

Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number UK MIA 6831

2: Name of authorisation holder GENUS PHARMACEUTICALS LIMITED

3: Address(es) of manufacturing site(s) GENUS PHARMACEUTICALS LIMITED, MANCHESTER ROAD, LINTHWAITE, HUDDERSFIELD, HD7 5QH, UNITED KINGDOM

4: Legally registered address of authorisation holder GENUS PHARMACEUTICALS LIMITED, MANCHESTER ROAD, LINTHWAITE, HUDDERSFIELD, HD7 5QH, 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 15/04/2025

9: Annexes attached Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

GENUS PHARMACEUTICALS LIMITED, MANCHESTER ROAD, LINTHWAITE, HUDDERSFIELD, HD7 5QH, 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) [1.2.1.11] Semi-solids [1.2.2] Batch certification [1.4] Other products or manufacturing activity [1.4.1] Manufacture of: [1.4.1.3] Other Medical Devices [1.5] Packaging

[1.5.2] Secondary packaging

Part 2 - IMPORTATION OF MEDICINAL PRODUCTS

[2.2] Batch certification of imported medicinal products

[2.2.2] Non-sterile products