Certificate of suitability
No. CEP 2022-356 - Rev 01

Name of the substance:
CYCLOPHOSPHAMIDE MONOHYDRATE

Details of holder:
ANHUI POLY PHARM. CO., LTD.
No.58 Xiahong Road
Hi-tech Industrial Development Zone
China-246 000 Anqing, Anhui Province
SPOR ORG ID: 100047725
SPOR LOC ID: 100078876

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 **CYCLOPHOSPHAMIDE MONOHYDRATE** No. 711 and any supplementary tests deemed necessary. The approved site(s) of production, specification and any supplementary test procedure(s) are included on the following pages, which constitute an integral part of this certificate.

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

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

The re-test period of the substance is 18 months if stored at a temperature not exceeding 30°C in double polyethylene bags, inside a triple laminated aluminium bag and placed in a fibre drum, or 24 months if stored at a temperature not exceeding 25°C in double polyethylene bags, inside a triple laminated aluminium bag and placed in 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.

Necessary information from the submitted dossier shall be shared with authorised users in order to enable them to evaluate the suitability of this substance for its intended use. This includes informing them of any relevant change in the associated dossier.

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

This certificate is granted within the framework of Resolution AP-CSP (07) 1 adopted by the Council of Europe Public Health Committee (Partial Agreement) (CD-P-SP) in February 2007. With regard to its use in the member states of the European Union/European Economic Area, it is granted in accordance with the provisions of Directive 2001/83/EC and Regulation (EU) 2019/6 as amended, and the related guidelines.

This certificate is valid from 15 November 2024.

On behalf of the
Director of EDQM