



VIRCHOW LABORATORIES LIMITED

4100
4101ISO-14001
ISO-9001

FP/MA/009/1

CERTIFICATE OF ANALYSIS

Product : Sulfamethoxazole Ph. Eur
Batch No. : 24140818
Date of Mfg. : Aug 2018
Retest Date. : Jul 2023
Batch Quantity : 40 x 25 Kg = 1000 Kg

A.R. No. : SMX/2414/18
In-House B.No. : Aug/SMX/148
Sampled by : K.J.Ravisankar
Date of Analysis : 15.08.2018

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	171°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 reaction of primary aromatic amines
04	Appearance of Solution a) Clarity of Solution b) Colour of Solution	1.1 NTU Complies	Not more than 3.0 NTU Not more intensely coloured than Reference solutions Y _s , BY _s or GY _s
05	Acidity	0.17 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(Isoxamine) 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* 0.034% Below Disregard Limit* Below Disregard Limit* Below Disregard Limit* 0.032% 0.029% Below Disregard Limit* 0.095%	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	Heavy metals	Less than 20 ppm	Maximum 20 ppm
08	Loss on Drying	0.34% w/w	Maximum 0.50% w/w
09	Sulphated ash	0.04% w/w	Maximum 0.10% w/w
10	Assay	100.4% w/w	Not less than 99.0 % and not more than 101.0 %, calculated with reference to the dried substance
11	Additional tests: a) Sieve test b) Bulk Density c) Related substances by TLC	99.9% < 90microns ----- 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. Eur. 9 specification No. FP/SP/009.

Date of Release : 16.08.2018

Analysed by :
(Chemist) 16/08/18Checked by :
(Sr.Chemist) 16/08/18Approved by :
(Asst.Q.C.Manager) 16/08/18

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 01 and in full compliance with the GMP requirements of the local regulatory authority: Drug Control Administration, Government of Telangana State. GMP certificate No. I1340/E(J)/TS/2016, valid till Jan-2019, has been issued by the Drugs Control Administration after inspection as per WHO guidelines.

Q.A.Manager: 16/08/18

Factory Regd. Off. : Plot No. 4 to 10, S.V. Co-op. Industrial Estate, IDA, Joodimetta, Hyderabad-500 055, India
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Drug Licence No. 57/H/D/AP/906/B/R, TIN / CST : 36760278559, CIN No. : U14232TG1982PL0003303

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