

Certification of Substances Department

Certificate of suitability
No. R1-CEP 2005-059-Rev 02

1 *Name of the substance:*

2 **PYRAZINAMIDE**

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

THIS CERTIFICATE SUPERSEDES THE PREVIOUS CERTIFICATE

11

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12 After examination of the information provided on the manufacturing method and subsequent
13 processes (including purification) for this substance on the site(s) of production listed in annex, we
14 certify that the quality of the substance is suitably controlled by the current version of the
15 monograph **PYRAZINAMIDE** no. 859 of the European Pharmacopoeia, current edition including
16 supplements.

17 In the last steps of the synthesis water is used as solvent.

18 The substance is packed in double polyethylene bags placed in a polyethylene drum.

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

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

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

25 Failure to comply with these provisions will render this certificate void.