Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number **UK MIA 36687**

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

TORRENT PHARMA (UK) LIMITED, 3RD FLOOR, NEXUS BUILDING, 4 GATWICK ROAD, CRAWLEY, RH10 9BG, 3: Address(es) of manufacturing site(s)

UNITED KINGDOM

TORRENT PHARMA (UK) LIMITED, 3RD FLOOR, NEXUS 4: Legally registered address of authorisation holder

BUILDING, 4 GATWICK ROAD, CRAWLEY, RH10 9BG,

UNITED KINGDOM

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

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

2012/1916)

7: Name of responsible officer of the competent authority of the

member state granting the manufacturing authorisation

Confidential

8: Authorisation Date 14/02/2025

9: Annexes attached Annex 1 and/or Annex 2

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

[2.2] Batch certification of imported medicinal products

[2.2.2] Non-sterile products

Issue Date: 14 Feb 2025