

Certification of Substances Department

Certificate of suitability No. CEP 2007-235 - Rev 08

1 *Name of the substance:*

2 **ERYTHROMYCIN ETHYLSUCCINATE**

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 **ERYTHROMYCIN ETHYLSUCCINATE** No. 274 and any
13 supplementary tests deemed necessary which are mentioned below. The approved site(s) of
14 production and any supplementary test procedure(s) are included on the following pages as
15 annexes, which constitute an integral part of this certificate.

16 Any unspecified impurity detected by the test for related substances of the monograph is limited
17 to not more than 0.2%.

18 – Test for residual solvents by gas chromatography (Annex 2)
19 Acetone not more than 5000 ppm

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

21 The re-test period of the substance is 5 years if stored in a double polyethylene bag, placed in a
22 polyethylene drum.

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

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

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

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