



VIRCHOW LABORATORIES LIMITED

REVIEWED
Triana N.S. : 31/07/2024, 09:58:31

FP/MA/009/1

CERTIFICATE OF ANALYSIS

Product : Sulphamethoxazole BP 2018(Micronized) A.R.No. : SMX/1174/24
Batch No. : 11740724 In-House Batch No. : Jul/SMX/048
Date of Mfg : Jul 2024 Sampled by : M.Balakrishna
Date of Expiry : Jun 2029 Date of Analysis : 09.07.2024
Batch Quantity : 40 x 25 Kg = 1000Kg L/C No. : 014ITSY124132
Date : 240604

S.No.	TESTS	OBSERVATIONS	SPECIFICATIONS
01	Appearance	White crystalline powder	A White or almost white Crystalline Powder
02	Solubility	Complies	As per BP 2018
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 Sulphamethoxazole CRS As per BP 2018 Should give the positive reactions of primary aromatic amines
04	Appearance of Solution a) Clarity of Solution b) Colour of Solution	1.2 NTU Complies	Not more than 3.0 NTU Not more intensely coloured than Reference solutions Y _s , BY _s or GY _s
05	Acidity	0.19 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* 0.043% Below Disregard Limit* Below Disregard Limit* Below Disregard Limit* 0.033% 0.040% Below Disregard Limit* 0.116%	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	0.25% 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: a) Particle size (by Malvern Laser Diffraction Dry Powder Method) b) Bulk Density c) Related substances by TLC	100% : 29 microns Less than 0.5%	100% < 40 microns Not more than 0.5% each, (As Per Ph.Eur.4)

* Below Disregard limit = 0.025%

Remarks : The Sample Complies as per BP 2018 specification No. FP/SP/009.

Date of Release : 10.07.2024

Analysed by : *JS*
10/07/24

Checked by : *BS*
10/07/24

Approved by : *AB*
10/07/24

STANDARISASI CERTIFICATE OF ANALYSIS API PRODUK

No	Nama Bahan	Manufaktur	Referensi pada CoA Manufaktur saat ini	Referensi pada CoA yang diusulkan	Penyesuaian Parameter			Nomor SPBB	Keterangan
					Parameter yang Dihilangkan	Parameter yang Ditambah	Parameter yang direvisi		
1	Sulfamethoxazole	Virchow Laboratories Limited	BP 2018	USP47/ FI VI	Identifikasi KLT dan Kimia	Selenium : ≤ 30 ppm (sesuai FI VI)	Pemerian disesuaikan dengan USP 47	RD 02-SBA/142.02	Penyesuaian CoA dari Manufaktur
					Acidity		Kelarutan disesuaikan dengan USP 47		
					Kejernihan dan warna larutan		Jarak lebur : 168 - 172		
					-		Cemaran KLT : 0.2 %		
					-	Cemaran organik disesuaikan dengan USP	Identifikasi disesuaikan dengan USP 47 (HPLC)		Update SPBB dan Penyesuaian CoA dari Manufaktur
					-				
					-				
						Cemaran organik disesuaikan dengan USP			Update SPBB
						Particle Size			
						Bulk dan tap density			

Diperiksa Oleh

Disetujui Oleh,

Koordinator QC

alhan 23/10

Koordinator IS

Wahid 10/23/24

Koordinator QA

M. C. 08/10/24

Manager QA

[Signature]