Certification of Substances Department

Certificate of suitability
No. R1-CEP 2000-012-Rev 08

Name of the substance:
CARBIDOPA

Name of holder:
BACHEM S.A.
Succursale de Vionnaz
Route du Simplon 22
Switzerland-1895 Vionnaz

Site(s) of production:
SEE ANNEX 1

THIS CERTIFICATE SUPERSEDES THE PREVIOUS CERTIFICATE
R1-CEP 2000-012-REV 07

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 **CARBIDOPA** no. 755 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.

The following impurity is detected by the test for related substances of the monograph and its limit is set at:

Ph. Eur. Impurity G	not more than 0.15%

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

Ethanol	not more than 5000 ppm

A risk management summary for elemental impurities has been provided. (Annex 3)

The re-test period of the substance is 5 years if stored in double polyethylene bags, 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.

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 **15 January 2006** 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 three annexes, the first of 1 page, the second of 2 pages, and the third of 1 page.

This certificate has:

lines.

On behalf of the
Director of EDQM

Strasbourg, 16 December 2019

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

BACHEM S.A., as holder of the certificate of suitability

R1-CEP 2000-012-Rev 08 for Carbidopa

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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