



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 : TIMOTHY THANCHUNGUNGA,
Assistant Director (F & D),
CMO West Office,
Kulikawn, Aizawl- 796005
2. Serial No. and date of Inspector's memorandum : B.11012/5/2024-CMO(W)/DRUGS/44
Dated Aizawl, the 21st January, 2025
3. Number of Sample : SMP/MZ/TMT/2024-2025/039
4. Date of receipt : 03-FEB-2025
5. Names of drugs purporting to be contained in the sample: Cinnarizine & Dimenhydrinate Mouth Dissolving Tablets
(Hizanex PLUS)

Lab. Sample No.	Report No.	Batch No.	Date of Mfg. & Exp	Marketed By	Mfg. By
LSD/GUW/2025-26/0168	GUW/LS/2025-26/175	GENT9560D	09/2024 08/2026	NA	GENTECH HEALTHCARE PVT.LTD. 1470,HSIIDC,RAI- 131029, (INDIA)

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 01-May-2025 To 05-May-2025

COMPOSITION : Each uncoated mouth dissolving tablet contains:

Cinnarizine I.P. 20 mg.
Dimenhydrinate B.P. 40 mg.

Protocol Applied : Manufacturer's Specification

Sr No.	Test Name	Result	Limits
1	Description	Light orange colour, round, bi-convex, uncoated mouth dissolving tablet, plain on both sides, packed in aluminium foil strip.	NA
2	Identification	Gives positive test for Cinnarizine & Dimenhydrinate.	NA
3	Average weight	0.1313 gm.	NA
4	Uniformity of weight	Passes the test.	± 7.5%
5	Disintegration	Passes the test (All six units disintegrated within 1minute 26 seconds.)	NMT 3 minutes

Assay

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

1	Cinnarizine	18.97 mg/Tablet	20 mg/Tablet	94.85	90 % to 110 %	Manufacturer's Specification
2	Dimenhydrinate	36.07 mg/Tablet	40 mg/Tablet	90.175	90 % to 110 %	

In the opinion of the under signed the sample referred to above **is of standard quality** as defined in the Drugs and Cosmetics Act, 1940, and Rules thereunder for the reasons given below:-

The sample conforms to Manufacturer's specification with respect to the above tests only.

Date: 07-MAY-2025

GOVERNMENT ANALYST

Dilip Kr. Sarkar
Government Analyst
R.D.T.L., Guwahati-22

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

