Medicines and Healthcare products Regulatory Agency

CERTIFICATE NUMBER : UK MIA(IMP) 25044 Insp IMP 25044/37420384-0001[I]

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER*(1),(2)*

Part 1

Issued following an inspection in accordance with :
Part 6 of The Medicines for Human Use (Clinical Trials) Regulations 2004 (SI 2004/1031)

The competent authority of United Kingdom confirms the following :

The Manufacturer : BDD PHARMA LIMITED

Site address : BDD PHARMA LIMITED, BIOCITY SCOTLAND, BO'NESS ROAD, MOTHERWELL, ML1 5UH, UNITED KINGDOM

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. UK MIA(IMP) 25044 in accordance with Part 6 of The Medicines for Human Use (Clinical Trials) Regulations 2004 (SI 2004/1031)

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on 11/03/2025 , it is considered that it complies with

- The principles and guidelines of Good Manufacturing Practice laid down in Regulation B17 of the Human Medicines Regulations 2012 (as amended)

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 MHRA-GMDP. If it does not appear, please contact the issuing authority.

- *(1) Guidance on the interpretation of this template can be found in the Help menu of MHRA-GMDP database.*
- *(2) These requirements fulfil the GMP recommendations of WHO.*

Part 2

Human Investigational Medicinal Products

1. MANUFACTURING OPERATIONS

[1.2] Non-sterile investigational medicinal products

[1.2.1] Non-Sterile Products (processing operations for the following dosage forms)

[1.2.1.1] Capsules, hard shell

[1.2.1.2] Capsules, soft shell

[1.2.1.5] Liquids for external use

[1.2.1.6] Liquids for internal use

[1.2.1.8] Other solid dosage forms

[1.2.1.9] Pressurised preparations

[1.2.1.11] Semi-solids

[1.2.1.13] Tablets

Melatonin

[1.2.1.17] Other non-sterile medicinal products

Manufacture of intermediates, Overencapsulation,Buccal film, Any authorised products listed above may incorporate radiolabel and may contain biotechnology

[1.2.2] Batch certification

[1.3] Biological investigational medicinal products

[1.3.1] Biological medicinal products

[1.3.1.5] Biotechnology products

Use of Biotechnology drug substance, blend or intermediate in manufacture of non-sterile finished dosage form

[1.3.1.8] Other biological medicinal products

Any authorised products listed above may incorporate radiolabel. Radiolabelling of pre-formulated biological medicinal products.

[1.3.2] Batch certification

[1.3.2.5] Biotechnology products

Use of Biotechnology drug substance, blend or intermediate in manufacture of non-sterile finished dosage form

[1.3.2.8] Other biological medicinal products

Any authorised products listed above may incorporate radiolabel. Radiolabelling of pre-formulated biological medicinal products.

[1.5] Packaging

[1.5.1] Primary packaging

[1.5.1.1] Capsules, hard shell

[1.5.1.2] Capsules, soft shell

[1.5.1.5] Liquids for external use

[1.5.1.6] Liquids for internal use

[1.5.1.8] Other solid dosage forms

[1.5.1.9] Pressurised preparations

[1.5.1.11] Semi-solids

[1.5.1.13] Tablets

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[1.5.1.17] Other non-sterile medicinal products

Buccal films, ntermediates, Overencapsulated products, Radio-labelled products

[1.5.2] Secondary packaging

[1.6] Quality control testing

[1.6.3] Chemical/Physical

2. IMPORTATION OF MEDICINAL PRODUCTS

[2.3] Other Importation Activities

[2.3.1] Site of Physical Importation

[2.3.2] Importation of Intermediate which undergoes further processing

[2.3.4] Other

Importation of QP certified IMPs from the "approved countries for import" list

08/05/2025 Name and signature of the authorised person of the Competent Authority of United Kingdom

Confidential

Medicines and Healthcare products Regulatory Agency

Tel : Confidential

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