

Certification of Substances Department

Certificate of suitability
No. R0-CEP 2015-349-Rev 00

1 *Name of the substance:*

2 **EPIRUBICIN HYDROCHLORIDE**

3 *Name of holder:*

4 **STERLING BIOTECH LIMITED**

5 Jambusar State Highway

6 Taluka Padra, District Vadodara

7 India-391 421 Masar Village, Gujarat

8 *Site(s) of production:*

9 **SEE ANNEX 1**

10 After examination of the information provided on the manufacturing method and subsequent
11 processes (including purification) for this substance on the site(s) of production listed in annex, we
12 certify that the quality of the substance is suitably controlled by the current version of the
13 monograph **EPIRUBICIN HYDROCHLORIDE** no. 1590 of the European Pharmacopoeia, current
14 edition including supplements, only if it is supplemented by the test(s) mentioned below, based on
15 the analytical procedure(s) given in annex.

16 Any unspecified impurity detected by the test for related substances of the monograph is
17 limited to not more than 0.10%.

18 – Tests for residual solvents by gas chromatography

19 Dichloromethane not more than 600 ppm (Annex 2)

20 Methanol not more than 3000 ppm

21 Ethanol not more than 5000 ppm

22 1-Propanol not more than 5000 ppm

23 Chloroform not more than 60 ppm (Annex 3)

24 Dimethyl sulfoxide not more than 5000 ppm

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

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

28 The substance is packed in double polyethylene bags in an aluminium bag placed in a
29 polyethylene container.

30 The holder of the certificate has declared the absence of use of material of human or animal
31 origin in the manufacture of the substance.

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