

# Medicines and Healthcare products Regulatory Agency

## MANUFACTURER'S AUTHORISATION

<b>1: Authorisation Number</b>	UK MIA 36687
<b>2: Name of authorisation holder</b>	TORRENT PHARMA (UK) LIMITED CENTRAL PHARMA (CONTRACT PACKING) LIMITED, CAXTON ROAD, BEDFORD, MK41 0XZ, UNITED KINGDOM
<b>3: Address(es) of manufacturing site(s)</b>	TORRENT PHARMA (UK) LIMITED, 3RD FLOOR, NEXUS BUILDING, 4 GATWICK ROAD, CRAWLEY, RH10 9BG, UNITED KINGDOM
<b>4: Legally registered address of authorisation holder</b>	TORRENT PHARMA (UK) LIMITED, 3RD FLOOR, NEXUS BUILDING, 4 GATWICK ROAD, CRAWLEY, RH10 9BG, UNITED KINGDOM
<b>5: Scope of authorisation and dosage forms</b>	ANNEX 1 and/ or ANNEX 2
<b>6: Legal Basis of authorisation</b>	Regulation 17 of The Human Medicines Regulations 2012 (SI 2012/1916)
<b>7: Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation</b>	Confidential
<b>8: Authorisation Date</b>	18/06/2024
<b>9: Annexes attached</b>	Annex 1 and/or Annex 2

### SCOPE OF AUTHORISATION

#### Annex 1

Name and address of the site:

**CENTRAL PHARMA (CONTRACT PACKING) LIMITED, CAXTON ROAD, BEDFORD, MK41 0XZ, UNITED KINGDOM**

Human Medicinal Products
Authorised Operations
MANUFACTURING OPERATIONS (according to part 1) IMPORTATION OF MEDICINAL PRODUCTS (according to part 2)
<b>Part 1 - MANUFACTURING OPERATIONS</b> <b>[ 1.2 ] Non-sterile products</b> [ 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
- [ 1.2.1.13 ] Tablets
- [ 1.2.1.17 ] Other non-sterile medicinal products

Assembly of pressurised aerosols and sterile products. Previously sealed hormones and cytotoxic/cytostatic products. Secondary packaging of penicillin

**[ 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
  - [ 1.5.1.13 ] Tablets
  - [ 1.5.1.17 ] Other non-sterile medicinal products

Assembly of pressurised aerosols and sterile products. Previously sealed hormones and cytotoxic/cytostatic products. Secondary packaging of penicillin.

- [ 1.5.2 ] Secondary packaging

**[ 1.6 ] Quality control testing**

- [ 1.6.3 ] Chemical/Physical

**Part 2 - IMPORTATION OF MEDICINAL PRODUCTS**

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

- [ 2.2.1 ] Sterile Products
  - [ 2.2.1.1 ] Aseptically prepared

**SCOPE OF AUTHORISATION**

**Annex 1**

Name and address of the site:

**TORRENT PHARMA (UK) LIMITED**, 3RD FLOOR, NEXUS BUILDING, 4 GATWICK ROAD, CRAWLEY, RH10 9BG, UNITED KINGDOM

Human Medicinal Products
Authorised Operations
MANUFACTURING OPERATIONS (according to part 1) IMPORTATION OF MEDICINAL PRODUCTS (according to part 2)

**Part 1 - MANUFACTURING OPERATIONS**

**[ 1.2 ] Non-sterile products**

- [ 1.2.2 ] Batch certification

**Part 2 - IMPORTATION OF MEDICINAL PRODUCTS**

MHRA-GMDP

MHRA

MHRA-GMDP

MHRA