



Certificate No: UK MIA(IMP) 10284 Insp IMP 10284/18457585-0010

Medicines and Healthcare products Regulatory Agency

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER

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 the United Kingdom confirms the following:

The manufacturer	SHARP CLINICAL SERVICES (UK) LIMITED
Site address	UNIT 28 HEADS OF THE VALLEY INDUSTRIAL ESTATE RHYMNEY TREDEGAR NP22 5RL UNITED KINGDOM

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. MIA(IMP) 10284 in accordance with Art. 13 of Directive 2001/20/EC transposed in the following national legislation: 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 14/10/2021, 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 only valid when presented with all pages and both parts 1 and 2.

The authenticity of this certificate may be verified in MHRA-GMDP database. If it does not appear please contact the issuing authority.



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Part 2

Human Investigational Medicinal Products for phase I, II, III clinical trials

1. MANUFACTURING OPERATIONS

1.1 Sterile products

1.1.3 Batch Certification

1.2 Non-sterile products

1.2.1 Non-sterile products (processing operations for the following dosage forms)

1.2.1.1 Capsules, hard shell

1.2.2 Batch Certification

1.3 Biological medicinal products

Not Authorised

1.4 Other products or manufacturing activity

1.4.1 Manufacture of

1.4.1.1 Herbal products

1.4.1.3 Other

Importation of QP certified IMPs from a country on the approved country for import list/
Automation of primary manufacturing processes

1.5 Packaging

1.5.1 Primary packaging

1.5.1.1 Capsules, hard shell

1.5.1.2 Capsules, soft shell

1.5.1.3 Chewing gums

1.5.1.8 Other solid dosage forms

1.5.1.13 Tablets

1.5.2 Secondary packaging

1.6 Quality control testing

Not Authorised

2. IMPORTATION OF MEDICINAL PRODUCTS

2.1 Quality control testing of imported medicinal products

Not Authorised

2.2 Batch certification of imported medicinal products



2.2.1 Sterile Products

2.2.1.1 Aseptically prepared products

2.2.1.2 Terminally sterilised products

2.2.2 Non-sterile products

2.2.3 Biological medicinal products

2.2.3.2 Immunological products

2.2.3.5 Biotechnology products

2.2.3.6 Human or animal extracted products

2.2.3.8 Other biological medicinal products

Microbial derived.

2.3 Other importation activities

2.3.1 Site of Physical Importation



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3. MANUFACTURING OPERATIONS

3.1 Manufacture of Active Substance by Chemical Synthesis

Not Authorised

3.2 Processing Activities of Active Substance from Natural Sources

Not Authorised

3.3 Manufacture of Active Substance using Biological Processes

Not Authorised

3.4 Manufacture of sterile active substance

Not Authorised

3.5 General Finishing Steps

Not Authorised

3.6 Quality Control Testing

Not Authorised

4 Other Activities

Not Authorised



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Any restrictions or clarifying remarks related to the scope of this certificate:

This was a focused remote inspection following a variation to add oversight process for IMP from listed countries.

1. Building(s)/Area(s)
N/A
2. Room(s)
N/A
3. Line(s) Equipment(s)
N/A
4. QC testing
N/A
5. Medicinal Product(s)/IMP(s)
N/A

**Name of the authorised person of the
Competent Authority of the United Kingdom**

Dr A J Gray
Head of Inspectorate
inspectionplanning@mhra.gov.uk

Date: 22/10/2021