



# VIRCHOW LABORATORIES LIMITED

4100  
4101 ISO-14001  
ISO-9001  
ANALYSIS  
REGISTRAR

170046/0001

## CERTIFICATE OF ANALYSIS

|                                      |                                  |  |
|--------------------------------------|----------------------------------|--|
| Product : Sulfamethoxazole Ph. Eur   | A.R.No. : SMX0037021             |  |
| Batch No. : 03700423                 | In-House Batch No. : ApoSMX00577 |  |
| Date of Mfg : Apr 2021               | Sampled by : P.Bhagavan Reddy    |  |
| Expiry Date : Mar 2026               | Date of Analysis : 12.04.2021    |  |
| 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<br>a) Melting Point<br>b) IR<br><br>c) TLC<br>d) Chemical Test                                                                                                                                                                                                                                                           | 170°C<br>Positive<br><br>Complies<br>Complies                                                                                                                    | 164°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 amine                |
| 04    | Appearance of Solution<br>a) Clarity of Solution<br>b) Colour of Solution                                                                                                                                                                                                                                                               | 1.0 NTU<br>Complies                                                                                                                                              | Not more than 3.0 NTU<br>Not more intensely coloured than Reference solutions Y <sub>1</sub> , Y <sub>2</sub> , or GY <sub>2</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 (Sulfadiazyl SMX)<br>c) Impurity C (Isoniazide)<br>d) Impurity D (Sulfanilic Acid)<br>e) Impurity E (Sulfamethoxazole)<br>f) Impurity F (Isoniazide SMX)<br>g) Any other impurity<br>1) Unknown Impurity – I<br>2) Unknown Impurity – II<br>h) Total Impurity | Below Discard Limit*<br>0.043%<br>Below Discard Limit*<br>Below Discard Limit*<br>Below Discard Limit*<br>0.025%<br><br>0.043%<br>Below Discard Limit*<br>0.118% | 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><br>Not more than 0.100%<br>Not more than 0.100%<br>Not more than 0.100% |
| 07    | Loss on Drying                                                                                                                                                                                                                                                                                                                          | 0.35% w/w                                                                                                                                                        | Maximum 0.50% w/w                                                                                                                                                                                                        |
| 08    | Sulfated ash                                                                                                                                                                                                                                                                                                                            | 0.05% w/w                                                                                                                                                        | Maximum 0.10% w/w                                                                                                                                                                                                        |
| 09    | Assay                                                                                                                                                                                                                                                                                                                                   | 100.5% 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                                                                                                                                                                                                                                                | 99.8% < 90 microns<br>-----<br>Less than 0.5%                                                                                                                    | -----<br>-----<br>Not more than 0.5% each, (As Per Ph. Eur.4)                                                                                                                                                            |

\* Below Discard limit = 0.025%

Remarks: The Sample Complies as per Ph. Eur 10 specification No. SP03P003.  
Date of Release: 12.04.2021

Analyzed by: *P. B. Reddy*  
(Chemist)

Checked by: *P. B. Reddy*  
(Sr. Chemist)

Approved by: *P. B. Reddy*  
(Sr. Q.C. Manager)

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. RI-CEP 1993-173-Rev 02 and is in full compliance with the GMP requirements of the local regulatory authority: Drug Control Administration, Government of Telangana State. GMP certificate No. 8266/EL/2018, valid till Feb-2022, has been issued by the Drug Control Administration after inspection as per WHO guidelines.

Q.C. Manager: *P. B. Reddy*

Factory Regd. Off.: Plot No. 4 to 10, S.V. Co-op. Industrial Estate, IDA, Jeedimetla, Hyderabad-500 056, India.  
Phones: +91-40- 44445578, 44448800, 23090688, 23098206, Fax: +91-40- 23098677, 23098205.  
E-mail: [hyd1\\_virchow@sancharnet.in](mailto:hyd1_virchow@sancharnet.in), <http://www.virchow.com>  
Drug Licence No. 57HD/AP/96/S/R, OSTIN : 36AAACV7245F1ZB, CIN No. : U24232TG1982PLC003068.