

Certification of Substances Department

## Certificate of suitability No. CEP 2022-457 - Rev 01

1 *Name of the substance:*

2 **SULFADOXINE**

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 **SULFADOXINE** No. 740 and any supplementary tests deemed  
14 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 60 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.