

Certification of Substances Division

**Certificate of suitability
No. R1-CEP 2002-020-Rev 07**

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 06

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 or
19 polyethylene liners placed in polypropylene bags.

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

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

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


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

27 This certificate is renewed from **16 September 2008** according to the provisions of Resolution
28 AP-CSP (07) 1, and of Directive 2001/83/EC and Directive 2001/82/EC and any subsequent
29 amendment, and the related guidelines.

30 This certificate has one annex of 1 page.

31 This certificate has:

32 lines.


On behalf of the
Director of EDQM



Strasbourg, 15 June 2015

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

FARMSON PHARMACEUTICAL GUJARAT PVT. LTD., as holder of the certificate of suitability

R1-CEP 2002-020-Rev 07 for Paracetamol

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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Annex 1: Site(s) of production for R1-CEP 2002-020-Rev 07

Production of intermediate(s):

JNP PRODUCTS
Plot No. 748/1, G.I.D.C. Industrial Estate
District Bharuch
India-392 110 Jhagadia, Gujarat

Production of Paracetamol:

FARMSON PHARMACEUTICAL GUJARAT PVT. LTD.
14, G.I.D.C. Industrial Estate, Nandesari
Vadodara District
India-391 340 Vadodara, Gujarat

Farmson Analgesics
28-35 G.I.D.C. Industrial Estate
Nandesari
India-391 340 Vadodara, Gujarat