Certification of Substances Department

ATTESTATION OF INSPECTION

Inspected site	FARMSON PHARMACEUTICAL GUJARAT PVT. LTD. 14, G.I.D.C. Industrial Estate, Nandesari Vadodara District India-391 340 Vadodara, Gujarat
Holder of the Certificate of Suitability	FARMSON PHARMACEUTICAL GUJARAT PVT. LTD. 14, G.I.D.C. Industrial Estate, Nandesari Vadodara District India-391 340 Vadodara, Gujarat
References of CEP dossier	CEP 2002-020 / Paracetamol
Inspection dates	22/05/2017 to 24/05/2017
Inspector / Name of organisation	Dr TASI Gergely, OGYEI, NATIONAL INSTITUTE OF PHARMACY AND NUTRITION, HUNGARY Mr TEMLEITNER Arpad, EDQM, COUNCIL OF EUROPE
Scope of the inspection	The inspection focused on the compliance with the information provided in the above-mentioned application for a certificate of suitability, as well as the implementation of a suitable Quality Management System based on the Good Manufacturing Practice as laid down in the EU Rules governing Medicinal Products in the European Union, Volume 4.
Conclusion	The company operates in accordance with the application submitted and the requirements of the Resolution AP-CSP (07) 1. This attestation is valid only in conjunction with a valid version of a CEP for the dossier mentioned above.

EDQM Inspection Reference number: INSP 2014-006 P02

Strasbourg, 25 August 2017

On behalf of the
Director of EDQM

Address: 7 Allée Kastner, CS 30026
F-67081 Strasbourg (France)
Tel: +33 (0) 3 88 41 30 30 – Fax: +33 (0) 3 88 41 27 71 - e-mail: cep@edqm.eu
Internet: http://www.edqm.eu

Certification of Substances Division

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

Name of the substance:
PARACETAMOL

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

Site(s) of production:
SEE ANNEX 1

THIS CERTIFICATE SUPERSEDES THE PREVIOUS CERTIFICATE
R1-CEP 2002-020-REV 06

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

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

The re-test period of the substance is 66 months if stored in double polyethylene bags or polyethylene liners placed in polypropylene bags.

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

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

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

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

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

This certificate has one annex of 1 page.

This certificate has:

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*):

Address: 7 Allée Kastner, CS 30026
F-67081 Strasbourg (France)
Tel: +33 (0) 3 88 41 30 30 – Fax: +33 (0) 3 88 41 27 71 - e-mail: cep@edqm.eu
Internet: http://www.edqm.eu

Certification of Substances Division

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