

Certification of Substances Department

Certificate of suitability No. CEP 2021-143 - Rev 02

1 *Name of the substance:*

2 **AZITHROMYCIN**

3 *Details of holder:*

4 **ANUH PHARMA LTD.**

5 3-A, Shivsagar Estate, North Wing

6 Dr Annie Besant Road, Worli

7 India-400 018 Mumbai, Maharashtra

8 SPOR ORG ID: 100021566

9 SPOR LOC ID: 100030259

10 After examination of the information provided on the production method and control strategy for the
11 substance, we certify that its quality is suitably controlled by the current version of the European
12 Pharmacopoeia monograph for **AZITHROMYCIN** No. 1649 and any supplementary tests deemed
13 necessary. The approved site(s) of production, specification and any supplementary test
14 procedure(s) are included on the following pages, which constitute an integral part of this certificate.

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

16 The section miscellaneous information includes a risk management summary for elemental
17 impurities.

18 The re-test period of the substance is 60 months if stored in double polyethylene bags, placed in
19 a polyethylene drum.

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

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

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

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

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