VIRCHOW

VIRCHOW LABORATORIES LIMITED

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

FP/MA/009/1

CERTIFICATE OF ANALYSIS

Product	:	Sulfamethoxazole Ph.Eur	A.R.No.	:	SMX/1265/20
Batch No.	:	12650620	In-House Batch No.	:	Jun/SMX/026
Date of Mfg	:	Jun 2020	Sampled by	:	N.V.V.Satyanarayana
Retest Date	:	May 2025	Date of Analysis	:	04.06.2020
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	171°C	169°C – 172°C
	b) IR	Positive	The infrared absorption spectrum of sample is concordant with the spectrum of Sulfamethoxazole CRS
	c) TLC	Complies	As per Ph.Eur
	d) Chemical Test	Complies	Should give the positive reactions of primary aromatic amines
04	Appearance of Solution		
	a) Clarity of Solution	1.1 NTU	Not more than 3.0 NTU
	b) Colour of Solution	Complies	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)	Below Disregard Limit*	Not more than 0.100%
	b) Impurity B (Sulfanilyl SMX)	0.034%	Not more than 0.100%
	c) Impurity C (Isoxamine)	Below Disregard Limit*	Not more than 0.100%
	d) Impurity D (Sulfanilic Acid)	Below Disregard Limit*	Not more than 0.100%
	e) Impurity E (Sulfanilamide)	Below Disregard Limit*	Not more than 0.100%
	f) Impurity F (Isomeric SMX)	Below Disregard Limit*	Not more than 0.100%
	g) Any other impurity		
	1) Unknown Impurity – I	0.028%	Not more than 0.100%
	2) Unknown Impurity – II	0.029%	Not more than 0.100%
	h) Total Impurity	0.091%	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	100.6% 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	99.7%<90 microns	--------
	ii) Bulk Density	--------	--------
	iii) Related substances by TLC	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.Eur9 specification No. FP/SP/009.

Date of Release : 05.06.2020

Analysed by : (Chemist) 05/06/20 Checked by: (Asst.Q.C.Manager) 05/06/20 Approved by: (Sr.Q.C.Manager) 05/06/20

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.8256/E1/2018, valid till Feb-2022, has been issued by the Drug Control Administration after inspection as per WHO guidelines.

CANARA BANK
- 0239 -
PRIME CORPORATE BRANCH
SECUNDERABAD-500 003

Q.A.Manager: 05/06/20

Factory Regd. Off.: Plot No. 4 to 10, S.V. Co-op. Industrial Estate, IDA. Jeedimetla, Hyderabad-500 055, India.
Phones : +91-40- 44445678, 44445600, 23096688, 23098206, Fax : +91-40- 23096677, 23098205.
E-mail : hyd1_virchow@sancharnet.in, http://www.virchows.com
Drug Licence No. 57/HD/AP/96/B/R, GSTIN : 36AAACV7245F1ZB, CIN No.: U24232TG1982PLC003368.