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COUNCIL OF EUROPE
CONSEIL DE L'EUROPE

**Certification of Substances Department**

CEP_RZ_PH_2018-158-1274330
GSA/vme

Strasbourg, 23 January 2020

**Re: R0-CEP 2018-158-Rev 00 / Rabeprazole sodium hydrate**

Dear Mr MANDAPATI,

Please find enclosed the certificate granted for **Rabeprazole sodium hydrate** following the evaluation of the dossier.

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,

P.P. Alma KISO
Scientific Officer

Hélène BRUGUERA
Head of Department

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Certification of Substances Department

# Certificate of suitability
# No. R0-CEP 2018-158-Rev 00

*Name of the substance:*
**RABEPRAZOLE SODIUM HYDRATE**

*Name of holder:*

*Site(s) of production:*
**SEE ANNEX 1**

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 **RABEPRAZOLE SODIUM HYDRATE** no. 2331 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 the following impurity by gas chromatography (Annex 2)

| | |
|---|---|
| 2-Chloromethyl-3-methyl-4-(3-methoxy propoxy) pyridine hydrochloride | not more than 12.5 ppm |

- Test for residual solvents by gas chromatography (Annex 3)

| | |
|---|---|
| Isopropyl ether | not more than 5000 ppm |
| Methanol | not more than 3000 ppm |
| Methylene dichloride | not more than 600 ppm |

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

The substance is packed in double polyethylene bags (outer black), placed in a polyethylene container.

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

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

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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 granted within the framework of the procedure established by the European Pharmacopoeia Commission [Resolution AP-CSP (07) 1] for a period of five years starting from **23 January 2020**. Moreover, it is granted according to the provisions of Directive 2001/83/EC and Directive 2001/82/EC and any subsequent amendment, and the related guidelines.

This certificate has three annexes, the first of 1 page, the second and the third of 3 pages each.
This certificate has:
lines.

On behalf of the
Director of EDQM

Strasbourg, 23 January 2020

**CONSIDER THIS DATE**

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

**NOSCH LABS PRIVATE LIMITED**, as holder of the certificate of suitability

**R0-CEP 2018-158-Rev 00 for Rabeprazole sodium hydrate**

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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