

# VIRCHOW LABORATORIES LIMITED

4100  
4101



ISO-14001  
ISO-9001

FP/MA/009/1

## CERTIFICATE OF ANALYSIS

Product : Sulfamethoxazole Ph.Eur  
Batch No. : 12650620  
Date of Mfg : Jun 2020  
Re-test Date : May 2025  
Batch Quantity : 40 x 25 Kg = 1000Kg

A.R.No. : SMX/1265/20  
In-House Batch No. : Jun/SMX/026  
Sampled by : N.V.V. Satyanarayana  
Date of Analysis : 04.06.2020

| 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<br>a) Melting Point<br>b) IR<br><br>c) TLC<br>d) Chemical Test                                                                                                                                                                                                                                                              | 171°C<br>Positive<br><br>Complies<br>Complies                                                                                                                                                    | 169°C - 172°C<br>The infrared absorption spectrum of sample is concordant with the spectrum of Sulfamethoxazole CRS<br><br>As per Ph.Eur<br>Should give the positive reactions of primary aromatic amines                                    |
| 04    | Appearance of Solution<br>a) Clarity of Solution<br>b) Colour of Solution                                                                                                                                                                                                                                                                  | 1.1 NTU<br>Complies                                                                                                                                                                              | Not more than 3.0 NTU<br>Not more intensely coloured than Reference solutions Y <sub>5</sub> , BY <sub>5</sub> or GY <sub>5</sub>                                                                                                            |
| 05    | Acidity                                                                                                                                                                                                                                                                                                                                    | 0.18 ml                                                                                                                                                                                          | Not more than 0.30 ml of 0.1M sodium hydroxide solution                                                                                                                                                                                      |
| 06    | Related substances by HPLC<br>a) Impurity A (Acetyl SMX)<br>b) Impurity B (Sulfanilic SMX)<br>c) Impurity C (Isosulfanilic SMX)<br>d) Impurity D (Sulfanilic Acid)<br>e) Impurity E (Sulfanilamide)<br>f) Impurity F (Isomeric SMX)<br>g) Any other impurity<br>1) Unknown Impurity -- I<br>2) Unknown Impurity -- II<br>h) Total Impurity | Below Disregard Limit*<br>0.034%<br>Below Disregard Limit*<br>Below Disregard Limit*<br>Below Disregard Limit*<br>Below Disregard Limit*<br>Below Disregard Limit*<br>0.028%<br>0.029%<br>0.091% | Not more than 0.100%<br>Not more than 0.100%<br>Not more than 0.100%<br>Not more than 0.100%<br>Not more than 0.100%<br>Not more than 0.100%<br>Not more than 0.100%<br>Not more than 0.100%<br>Not more than 0.100%<br>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:<br>i) Sieve test<br>ii) Bulk Density<br>iii) Related substances by TLC                                                                                                                                                                                                                                                   | 99.7% < 90 microns<br>-----<br>Less than 0.5%                                                                                                                                                    | -----<br>-----<br>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.

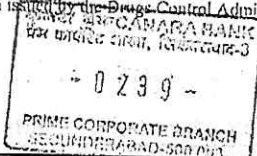
Date of Release : 05.06.2020

Analysed by : 05/06/20  
(Chemist)

Checked by : 05/06/20  
(Asst. Q.C. Manager)

Approved by : 05/06/20  
(Sr. Q.C. Manager)

We, Virchow Laboratories Limited, as a manufacturer of Sulfamethoxazole hereby 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. R256/E1/2018, valid till Feb-2022, has been issued by the Drug Control Administration after inspection as per WHO guidelines.



Q.A. Manager: 05/06/20

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