edqm European Directorate for the Quality of Medicines & HealthCare

COUNCIL OF EUROPE
CONSEIL DE L'EUROPE

Certification of Substances Division

Certificate of suitability
No. R0-CEP 2012-039-Rev 01

Name of the substance:
DOXORUBICIN HYDROCHLORIDE

Name of holder:
STERLING BIOTECH LIMITED
Jambusar State Highway
Taluka Padra, District Vadodara
India-391 421 Masar Village, Gujarat

Site(s) of production:
SEE ANNEX 1

THIS CERTIFICATE SUPERSEDES THE PREVIOUS CERTIFICATE
R0-CEP 2012-039-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 **DOXORUBICIN HYDROCHLORIDE** no. 714 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.

Any unspecified impurity detected by the test for related substances of the monograph is limited to not more than 0.10% and total impurities are limited to not more than 1.0%.

– Tests for residual solvents by gas chromatography (Annex 2)

Chloroform	not more than 60 ppm
Ethyl acetate	not more than 5000 ppm
Acetone	not more than 0.5%
Total of acetone and alcohol	not more than 1.5%

In the last steps of the synthesis water is used as solvent.

The re-test period of the substance is 30 months if stored in double polyethylene bags placed in a polyethylene jar.

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