



FORM 13
(See rule 46)

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

- Name of Inspector from whom received : Sarah Laldintluuangi Assistant Director (Food and Drugs)
Sr. CMO Office
Serchhip-796181
- Serial No. and date of Inspector's memorandum : 013/2024 , 10-OCT-2024
- Number of Sample : NIL
- Date of receipt : 30-OCT-2024
- Names of drugs purporting to be contained in the sample : Fexofenadine Hydrochloride Tablets I.P. 120 mg

Lab. Sample No.	Report No.	Batch No.	Date of Mfg.	Date of Exp.	Mfg. By
LSD/GUW/2024-25/1492	GUW/LS/2024-25/1523	UGT231163	Aug-2023	Jul-2025	Unimarck Healthcare Ltd., Plot No.: 24, 25 & 37 Sector 6A, SIDCUL, Haridwar - 249403 (Uttarakhand)

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

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

Date of Testing : From 11-Dec-2024 To 06-Jan-2025

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 colored, round, bi-convex, film coated tablets, in blister pack.	NA
2	Identification	Gives positive test for Fexofenadine Hydrochloride.	NA
3	Average weight	0.3391 g	NA
4	Uniformity of weight	Complies.	NA
5	Dissolution	Does not comply.	
6	Dissolution (10 Minutes)	Does not comply.	NLT 60%of claim

7	Level S1 (6 units)	Does not comply. Release of Fexofenadine Hydrochloride of each individual unit is found as follows: Unit 1=44.3%; Unit 2=47.3%; Unit 3=43.9%; Unit 4=46.3%; Unit 5=37.3%; Unit 6=38.8%. Release of Fexofenadine Hydrochloride of all 06 units are found less than 65% of claim i.e. (Q+5%). Where Q is 60% of claim.	Each unit is not less than Q+5% i.e., 65% of claim where Q is 60%.
8	Level S2 (6 units)	Does not comply. Release of Fexofenadine Hydrochloride of each individual unit is found as follows: Unit 1=49.7%; Unit 2=47.6%; Unit 3=51.7%; Unit 4=43.4%; Unit 5=53.1%; Unit 6=48.7%. Average release of Fexofenadine Hydrochloride of 12 units (S1+S2) is 45.9% of claim which is less than Q i.e. 60% of claim. Release of 05 units are found less than (Q-15%) i.e. 45% of claim.	Average of 12 units (S1+S2) \geq 60% of claim and no unit is less than 45% of claim (Q-15%)
9	Level S3 (12 units)	Does not comply. Release of Fexofenadine Hydrochloride of each individual unit is found as follows: Unit 1=53.1%; Unit 2=48.6%; Unit 3=41.5%; Unit 4=43.8%; Unit 5=43.4%; Unit 6=49.6%; Unit 7=48.8%; Unit 8=43.4%; Unit 9=53.0%; Unit 10=41.5%; Unit 11=49.6%; Unit 12=43.4%. Average release of Fexofenadine Hydrochloride of 24 units (S1+S2+S3) is 46.2% of claim which is less than Q i.e. 60% of claim. Out of 24 units release of 11 units are found less than (Q-15%) i.e. 45% of claim.	Average of 24 units (S1+S2+S3) \geq 60% of claim, not more than 2 units are less than 45% of claim (Q-15%) and no unit is less than 35% of claim (Q-25%)
10	Dissolution (30 Minutes)	Does not comply.	NLT 80% of claim
11	Level S1 (6 units)	Does not comply. Release of Fexofenadine Hydrochloride of each individual unit is found as follows: Unit 1=64.0%; Unit 2=65.6%; Unit 3=64.1%; Unit 4=65.7%; Unit 5=62.2%; Unit 6=62.8%. Release of Fexofenadine Hydrochloride of all 06 units are found less than 85% of claim i.e. (Q+5%). Where Q is 80% of claim.	Each unit is not less than Q+5% i.e., 85% of claim, where Q is 80%.
12	Level S2 (6 units)	Does not comply. Release of Fexofenadine Hydrochloride of each individual unit is found as follows: Unit 1=59.7%; Unit 2=62.8%; Unit 3=62.2%; Unit 4=63.9%; Unit 5=66.9%; Unit 6=62.0%. Average release of Fexofenadine Hydrochloride of 12 units (S1+S2) is 63.5% of claim which is less than Q i.e. 80% of claim. Release of 09 units found less than (Q-15%) i.e. 65% of claim.	Average of 12 units (S1+S2) \geq 80% of claim and no unit is less than 65% of claim (Q-15%)
13	Level S3 (12 units)	Does not comply. Release of Fexofenadine Hydrochloride of each individual unit is found as follows: Unit 1=62.9%; Unit 2=61.7%; Unit 3=59.7%; Unit 4=64.9%; Unit 5=66.9%; Unit 6=63.8%; Unit 7=63.3%; Unit 8=62.9%; Unit 9=63.3%; Unit 10=62.9%; Unit 11=63.8%; Unit 12=64.9%. Average release of Fexofenadine Hydrochloride of 24 units (S1+S2+S3) is 63.5% of claim which is less than Q i.e. 80% of claim. Out of 24 units release of 20 units are found less than (Q-15%) i.e. 65% of claim.	Average of 24 units (S1+S2+S3) \geq 80% of claim, not more than 2 units are less than 65% of claim (Q-15%) and no unit is less than 55% of claim (Q-25%)

Assay

Sr.No	Ingredient Name	Found	Claim	% of claim	Limits	Procedure / Method

1	Fexofenadine Hydrochloride	115.8 mg/Tablet	120 mg/Tablet	96.5	95 % to 105 %	I.P. 2022
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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 comply as per I.P. 2022 with respect to the test for "Dissolution" of Fexofenadine Hydrochloride.

Date: 10-JAN-2025

Rinku Kalita
GOVERNMENT ANALYST
Rinku Kalita
Government Analyst
R.D.T.L., Guwahati-22

Report in red color paper indicates the sample is not of standard quality.

----- END OF REPORT -----