

**ANHUI POLY PHARMACEUTICAL  
COMPANY LIMITED**  
Ms Jingda YIN  
No.58 Xiahong Road  
Hi-tech Industrial Development Zone  
China – 246 000 Anqing, Anhui Province

CEP 2024-082-P01

Strasbourg, 16 February 2024

**By electronic communication**

### ACKNOWLEDGEMENT OF RECEIPT

**Re: CEP 2024-082 / GADOBUTROL MONOHYDRATE**

Dear Ms Jingda YIN,

We acknowledge receipt of the confidential dossier that you submitted for a certificate of suitability to the monographs of the European Pharmacopoeia.

- Reference number: **CEP 2024-082** (to be mentioned in any correspondence)
- Substance: **GADOBUTROL MONOHYDRATE**
- Type of application: **Chemical**
- **Estimated timelines:** **115 working days.**

Please note that there is currently a delay of approximately 46 working days in the treatment of new applications.

*For more detail on EDQM timelines please see the EDQM policy on the management of applications as well as the calendar of EDQM working days at [www.edqm.eu/en/certification](http://www.edqm.eu/en/certification)*

The dossier will be dealt with in accordance with the procedure described in Resolution AP-CSP (07) 1 and in particular, will be kept and assessed under conditions that guarantee the confidentiality of the submitted data.

For any question regarding this application, please contact us using the following e-mail address:  
[cep@edqm.eu](mailto:cep@edqm.eu)

Yours faithfully,

Certification of Substances Department