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 2011-177-Rev 00

Name of the substance:
DIOSMIN
Micronised, non-micronised

Name of holder:
HUNAN YUANTONG PHARMACEUTICAL CO., LTD.
No. 747, Kangwan Road
Liuyang Economic Development Zone
China-410 331 Changsha City, Hunan Province

Site(s) of production:
SEE ANNEX 1

THIS CERTIFICATE SUPERSEDES THE PREVIOUS CERTIFICATE
R0-CEP 2011-177-REV 03

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 **DIOSMIN** no. 1611 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.

– Tests for residual solvents by gas chromatography

Methanol	not more than 3000 ppm	(Annex 2)
Acetic acid	not more than 5000 ppm	
Pyridine	not more than 200 ppm	(Annex 3)

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.

– Test for particle size by laser diffraction (micronised) (Annex 4)

$d_{0.99}$	not more than 10 µm
$d_{0.95}$	not more than 5 µm
$d_{0.80}$	not more than 2 µm

– Test for fineness by sieve method (non-micronised) (Annex 5)

100%	pass through 80 mesh sieve

Address: 7 Allée Kastner, CS 30026
F-67081 Strasbourg (France)
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Internet: http://www.edqm.eu

The re-test period of the substance is 36 months if stored in double polyethylene bags placed in a paperboard 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.

This certificate is renewed from **4 December 2017** 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 five annexes, the first of 1 page, the second of 2 pages, the third of 3 pages, the fourth and the fifth of 1 page each.

This certificate has:

lines.

On behalf of the
Director of EDQM

Strasbourg, 10 November 2017

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

HUNAN YUANTONG PHARMACEUTICAL CO., LTD., as holder of the certificate of suitability

R1-CEP 2011-177-Rev 00 for Diosmin

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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