European Directorate for the Quality of Medicines & HealthCare | Direction européenne de la qualité du médicament & soins de santé

COUNCIL OF EUROPE
CONSEIL DE L'EUROPE

Certification of Substances Department

Certificate of suitability
No. R1-CEP 2014-046-Rev 00

Name of the substance:
FUSIDIC ACID

Name of holder:
JOYANG LABORATORIES
Haidu North Road
Sheyang Economic Development Zone
China-224 300 Yancheng, Jiangsu Province

Site(s) of production:
SEE ANNEX 1

THIS CERTIFICATE SUPERSEDES THE PREVIOUS CERTIFICATE
R0-CEP 2014-046-REV 01

After examination of the information provided on the manufacturing method and subsequent processes (including purification) for this substance on the site(s) of production listed in annex, we certify that the quality of the substance is suitably controlled by the current version of the monograph **FUSIDIC ACID** no. 798 of the European Pharmacopoeia, current edition including supplements, only if it is supplemented by the test(s) mentioned below, based on the analytical procedure(s) given in annex.

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

n-Hexane	not more than 290 ppm
Methanol	not more than 3000 ppm
Ethanol	not more than 5000 ppm

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

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

The re-test period of the substance is 3 years if stored at a temperature not exceeding 25°C in a polyethylene bag in an aluminium foil bag, placed in carton drums.

The holder of the certificate has declared the use of material of human or animal origin in the manufacture of the substance and there is no risk of viral contamination.

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

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

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

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

This certificate is renewed from **10 July 2020** according to the provisions of Resolution AP-CSP (07) 1, and of Directive 2001/83/EC and Directive 2001/82/EC and any subsequent amendment, and the related guidelines.

This certificate has two annexes, the first of 1 page, and the second of 2 pages.
This certificate has:
lines.

On behalf of the
Director of EDQM

Strasbourg, 25 June 2020

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

JOYANG LABORATORIES, as holder of the certificate of suitability

R1-CEP 2014-046-Rev 00 for Fusidic acid

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*):

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F-67081 Strasbourg (France)
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Certification of Substances Department

Annex 1: Site(s) of production for R1-CEP 2014-046-Rev 00

Production of Fusidic acid:
JOYANG LABORATORIES
Haidu North Road
Sheyang Economic Development Zone
China-224 300 Yancheng, Jiangsu Province

Residual solvents:

Chromatographic condition:

- Column: DB-624, 30m ×0.53mm× 3.0μm
- Detector: Hydrogen FID
- Carrier gas: N_2
- Injection port temperature: 200 °C
- Flow rate: 4mL/min
- Column temperature: Maintain at 40°C for 6minutes, increase to 200 °C at the rate of 30 °C/minute. Keep the temperature for 3 minutes.
- Detector temperature: 250 °C
- Injection volume: 1mL

Headspace conditions:
Sample vial temperature: 80℃
Equilibration time: 30 minutes

Reference solution: dissolve 0.3g Methanol, 0.5g Ethanol, 0.029g n-hexane, 0.5g Ethyl acetate in dimethyl sulfoxide and dilute to 100mL with the same solvent. Transfer 10mL of this solution to a 100mL volumetric flask. Dilute to the scale with dimethyl sulfoxide. Transfer 5mL of above solution to headspace bottle. Seal the headspace bottle for use.

Sample solution: dissolve 0.50g of the fusidic acid in 5mL of dimethyl sulfoxide. Seal the headspace bottle for use.

Blank solution: transfer 5mL of dimethyl sulfoxide in a 20mL headspace bottle.

System suitability:
RSD of six injections of reference solution should be not more than 10%.

Operation procedures:

Inject 1.0mL of standard solution and sample solution, record the chromatogram and data.

Calculation:

$$\text{Residual solvent (ppm)} = \frac{A_i \times W_s \times 10 \times 5}{A_s \times W_i \times 100 \times 100} \times 10^6$$

Where,

A_i peak area of solvent in sample solution;

A_s: peak area of solvent in reference solution;

Wi: weight of sample (g);

W_s: weight of each component in reference to be examined (g);