

# Medicines and Healthcare products Regulatory Agency

CERTIFICATE NUMBER : UK MIA(IMP) 12689 Insp IMP 12689/27547-0023[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 : PAREXEL INTERNATIONAL LIMITED

Site address : PAREXEL INTERNATIONAL LIMITED, CLINICAL PHARMACOLOGY RESEARCH UNIT, LEVEL 7, NORTHWICK PARK HOSPITAL, WATFORD ROAD, HARROW, HA1 3UJ, UNITED KINGDOM

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. UK MIA(IMP) 12689 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 30/11/2021 , 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 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.

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- (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

##### [ 1.1 ] Sterile Investigational Medicinal Products

[ 1.1.1 ] Aseptically prepared (processing operations for the following dosage forms)

[ 1.1.1.1 ] Large volume liquids

[ 1.1.1.3 ] Semi-solids

[ 1.1.1.4 ] Small volume liquids

[ 1.1.3 ] Batch certification

**[ 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

[ 1.2.1.5 ] Liquids for external use

[ 1.2.1.6 ] Liquids for internal use

[ 1.2.2 ] Batch certification

**[ 1.3 ] Biological investigational medicinal products**

[ 1.3.2 ] Batch certification

[ 1.3.2.5 ] Biotechnology products

**[ 1.4 ] Other products or manufacturing activity**

[ 1.4.1 ] Manufacture of:

[ 1.4.1.3 ] Other

Assemble and Import closed containers of cytostatics/cytotoxics, where there will be minimal risk of

**[ 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

[ 1.5.1.5 ] Liquids for external use

[ 1.5.1.6 ] Liquids for internal use

[ 1.5.1.9 ] Pressurised preparations

[ 1.5.1.11 ] Semi-solids

[ 1.5.1.12 ] Suppositories

[ 1.5.1.13 ] Tablets

[ 1.5.2 ] Secondary packaging

**2. IMPORTATION OF MEDICINAL PRODUCTS**

**[ 2.2 ] Batch certification of imported medicinal products**

[ 2.2.1 ] Sterile Products

[ 2.2.1.1 ] Aseptically prepared

[ 2.2.1.2 ] Terminally sterilised

[ 2.2.2 ] Non-sterile products

[ 2.2.3 ] Biological medicinal products

[ 2.2.3.5 ] Biotechnology 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

Assemble and Import closed containers of cytostatics/cytotoxics, where there will be minimal risk of

**Restrictions or Remarks**

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

Any restrictions related to the scope of this certificate:

<b>Building</b>	<b>Room Line/equipment</b>	<b>QC Testing</b>	<b>Products</b>
This previous full scope inspection included the original cleanrooms in V block, level 7 and the new cleanrooms in N block, level 7			

01/12/2021 Name and signature of the authorised person of the Competent Authority of United Kingdom  
Confidential  
Medicines and Healthcare products Regulatory Agency  
Tel : Confidential