edqm
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 2016-301 - Rev 00

Name of the substance:
CELLULOSE, MICROCRYSTALLINE

Name of holder:
RANQ REMEDIES PVT. LTD.
D-14, Kurkumbh MIDC
Taluka Daund, District Pune
India-413 802 Kurkumbh, Maharashtra

Site(s) of production:
SEE ANNEX 1

THIS CERTIFICATE SUPERSEDES THE PREVIOUS CERTIFICATE
R0-CEP 2016-301 - REV 00

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 **CELLULOSE, MICROCRYSTALLINE** no. 316 of the European Pharmacopoeia, current edition including supplements.

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 substance is packed in a polyethylene bag, placed in a polyethylene woven bag.

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.

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.

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F-67081 Strasbourg (France)
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This certificate is renewed from **7 November 2022** 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 one annex of 1 page.

This certificate has:

lines.

On behalf of the
Director of EDQM

Strasbourg, 20 December 2022

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

RANQ REMEDIES PVT. LTD., as holder of the certificate of suitability

R1-CEP 2016-301 - Rev 00 for Cellulose, microcrystalline

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*):

Certification of Substances Department

Annex 1: Site(s) of production for R1-CEP 2016-301 - Rev 00

Production of Cellulose, microcrystalline:

RANQ REMEDIES PVT. LTD.
D-14, Kurkumbh MIDC
Taluka Daund, District Pune
India-413 802 Kurkumbh, Maharashtra