



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 : Lalruatadika Varte, Drugs Inspector
Office of the Chief Medical Officer
Kolasib, Mizoram- 796082
- Serial No. and date of Inspector's memorandum : 001/IPA-KLB/III-25, 02-JUN-2025
- Number of Sample : NIL
- Date of receipt : 26-JUN-2025
- Names of drugs purporting to be contained in the sample : Dexlansoprazole (Modified Release) Capsules (60 mg)

Lab. Sample No.	Report No.	Batch No.	Date of Mfg. & Exp	Marketed By	Mfg. By
LSD/GUW/2025-26/0868	GUW/LS/2025-26/862	24S1GCA010	Jan-2024 Dec-2025	NA	SYNOKEM PHARMACEUTICALS LTD, Plot No.: 56-57, Sector-6A, I.I.E (SIDCUL), Ranipur (BHEL), Haridwar-249403 (Uttarakhand)

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 03-Oct-2025 To 16-Oct-2025

COMPOSITION : Each HPMC Capsule contains:
Dexlansoprazole IP 60 mg
(As Modified Release Pellets)

Protocol Applied : Manufacturer Specification

Sr No.	Test Name	Result	Limits
1	Description	White and blue colored pellets filled in hard gelatin capsules, in blister pack.	NA
2	Identification	Gives positive test for Dexlansoprazole.	NA
3	Filled Content	0.2595 g	NA
4	Uniformity of weight	Complies.	+ - 10 % of Average weight
5	Dissolution (Acid Stage)	Complies.	NMT 10 % of claim

6	Dissolution (Buffer Stage)	Complies.	NLT 75 % of claim
7	Disintegration	Complies. (Time taken for disintegration 08 minutes 30 seconds)	NMT 30 minutes

Assay

Sr.No	Ingredient Name	Found	Claim	% of claim	Limits	Procedure / Method
1	Dexlansoprazole	56.87 mg/Capsule	60 mg/Capsule	94.783	90 % to 110 %	Manufacturer Specification

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

The sample conform to claim as per Manufacturer Specification in respect of test performed.

Date: 07-NOV-2025

GOVERNMENT ANALYST

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

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