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

EVERZINC
Ms Valérie Rousseau
1550 Brouillette Street
Canada – J2T 2G8 St-Hyacinthe
Quebec

CEP 2017-015-P02
Procedure owner: VVU

Strasbourg, 25 May 2022

Re: CEP 2017-015 / Zinc oxide

Dear Ms Valérie Rousseau,

Please find enclosed the certificate granted following the treatment of your dossier.

If you find a mistake on the CEP, you should notify the EDQM within 3 months. After this period, any complaint may no longer be accepted.

You are reminded that 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.

For any question regarding the application, please contact us using the following e-mail address: CEP@edqm.eu

Yours faithfully,

Certification of Substances Department

Address: 7 Allée Kastner, CS 30026
F-67081 Strasbourg (France)
Tel: +33 (0) 3 88 41 30 30 - e-mail: cep@edqm.eu
Internet: http://www.edqm.eu

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Certification of Substances Department

Certificate of suitability
No. R0-CEP 2017-015 - Rev 01

Name of the substance:
ZINC OXIDE

Name of holder:
EVERZINC
1550 Brouillette Street
Canada-J2T 2G8 St-Hyacinthe, Quebec

Site(s) of production:
SEE ANNEX 1

THIS CERTIFICATE SUPERSEDES THE PREVIOUS CERTIFICATE
R0-CEP 2017-015 - 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 **ZINC OXIDE** no. 252 of the European Pharmacopoeia, current edition including supplements.

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

The substance is packed either in a polypropylene/polyethylene container or in a paper bag, or in a polyethylene bag placed in a fibre drum.

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)
Tel: +33 (0) 3 88 41 30 30 – e-mail: cep@edqm.eu
Internet: http://www.edqm.eu

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 **4 July 2018**. 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 one annex of 1 page.
This certificate has:
lines.

On behalf of the
Director of EDQM

Strasbourg, 25 May 2022

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

EVERZINC, as holder of the certificate of suitability

R0-CEP 2017-015 - Rev 01 for Zinc oxide

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*):

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

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Annex 1: Site(s) of production for R0-CEP 2017-015 - Rev 01

Production of Zinc oxide:

EVERZINC
1550 Brouillette Street
Canada-J2T 2G8 St-Hyacinthe, Quebec