

**Certification of Substances Department**

**Certificate of suitability  
No. R0-CEP 2021-398 - Rev 00**

1 *Name of the substance:*

2 **GLICLAZIDE**

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 **GLICLAZIDE** no. 1524 of the European Pharmacopoeia, current edition including  
14 supplements, only if it is supplemented by the test(s) mentioned below, based on the analytical  
15 procedure(s) given in annex.

16 – Test for residual solvents by gas chromatography (Annex 2)  
17 Dichloromethane not more than 600 ppm  
18 Dimethylformamide not more than 880 ppm  
19 Ethyl acetate not more than 5000 ppm

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

21 A risk management summary for elemental impurities has been provided. (Annex 3)

22 The re-test period of the substance is 12 months if stored in a double polyethylene bag, placed  
23 in a polyethylene drum.

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

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