

Regional Drugs Testing Laboratory Directorate General of Health Services, Guwahati (India) - 781022 Fax: 0361-2338555/2330555 Phone No.0361 2338555

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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

: Mrs. C. Ramdinmawii

Assistant Director (Food & Drugs) C.M.O. Office, Champhai-796321

Mizoram.

2. Serial No. and date of Inspector's memorandum

: 376/24

Date: 04/10/2024

3. Number of Sample

: Nil

4. Date of receipt

: 23-OCT-2024

5. Names of drugs purporting to be contained in the sample : Cyproheptadine HCl Syrup I.P. (Hungree);200ml

Lab. Sample No.	Report No.	Batch No.	Date of Mfg.	Date of Exp.	Mfg. By
LSD/GUW/2024- 25/1272	GUW/LS/2024- 25/1298	OHNL-018	02/2024	01/2026	LABORATE PHARMACEUTICALS INDIA LTD. (Unit- II)
Kiral State of the					#31,Rajban Road, Nariwala,
			1000000	7	Paonta Sahib (H.P.)

6. Condition of seals on

[the packet or on portion of sample or container]

Seals were intact & identical to the 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 07-Nov-2024 To 20-Nov-2024

COMPOSITION

Each 5 ml contains:

Cyproheptadine HCI

IP

eq. to anhydrous

Cyproheptadine HCI

2 mg

Protocol Applied: I.P. 2022

Sr No.	Test Name	Result			
1 Description		Yellow colour liquid in yellow colour transparent plastic bottle in paper box.			
2	Identification	Gives positive test for Cyproheptadine Hydrochloride.	NA		
3	Weight per ml	1.1497 g/ml.	NA		
4	pH	Complies (Found: 4.15).	3.5 to 4.5.		

Assay

Sr.No	Ingredient Name	Found	Claim	% of claim	Limits	Procedure Method
7711	Cyproheptadine Hydrochloride	2.14 mg/5ml	2 mg/5ml	107	90 % to 110 %	I.P. 2022

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 conforms to I.P. with respect to the above tests only.

Note. : As per the sample label the Batch No of the sample is OHNL-018 whereas in the Form -18 it is stated as 0HNL-018.

Date: 28-NOV-2024

GOVERNMENT ANALYST

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

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