



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 : B.LALZAMLIANA, Drugs Inspector (F and D)  
CMO West Office  
Kulikawn, Aizawl- 796005
- Serial No. and date of Inspector's memorandum : B.11012/5/2024-CMO (W)/DRUGS/54 , 25-FEB-2025
- Number of Sample : SMP/MZ/TMT/2024-2025/049
- Date of receipt : 06-MAR-2025
- Names of drugs purporting to be contained in the sample : Pantoprazole Gastro- resistant and Domperidone  
Prolonged-release Capsules IP (40mg+30mg)  
(Actodom-DSR Capsules)

| Lab. Sample No.      | Report No.         | Batch No. | Date of Mfg. & Exp   | Marketed By | Mfg. By                                                                                                                                                                                      |
|----------------------|--------------------|-----------|----------------------|-------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| LSD/GUW/2025-26/0748 | GUW/LS/2025-26/751 | PB32AE04  | Jun-2024<br>May-2026 | NA          | M/s. Pure & Cure Healthcare Pvt. Ltd., (A subsidiary of Akums Drugs & Pharmaceuticals Ltd.) Plot No. 26A, 27-30, Sector-8A , I.I. E., SIDCUL, Ranipur, Haridwar-249 403, Uttarakhand, India. |

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 18-Mar-2025 To 27-Jun-2025

COMPOSITION : Each hard gelatin capsule contains:  
Pantoprazole Sodium IP  
Eq. to Pantoprazole 40 mg  
(as gastro-resistant pellets)  
Domperidone IP 30 mg  
(as prolonged-release pellets)

**Protocol Applied : Manufacturer Specification**

| Sr No. | Test Name              | Result                                                                                                    | Limits |
|--------|------------------------|-----------------------------------------------------------------------------------------------------------|--------|
| 1      | Description            | Orange and blue colored pellets filled in white and blue colored hard gelatin capsules, in alu-alu strip. | NA     |
| 2      | Identification         | Gives positive test for Pantoprazole sodium and Domperidone.                                              | NA     |
| 3      | Average filled content | 0.2743 g                                                                                                  | NA     |
| 4      | Dissolution            | Complies.                                                                                                 | NA     |

|    |                                             |           |                     |
|----|---------------------------------------------|-----------|---------------------|
| 5  | Dissolution For Pantoprazole (Acid Stage)   | Complies. | NMT 10 % of claim   |
| 6  | Dissolution For Pantoprazole (Buffer Stage) | Complies. | NLT 70 % of claim   |
| 7  | Dissolution For Domperidone (1st Hour)      | Complies. | 15 to 40 % of claim |
| 8  | Dissolution For Domperidone (4th Hour)      | Complies. | 30 to 60 % of claim |
| 9  | Dissolution For Domperidone (8th Hour)      | Complies. | 55 to 85 % of claim |
| 10 | Dissolution For Domperidone (12th Hour)     | Complies. | NLT 70 % of claim   |

### Assay

| Sr.No | Ingredient Name                         | Found           | Claim         | % of claim | Limits        | Procedure / Method         |
|-------|-----------------------------------------|-----------------|---------------|------------|---------------|----------------------------|
| 1     | Pantoprazole Sodium eq. to Pantoprazole | 40.2 mg/Capsule | 40 mg/Capsule | 100.5      | 90 % to 110 % | Manufacturer Specification |
| 2     | Domperidone                             | 32.4 mg/Capsule | 30 mg/Capsule | 108        | 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-OCT-2025

GOVERNMENT ANALYST

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

END OF REPORT

सत्यमेव जयते