

Certification of Substances Department

Certificate of suitability
No. R1-CEP 2011-071-Rev 00

1 *Name of the substance:*

2 **GLYCINE**

3 *Name of holder:*

4 **GEO SPECIALTY CHEMICALS INC.**

5 739 Independence Parkway South

6 United States Am.,-77536 Deer Park, Texas

7 *Site(s) of production:*

8 **SEE ANNEX 1**

9 **THIS CERTIFICATE SUPERSEDES THE PREVIOUS CERTIFICATE**
10 **R0-CEP 2011-071-REV 01**

11 After examination of the information provided on the manufacturing method and subsequent
12 processes (including purification) for this substance on the site(s) of production listed in annex, we
13 certify that the quality of the substance is suitably controlled by the current version of the
14 monograph **GLYCINE** no. 614 of the European Pharmacopoeia, current edition including
15 supplements.

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

17 No elemental impurity classified in ICH Q3D is intentionally introduced in the manufacture of
18 the substance.

19 The substance is packed in either triple bags (metallocene polyethylene/polyethylene-vinyl
20 alcohol/metallocene polyethylene) placed in a cardboard box, or a polyethylene bag placed in a
21 fibre or plastic drum, or a polyethylene bag placed in a polypropylene bag.

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

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

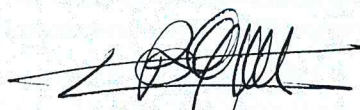
26 Manufacture of the substance shall take place in accordance with the Good Manufacturing Practice
27 and in accordance with the dossier submitted.

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

29 This certificate is renewed from **16 April 2018** according to the provisions of Resolution AP-CSP
30 (07) 1, and of Directive 2001/83/EC and Directive 2001/82/EC and any subsequent amendment,
31 and the related guidelines.

32 This certificate has one annex of 1 page.

33 This certificate has:
34 lines.



On behalf of the
Director of EDQM



Strasbourg, 20 March 2018

DECLARATION OF ACCESS *(to be filled in by the certificate holder under their own responsibility)*

GEO SPECIALTY CHEMICALS INC., as holder of the certificate of suitability

R1-CEP 2011-071-Rev 00 for Glycine

hereby authorises

(name of the pharmaceutical company)

to use the above-mentioned certificate of suitability in support of their application(s) for the following
Marketing Authorisation(s): *(name of product(s) and marketing number(s), if known)*

The holder also certifies that no significant changes to the operations as described in the CEP dossier
have been made since the granting of this version of the certificate.

Date and Signature *(of the CEP holder)*:

Address: 7 Allée Kastner, CS 30026
F-67081 Strasbourg (France)

Tel: +33 (0) 3 88 41 30 30 – Fax: +33 (0) 3 88 41 27 71 - e-mail: cep@edqm.eu

Internet: <http://www.edqm.eu>

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Annex 1: Site(s) of production for R1-CEP 2011-071-Rev 00

Production of Glycine:

GEO SPECIALTY CHEMICALS INC.
739 Independence Parkway South
United States Am.-77536 Deer Park, Texas