



# Andhra Organics Limited

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**METAPHARMACEUTICAL**

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0081225

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20/11/2025

## CERTIFICATE OF ANALYSIS

Product Name	: TRIMETHOPRIM EP	A.R. No.	: TMPFP250683
Dispatch Batch No.	: TMP25100678	Mfg. Date	: Oct'2025
In-house Batch No.	: TMP01250719	Retest/Exp. Date	: Sep'2030
Quantity	: 50Kg(02X25Kg)	Date of Analysis	: 03.11.2025
S.No.	Test(s)	Specification(s)	Result(s)
1.	Appearance	A White or yellowish white powder	A White powder
2.	Solubility	Very slightly soluble in water; slightly soluble in ethanol (96%) and Practically insoluble in heptane	Complies
3.	Identification by		
3.1	Infrared Absorption Spectrophotometry	The infrared absorption spectrum of sample is concordant with the spectrum of <i>Trimethoprim CRS</i>	Complies
3.2	Melting Point	199°C to 203°C	202.1°C
4.	Appearance of solution	The solution is not more intensively coloured than reference solution BY <sub>7</sub>	Complies
5.	Loss on drying	Not more than 1.0%	0.74% w/w
6.	Sulfated ash	Not more than 0.1%	0.04% w/w
7.	Assay by potentiometry (On dried basis)	99.0% and 101.0%	100.2% w/w
8.	Related substances by UHPLC		
	Impurity-A	Not more than 0.10%	BRT
	Impurity-B	Not more than 0.10%	BRT
	Impurity-C	Not more than 0.10%	BRT
	Impurity-D	Not more than 0.10%	BRT
	Impurity-E	Not more than 0.10%	BRT
	Impurity-F	Not more than 0.10%	BRT
	Impurity-G	Not more than 0.10%	BRT
	Impurity-H	Not more than 0.10%	BRT
	Impurity-I (Sum of E+Z isomers)	Not more than 0.10%	BRT
	Impurity-J	Not more than 0.10%	BRT
	Impurity-L	Not more than 0.10%	BRT
	Unspecified impurity	Not more than 0.10%	BRT
	Total impurities	Not more than 0.2%	BRT
9.	Impurity-K by GC	Not more than 5 ppm	2.1ppm

Remarks: This product complies as per the above Specification No. FP/SP/TMP/004.

Note: All impurities LOD & LOQ Values are Below Reporting Threshold (0.05%).

Prepared by:

Date: 14/11/25

Checked by:

Date: 14/11/25

Approved by:

Date: 14/11/25

QC086-F02-01