

CERTIFICATE OF ANALYSIS

Product :	Sulfamethoxazole Ph.Eur	A.R.No. :	SMX/0870/21
Batch No. :	08700421	In-House Batch No. :	Apr/SMX/077
Date of Mfg :	Apr 2021	Sampled by :	P.Bhagavan Reddy
Retest Date :	Mar 2026	Date of Analysis :	12.04.2021
Batch Quantity :	40 x 25 Kg = 1000Kg		

S.No.	TESTS	OBSERVATIONS	SPECIFICATIONS
01	Appearance	White crystalline powder	A White or almost white Crystalline Powder
02	Solubility	Complies	As per Ph.Eur
03	Identification a) Melting Point b) IR c) TLC d) Chemical Test	170°C Positive Complies Complies	169°C – 172°C The infrared absorption spectrum of sample is concordant with the spectrum of Sulfamethoxazole CRS As per Ph.Eur Should give the positive reactions of primary aromatic amines
04	Appearance of Solution a) Clarity of Solution b) Colour of Solution	1.0 NTU Complies	Not more than 3.0 NTU Not more intensely coloured than Reference solutions Y ₅ , BY ₅ or GY ₅
05	Acidity	0.18 ml	Not more than 0.30 ml of 0.1M sodium hydroxide solution
06	Related substances by HPLC a) Impurity A (Acetyl SMX) b) Impurity B (Sulfanilyl SMX) c) Impurity C (Isosamine) d) Impurity D (Sulfanilic Acid) e) Impurity E (Sulfanilamide) f) Impurity F (Isomeric SMX) g) Any other impurity 1) Unknown Impurity – I 2) Unknown Impurity – II h) Total Impurity	Below Disregard Limit* 0.044% Below Disregard Limit* Below Disregard Limit* Below Disregard Limit* 0.029% 0.045% Below Disregard Limit* 0.118%	Not more than 0.100% Not more than 0.100% Not more than 0.100% Not more than 0.100% Not more than 0.100% Not more than 0.100% Not more than 0.100% Not more than 0.100% Not more than 0.300%
07	Loss on Drying	0.29% w/w	Maximum 0.50% w/w
08	Sulphated ash	0.05% w/w	Maximum 0.10% w/w
09	Assay	100.5% w/w	Not less than 99.0 % and not more than 101.0 %, calculated with reference to the dried substance
10	Additional tests: i) Sieve test ii) Bulk Density iii) Related substances by TLC	99.8% < 90 microns ----- Less than 0.5%	----- ----- Not more than 0.5% each, (As Per Ph.Eur.4)

* Below Disregard limit = 0.025%

Remarks : The Sample Complies as per Ph.Eur10 specification No. FP/SP/009.

Date of Release : 12.04.2021

Analysed by: *Dr. 12/04/21*
(Chemist)Checked by: *12/04/21*
(Sr.Chemist)Approved by: *12/04/21*
(Sr.Q.C.Manager)

We, Virchow Laboratories Limited, as a manufacturer of Sulfamethoxazole here by certify that this batch has been produced by us as per the manufacturing process described in Certificate of Suitability No. R1-CEP 1999-172- Rev 02 and in full compliance with the GMP requirements of the local regulatory authority: Drug Control Administration, Government of Telangana State. GMP certificate No.8266/E1/2018, valid till Feb-2022, has been issued by the Drugs Control Administration after inspection as per WHO guidelines.

Q.A.Manager: *12/04/21*

Factory Regd. Off. : Plot No. 4 to 10, S.V. Co-op. Industrial Estate, IDA, Jeedimetla, Hyderabad-500 055, India.

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