

Certification of Substances Department

Certificate of suitability No. CEP 2024-082 - Rev 00

1 *Name of the substance:*

2 **GADOBUTROL MONOHYDRATE**

3 *Details of holder:*

4 **ANHUI POLY PHARM. CO., LTD.**

5 No.58 Xiahong Road

6 Hi-tech Industrial Development Zone

7 China-246 000 Anqing, Anhui Province

8 SPOR ORG ID: 100047725

9 SPOR LOC ID: 100078876

10 After examination of the information provided on the production method and control strategy for the
11 substance, we certify that its quality is suitably controlled by the current version of the European
12 Pharmacopoeia monograph for **GADOBUTROL MONOHYDRATE** No. 2735 and any supplementary
13 tests deemed necessary. The approved site(s) of production, specification and any supplementary
14 test procedure(s) are included on the following pages, which constitute an integral part of this
15 certificate.

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

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

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

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

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

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

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

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

- 31 Failure to comply with any of these provisions will render this certificate void.
- 32 This certificate is granted within the framework of Resolution AP-CSP (07) 1 adopted by the Council
33 of Europe Public Health Committee (Partial Agreement) (CD-P-SP) in February 2007. With regard
34 to its use in the member states of the European Union/European Economic Area, it is granted in
35 accordance with the provisions of Directive 2001/83/EC and Regulation (EU) 2019/6 as amended,
36 and the related guidelines.
- 37 This certificate is valid from 15 November 2024.

On behalf of the
Director of EDQM