

Certification of Substances Department

Certificate of suitability
No. R0-CEP 2018-033-Rev 00

1 *Name of the substance:*

2 **AMBROXOL HYDROCHLORIDE**

3 *Name 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 *Site(s) of production:*

9 **SEE ANNEX 1**

10 After examination of the information provided on the manufacturing method and subsequent
11 processes (including purification) for this substance on the site(s) of production listed in annex, we
12 certify that the quality of the substance is suitably controlled by the current version of the
13 monograph **AMBROXOL HYDROCHLORIDE** no. 1489 of the European Pharmacopoeia, current
14 edition including supplements.

15 In the last steps of the synthesis isopropyl alcohol and water are used as solvents. Their
16 residual content is limited by the test for loss on drying described in the monograph with a limit
17 of not more than 0.5%.

18 A risk management summary for elemental impurities has been provided. (Annex 2)

19 The re-test period of the substance is 36 months if stored in double polyethylene bags placed in
20 a polyethylene drum.

21 The holder of the certificate has declared the absence of use of material of human or animal
22 origin in the manufacture of the substance.

23 The submitted dossier must be updated after any significant change that may alter the quality,
24 safety or efficacy of the substance.

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