

**Certification of Substances Department**

**Certificate of suitability**  
**No. R0-CEP 2014-146-Rev 01**

1 *Name of the substance:*

2 **LOVASTATIN**

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 **THIS CERTIFICATE SUPERSEDES THE PREVIOUS CERTIFICATE**  
11 **R0-CEP 2014-146-REV 00**

12 After examination of the information provided on the manufacturing method and subsequent  
13 processes (including purification) for this substance on the site(s) of production listed in annex, we  
14 certify that the quality of the substance is suitably controlled by the current version of the  
15 monograph **LOVASTATIN** no. 1538 of the European Pharmacopoeia, current edition including  
16 supplements, only if it is supplemented by the test(s) mentioned below, based on the analytical  
17 procedure(s) given in annex.

18 – Test for residual solvents by gas chromatography (Annex 2)  
19 Methanol not more than 3000 ppm

20 The substance is packed in a double polyethylene bag placed in a polyethylene drum.

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

23 The submitted dossier must be updated after any significant change that may alter the quality,  
24 safety or efficacy of the substance.

25 Manufacture of the substance shall take place in accordance with the Good Manufacturing Practice  
26 and in accordance with the dossier submitted.

27 Failure to comply with these provisions will render this certificate void.