

Certification of Substances Department

Certificate of suitability No. CEP 2018-033 - Rev 02

1 *Name of the substance:*

2 **AMBROXOL HYDROCHLORIDE**

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 **AMBROXOL HYDROCHLORIDE** No. 1489 and any supplementary
13 tests deemed necessary. The approved site(s) of production, specification and any supplementary
14 test procedure(s) are included on the following pages, which constitute an integral part of this
15 certificate.

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

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

19 The re-test period of the substance is 60 months if stored in double polyethylene bags, placed in
20 either a fibre or a polyethylene 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.