

National Institute of Pharmacy and Nutrition

CERTIFICATE NUMBER : **OGYÉI/50486-5/2021**

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER^{1, 2}

Part 1

Issued following an inspection in accordance with :
Art. 111(5) of Directive 2001/83/EC as amended

The competent authority of Hungary confirms the following:

The manufacturer : **FARMSON PHARMACEUTICAL GUJARAT PRIVATE LIMITED**

Site address : **Plot No. 14, G.I.D.C. Industrial Estate, Vadodara District, Nandesari, Gujarat, 391340, India**

Has been inspected in connection with marketing authorisation(s) listing manufacturers located outside of the European Economic Area in accordance with Art. 111(4) of Directive 2001/83/EC .

Is an active substance manufacturer that has been inspected in accordance with Art. 111(1) of Directive 2001/83/EC .

Other

Distant Assessment

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on **2021-04-23** , it is considered that it complies with :

- The principles and guidelines of Good Manufacturing Practice laid down in Directive 2003/94/EC³
- The principles of GMP for active substances³ referred to in Article 47 of Directive 2001/83/EC .

This certificate reflects the status of the manufacturing site at the time of the inspection noted above and should not be relied upon to reflect the compliance status if more than three years have elapsed since the date of that inspection. However, this period of validity may be reduced or extended using regulatory risk management principles by an entry in the Restrictions or Clarifying remarks field. This certificate is valid only when presented with all pages and both Parts 1 and 2. The authenticity of this certificate may be verified in EudraGMDP. If it does not appear, please contact the issuing authority.

¹ The certificate referred to in paragraph 111(5) of Directive 2001/83/EC and 80(5) of Directive 2001/82/EC, shall also be required for imports coming from third countries into a Member State.

² Guidance on the interpretation of this template can be found in the Help menu of EudraGMDP database.

³ These requirements fulfil the GMP recommendations of WHO.

Part 2

Human Medicinal Products

Manufacture of active substance. Names of substances subject to inspection :

PARACETAMOL(en)

3. MANUFACTURING OPERATIONS - ACTIVE SUBSTANCES

Active Substance :PARACETAMOL

3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.1 Manufacture of active substance intermediates 3.1.2 Manufacture of crude active substance 3.1.3 Salt formation / Purification steps: salt formation
3.5	General Finishing Steps
	3.5.1 Physical processing steps: Micronisation 3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)
3.6	Quality Control Testing
	3.6.1 Physical / Chemical testing 3.6.2 Microbiological testing excluding sterility testing

Clarifying remarks (for public users)

This Distant Assessment had been carried out in the framework of EDQM Real Time Remote Inspection (RTEMIS) program. On-site inspection will be performed as soon as the travel restrictions are lifted.

2021-08-13

Name and signature of the authorised person of the
Competent Authority of Hungary



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