2024
5. Names of drugs purporting to be contained in the sample : Fexofenadine Hydrochloride Tablets I.P. .

Lab. Sample No.	Report No.	Batch No.	Date of Mfg.	Date of Exp.	Mfg. By
LSD/GUW/2024-25/0837	GUW/LS/2024-25/863	658-021	Nov-2023	Oct-2025	M/s. Signature Phytochemical Industries, 122, MI, Selaqui Industrial Area, Dehradun - 248 011.

6. Condition of seals on : Seals were intact & identical to the
[the packet or on portion of sample or container] specimen impression of the seal received from Drugs Inspector

7. Result of test or analysis with protocols or test or analysis applied : Please see below

Date of Testing : From 28-Aug-2024 To 10-Sep-2024

COMPOSITION : Each film coated tablet contains:
Fexofenadine Hydrochloride I.P. 120 mg

Protocol Applied : I.P. 2022

Sr No.	Test Name	Result	Limits
1	Description	Light pink colour, elongated, bi-convex, film coated tablet in blister strip.	NA
2	Identification	Gives positive test for Fexofenadine Hydrochloride.	NA
3	Average weight	0.3281 g	NA
4	Uniformity of weight	Complies.	NA
5	Dissolution	Does not comply.	

Level	Number Tested	Result	Acceptance Criteria
1 (at 10 min)	6	Drug release of 6 units are found as follows: i. 19.9%, ii. 32.3%, iii. 16.7%, iv. 37.6%, v. 32.4%, vi. 20.0%. Drug release of all 6 units are found less than 60%+5%	Each unit is not less than Q+5% where "Q" is 60% at 10 minutes.
S1 (at 30 min)	6	Drug release of 6 units are found as follows: i. 52.2%, ii. 65.5%, iii. 73.9%, iv. 59.5%, v. 55.2%, vi. 66.8%. Drug release of all 6 units are found less than 80%+5%	Each unit is not less than Q+5% where "Q" is 80% at 30 minutes.
S2 (at 10 min)	6	Drug release of 6 units are found as follows: i. 35.7%, ii. 28.4%, iii. 26.4%, iv. 13.4%, v. 29.1%, vi. 35.7%. 1. Average drug release of 12 units (S1+S2) 27.3% of claim. 2. Drug release of all 12 units are found less than 45% of claim, i.e, Q-15%.	Average of 12 units (S ₁ +S ₂) is $\geq 60\%$ and no unit is less than Q -15%.
S2 (at 30 min)	6	Drug release of 6 units are found as follows: i. 67.0%, ii. 63.6%, iii. 50.9%, iv. 63.1%, v. 66.4%, vi. 67.1%. 1. Average drug release of 12 units (S1+S2) 62.6% of claim. 2. Drug release of 6 units are found less than 65% of claim, i.e, Q-15%.	Average of 12 units (S ₁ +S ₂) is $\geq 80\%$ and no unit is less than Q -15%.
S3 (at 10 min)	12	Drug release of 12 units are found as follows: i. 31.2%, ii. 19.5%, iii. 24.4%, iv. 28.3%, v. 26.0%, vi. 32.1%, vii. 13.6%, viii. 28.4%, ix. 20.0%, x. 35.6%, xi. 37.7%, xii. 28.0. 1. Average drug release of 24 units (S1+S2+S3) 27.2% of claim. 2. Drug release of all 24 units are found less than 45% of claim i.e. Q-15%. 3. Drug release of 19 units are found less than 35% of claim i. e. Q-25%.	Average of 24 units (S ₁ +S ₂ +S ₃) is $\geq 60\%$ and not more than 2 units are less than Q-15% and no unit is less than Q -25%.
S3 (at 30 min)	12	Drug release of 12 units are found as follows: i. 58.4%, ii. 61.7%, iii. 49.4%, iv. 49.3%, v. 58.8%, vi. 61.8%, vii. 50.5%, viii. 43.2%, ix. 66.3%, x. 58.0%, xi. 62.5%, xii. 52.0%. 1. Average drug release of 24 units (S1+S2+S3) 60.4% of claim. 2. Drug release of 17 units are found less than 65% of claim, i.e, Q-15%. 3. Drug release of 07 units are found less than 55% of claim i.e. Q-25%.	Average of 24 units (S ₁ +S ₂ +S ₃) is $\geq 80\%$ and not more than 2 units are less than Q-15% and no unit is less than Q-25%.

Assay

Sr.No	Ingredient Name	Found	Claim	% of claim	Limits	Procedure / Method
1	Fexofenadine Hydrochloride	121.58 mg/Tablet	120 mg/Tablet	101.316	95 % to 105 %	I.P. 2022

In the opinion of the undersigned the sample referred to above is **not of standard quality** as defined in the Drugs and Cosmetics Act, 1940, and Rules there under for the reasons given below:-

The sample does not conform to I.P. with respect to the test for "Dissolution".

Date: 12-SEP-2024

GOVERNMENT ANALYST
Amar Jyoti Chamuah
Government Analyst
R.D.I.C., Guwahati-22

Report in red coloured paper indicates the sample is Not of Standard Quality.

END OF REPORT