

Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number UK MIA 36687

2: Name of authorisation holder TORRENT PHARMA (UK) LIMITED

3: Address(es) of manufacturing site(s) CENTRAL PHARMA (CONTRACT PACKING) LIMITED, CAXTON ROAD, BEDFORD, MK41 0XZ, UNITED KINGDOM

4: Legally registered address of authorisation holder TORRENT PHARMA (UK) LIMITED, 3RD FLOOR, NEXUS BUILDING, 4 GATWICK ROAD, CRAWLEY, RH10 9BG, UNITED KINGDOM

5: Scope of authorisation and dosage forms ANNEX 1 and/ or ANNEX 2

6: Legal Basis of authorisation Regulation 17 of The Human Medicines Regulations 2012 (SI 2012/1916)

7: Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation Confidential

8: Authorisation Date 28/12/2023

9: Annexes attached 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)
Part 1 - MANUFACTURING OPERATIONS [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 [1.2.1.2] 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

