# Certificate of suitability
# No. CEP 2021-398 - Rev 02

*Name of the substance:*
**GLICLAZIDE**

*Details of holder:*
**ANUH PHARMA LTD.**
3-A, Shivsagar Estate, North Wing
Dr Annie Besant Road, Worli
India-400 018 Mumbai, Maharashtra
SPOR ORG ID: 100021566
SPOR LOC ID: 100030259

After examination of the information provided on the production method and control strategy for the substance, we certify that its quality is suitably controlled by the current version of the European Pharmacopoeia monograph for **GLICLAZIDE** No. 1524 and any supplementary tests deemed necessary which are mentioned below. The approved site(s) of production and any supplementary test procedure(s) are included on the following pages as annexes, which constitute an integral part of this certificate.

- Test for residual solvents by gas chromatography (Annex 2)

| | |
|---|---|
| Dichloromethane | not more than 600 ppm |
| Dimethylformamide | not more than 880 ppm |
| Ethyl acetate | not more than 5000 ppm |

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

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

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

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

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

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

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