VIRCHOW LABORATORIES LIMITED

4100 4101 ASR ISO-14001 ISO-9001
American Systems REGISTRAR

FP/MA/009/1

CERTIFICATE OF ANALYSIS

Product	: Sulfamethoxazole Ph. Eur	A.R. No.	: SMX/0252/20
Batch No.	: **02520120**	In-House B.No.	: Jan/SMX/242
Date of Mfg.	: Jan 2020	Sampled by	: K.J.Ravisankar
Retest Date.	: Dec 2024	Date of Analysis	: 31.01.2020
Batch Quantity	: 40 x 25 Kg = 1000 Kg		

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_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(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* 0.046% Below Disregard Limit* Below Disregard Limit* Below Disregard Limit* Below Disregard Limit* 0.026% Below Disregard Limit* 0.072%	 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	0.04% w/w	Maximum 0.10% w/w
09	Assay	100.1% w/w	Not less than 99.0 % and not more than 101.0 %, calculated with reference to the dried substance
10	Additional tests: a) Sieve test b) Bulk Density c) Related substances by TLC	 98.9% < 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 : 01.02.2020

Analysed by : (Chemist) 01/02/20

Checked by: (Sr.Chemist) 02/02/20

Approved by: (Asst.Q.C.Manager) 03/02/20

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 03/02/20

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Drug Licence No. 57/HD/AP/96/B/R, TIN / CST : 36760278559, CIN No. : U24232TG1982PLC003368.