



Andhra Organics Limited

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Phone: +91-40-4444 5600, Fax: +91-40-23096677, Email: info@andhraorganics.com

CERTIFICATE OF ANALYSIS

Product Name	: TRIMETHOPRIM USP (Micronized)	A.R. No.	: TMPMFP250066
Dispatch Batch No.	: TMPM25070066	Mfg. Date	: Jul'2025
In-house Batch No.	: TMPM01250066	Retest/Exp. Date	: Jun'2030
Quantity	: 1000Kg(40X25Kg)	Date of Analysis	: 01.08.2025
S.No.	Test(s)	Specification(s)	Result(s)
1.0	Description	A White to cream colored, odorless crystals or crystalline powder.	A White, odorless crystalline powder.
2.0	Solubility	Soluble in benzyl alcohol, sparingly soluble in chloroform and methanol. Slightly soluble in alcohol and acetone. Very slightly soluble in water. Practically insoluble in ether and in carbon tetrachloride.	Complies
3.0	Identification		
3.1	Infrared Absorption spectrophotometry	The infrared absorption spectrum of sample should concordant with the spectrum of Trimethoprim RS	Complies
3.2	Ultraviolet Visible spectrophotometry	Calculate absorptivities, on the dried basis for the test sample only, at the wave length of maximum absorbance at about 287 nm do not differ by more than 3.0%.	1.01%
4.0	Melting range	Between 199°C and 203°C	200.5°C - 201.7°C
5.0	Loss on drying	Not more than 0.5% w/w	0.22% w/w
6.0	Residue on ignition	Not more than 0.1% w/w	0.03% w/w
7.0	Related substance 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 0.06%	BRT
	Total impurities	Not more than 0.2% w/w	BRT
8.0	Assay by potentiometry (On dried basis)	Not less than 98.5% and Not more than 101.0 % w/w	99.7% w/w
Additional Test:			
1.0	Particle size by Malvern dry powder method		
	Dv(10)	Less than 5µm	1.9µm
	Dv(50)	Less than 10µm	6.4µm
	Dv(90)	Less than 30µm	15.8µm

Remarks: This product complies as per the above Specification No. FP/SP/TMP/003.

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

Prepared by:

Date: 21/08/25

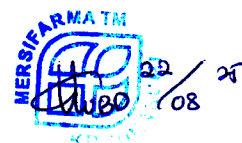
QC086-F02-01

Checked by:

Date: 21/08/25

Approved by:

Date: 21/08/25



Factory: Plot No. 110A, I.D.A, Pydibhimavaram (V), Ranasthalam (M), Srikakulam District -532 409, Andhra Pradesh, India. Phone: +91-8942-288225, Fax: +91-8942-288151, Email: factory@andhraorganics.com



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CERTIFICATE OF ANALYSIS

Product Name	: TRIMETHOPRIM USP (Micronized)	A.R. No.	: TMPMFP250065
Dispatch Batch No.	: TPM25070065	Mfg. Date	: Jul'2025
In-house Batch No.	: TPM01250065	Retest/Exp. Date	: Jun'2030
Quantity	: 1000Kg(40X25Kg)	Date of Analysis	: 01.08.2025

S.No.	Test(s)	Specification(s)	Result(s)
1.0	Description	A White to cream colored, odorless crystals or crystalline powder.	A White, odorless crystalline powder.
2.0	Solubility	Soluble in benzyl alcohol, sparingly soluble in chloroform and methanol. Slightly soluble in alcohol and acetone. Very slightly soluble in water. Practically insoluble in ether and in carbon tetrachloride.	Complies
3.0	Identification		
3.1	Infrared Absorption spectrophotometry	The infrared absorption spectrum of sample should concordant with the spectrum of Trimethoprim RS	Complies
3.2	Ultraviolet Visible spectrophotometry	Calculate absorptivities, on the dried basis for the test sample only, at the wave length of maximum absorbance at about 287 nm do not differ by more than 3.0%.	1.01%
4.0	Melting range	Between 199°C and 203°C	200.2°C - 201.3°C
5.0	Loss on drying	Not more than 0.5% w/w	0.20% w/w
6.0	Residue on ignition	Not more than 0.1% w/w	0.04% w/w
7.0	Related substance 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 0.06%	BRT
	Total impurities	Not more than 0.2% w/w	BRT
8.0	Assay by potentiometry (On dried basis)	Not less than 98.5% and Not more than 101.0 % w/w	99.7% w/w
Additional Test:			
1.0	Particle size by Malvern dry powder method		
	Dv(10)	Less than 5µm	1.6µm
	Dv(50)	Less than 10µm	5.2µm
	Dv(90)	Less than 30µm	14.2µm

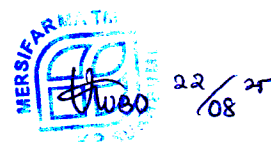
Remarks: This product complies as per the above Specification No. FP/SP/TMP/003.

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

Prepared by:
Date: 21/08/25
QC086-F02-01

Checked by:
Date: 21/08/25

Approved by:
Date: 21/08/25



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CERTIFICATE OF ANALYSIS

Product Name	: TRIMETHOPRIM USP (Micronized)	A.R. No.	: TMPMFP250063
Dispatch Batch No.	: TMPM25070063	Mfg. Date	: Apr'2025
In-house Batch No.	: TMPM01250063	Retest/Exp Date	: Mar'2030
Quantity	: 1000Kg(40X25Kg)	Date of Analysis	: 23.07.2025

S.No.	Test(s)	Specification(s)	Result(s)
1.0	Description	A White to cream colored, odorless crystals or crystalline powder.	A White, odorless crystalline powder.
2.0	Solubility	Soluble in benzyl alcohol, sparingly soluble in chloroform and methanol. Slightly soluble in alcohol and acetone. Very slightly soluble in water. Practically insoluble in ether and in carbon tetrachloride.	Complies
3.0	Identification		
3.1	Infrared Absorption spectrophotometry	The infrared absorption spectrum of sample should concordant with the spectrum of Trimethoprim RS	Complies
3.2	Ultraviolet Visible spectrophotometry	Calculate absorptivities, on the dried basis for the test sample only, at the wave length of maximum absorbance at about 287 nm do not differ by more than 3.0%.	1.04%
4.0	Melting range	Between 199°C and 203°C	200.4°C - 201.9°C
5.0	Loss on drying	Not more than 0.5% w/w	0.18% w/w
6.0	Residue on ignition	Not more than 0.1% w/w	0.03% w/w
7.0	Related substance 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 0.06%	BRT
	Total impurities	Not more than 0.2% w/w	BRT
8.0	Assay by potentiometry (On dried basis)	Not less than 98.5% and Not more than 101.0 % w/w	100.1% w/w
Additional Test:			
1.0	Particle size by Malvern dry powder method		
	Dv(10)	Less than 5µm	2.4µm
	Dv(50)	Less than 10µm	7.9µm
	Dv(90)	Less than 30µm	17.7µm

Remarks: This product complies as per the above Specification No. FP/SP/TMP/003.

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

Prepared by: *Sunitha*
Date: 21/08/25
QC086-F02-01

Checked by: *21/08/25*
Date:

Approved by: *21/08/25*
Date:



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