

Certification of Substances Division

Certificate of suitability
No. R1-CEP 2002-020-Rev 06

1 *Name of the substance:*

2 **PARACETAMOL**

3 *Name of holder:*

4 **FARMSON PHARMACEUTICAL GUJARAT PVT. LTD.**

5 14, G.I.D.C. Industrial Estate, Nandesari

6 Vadodara District

7 India-391 340 Vadodara, Gujarat

8 *Site(s) of production:*

9 **SEE ANNEX 1**

10 **THIS CERTIFICATE SUPERSEDES THE PREVIOUS CERTIFICATE**
11 **R1-CEP 2002-020-REV 05**

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 **PARACETAMOL** no. 49 of the European Pharmacopoeia, current edition including
16 supplements.

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

18 The re-test period of the substance is 66 months if stored in double polyethylene bags.

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

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

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

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