

Certification of Substances Department

Certificate of suitability No. CEP 2024-522 - Rev 01

1 *Name of the substance:*

2 **SULFADIMETHOXINE**

3 *Details of holder:*

4 **ANUH PHARMA LIMITED**

5 3 A Shivsagar Estate North Wing

6 Dr Annie Besant Road

7 Worli

8 India-400 018 Mumbai, Maharashtra

9 SPOR ORG ID: 100021566

10 SPOR LOC ID: 100030259

11 After examination of the information provided on the production method and control strategy for the
12 substance, we certify that its quality is suitably controlled by the current version of the European
13 Pharmacopoeia monograph for **SULFADIMETHOXINE** No. 2741 and any supplementary tests
14 deemed necessary. The approved site(s) of production, specification and any supplementary test
15 procedure(s) are included on the following pages, which constitute an integral part of this certificate.

16 In the last steps of the process, purified water is used as solvent.

17 No elemental impurity classified in ICH Q3D is intentionally introduced in the production of the
18 substance.

19 The re-test period of the substance is 24 months if stored in double polyethylene bags, placed in
20 either a polyethylene or a fibre drum.

21 No material of human or animal origin is used in the production of the substance.

22 The holder of the certificate should fulfil the following conditions in order to maintain the validity of
23 this certificate.

24 The dossier submitted must be updated in accordance with EDQM guidance on the requirements
25 for revision of certificates of suitability.

26 Production of the substance shall take place in accordance with the dossier submitted and Good
27 Manufacturing Practice.

28 Necessary information from the submitted dossier shall be shared with authorised users in order
29 to enable them to evaluate the suitability of this substance for its intended use. This includes
30 informing them of any relevant change in the associated dossier.