



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 : TIMOTHY THANCHUNGNUNGA, Assistant Director (F and D)
State FDA
Kulikawn, Aizawl- 796005
- Serial No. and date of Inspector's memorandum : B.11012/5/2024-CMO (W)/DRUGS/36 , 21-JAN-2025
- Number of Sample : SMP/MZ/TMT/2024-2025/031
- Date of receipt : 03-FEB-2025
- Names of drugs purporting to be contained in the sample : CO-TRIMOXAZOLE ORAL SUSPENSION IP (SEPTRAN PAEDIATRIC SUSPENSION 60 ml)

Lab. Sample No.	Report No.	Batch No.	Date of Mfg.	Date of Exp.	Mfg. By
LSD/GUW/2024-25/1736	GUW/LS/2024-25/1770	SH3862431	Sep-2024	Aug-2026	Sanpras Healthcare Pvt. Ltd., Plot No.81, STICE, Musalgaon, Sinnar, Dist. Nashik -422112. (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-Feb-2025 To 19-Feb-2025

COMPOSITION : Each 5 ml is purported to contain Trimethoprim IP 40 mg and Sulphamethoxazole IP 200 mg.

Protocol Applied : I.P. 2022

Sr No.	Test Name	Result	Limits
1	Description	Pink colored suspension filled in amber colored plastic bottles.	NA
2	Identification	Gives positive test for Trimethoprim and Sulphamethoxazole.	NA
3	Weight per ml	1.1329 g/ml	NA
4	pH	5.94	5. to 6.5 .

Assay

Sr.No	Ingredient Name	Found	Claim	% of claim	Limits	Procedure / Method
1	Trimethoprim	38.64 mg/5ml	40 mg/5ml	96.6	90 % to 110 %	I.P. 2022

2	Sulphamethoxazole	181.71 mg/5ml	200 mg/5ml	90.855	90 % to 110 %	I.P. 2022
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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 I.P. 2022 in respect of test performed.

Date: 24-FEB-2025

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

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