

Certification of Substances Department

LINARIA CHEMICALS (THAILAND) LTD.

Mr Hemant Kumar PATEL
309 Bangpoo Industrial Estate, Soi 6C,
Sukhumvit Road
Moo4, Tumbol Phraksa, Ampur Muang
Samutprakan
Thailand-10280 Samutprakan

CEP_RZ_PH_2015-283-1091291
ROT / mr

Strasbourg, 2 May 2018

Re: R0-CEP 2015-283-Rev 00 / Pyrazinamide

Dear Mr PATEL,

Following the inspection of your manufacturing site carried out on 13 to 15 December 2017, we inform you that EDQM has decided to grant the above mentioned Certificate of Suitability for **Pyrazinamide**.

Therefore, please find enclosed the certificate.

If you find a mistake on the CEP, you should notify EDQM within 3 months. After this deadline, any complaint will no longer be considered valid.

You are informed that the EDQM may share the assessment reports for this application with the National Competent Authorities of the Ph. Eur. Member states, and with the EMA including EMA committees and working parties/groups and the members and experts thereof.

In accordance with Resolution AP-CSP (07) 1, and as mentioned on the certificate, the submitted dossier must be updated after any change to its content, and this must be reported to EDQM.

This certificate is valid 5 years. It is your responsibility to ask for the renewal of the certificate in due time.

Yours faithfully,


pp. Marta MIQUEL
Scientific Officer


 Hélène BRUGUERA
Head of Department

Certification of Substances Department

Certificate of suitability
No. R0-CEP 2015-283-Rev 00

1 *Name of the substance:*

2 **PYRAZINAMIDE**

3 *Name of holder:*

4 **LINARIA CHEMICALS (THAILAND) LTD.**

5 309 Bangpoo Industrial Estate, Soi 6C, Sukhumvit Road

6 Moo4, Tumbol Phraksa, Ampur Muang Samutprakan

7 Thailand-10280 Samutprakan

8 *Site(s) of production:*

9 **SEE ANNEX 1**

10 After examination of the information provided on the manufacturing method and subsequent
11 processes (including purification) for this substance on the site(s) of production listed in annex, we
12 certify that the quality of the substance is suitably controlled by the current version of the
13 monograph **PYRAZINAMIDE** no. 859 of the European Pharmacopoeia, current edition including
14 supplements.

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

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

18 The substance is packed in double polyethylene bags, placed in a fibre or polyethylene drum.

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

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

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

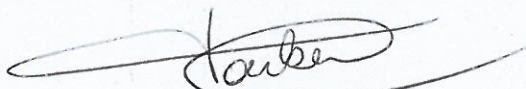
25 Failure to comply with these provisions will render this certificate void.

26 This certificate is granted within the framework of the procedure established by the European
27 Pharmacopoeia Commission [Resolution AP-CSP (07) 1] for a period of five years starting from
28 **2 May 2018**. Moreover, it is granted according to the provisions of Directive 2001/83/EC and
29 Directive 2001/82/EC and any subsequent amendment, and the related guidelines.

30 This certificate has one annex of 1 page.

31 This certificate has:

32 lines.



On behalf of the
Director of EDQM



Strasbourg, 2 May 2018

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

LINARIA CHEMICALS (THAILAND) LTD., as holder of the certificate of suitability

R0-CEP 2015-283-Rev 00 for Pyrazinamide

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>

Certification of Substances Department

Annex 1: Site(s) of production for R0-CEP 2015-283-Rev 00

Production of Pyrazinamide:

LINARIA CHEMICALS (THAILAND) LTD.

309 Bangpoo Industrial Estate, Soi 6C, Sukhumvit Road

Moo4, Tumbol Phraksa, Ampur Muang Samutprakan

Thailand-10280 Samutprakan