

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 | 25/03/2024 |
| 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 |

[2.2] Batch certification of imported medicinal products

[2.2.2] Non-sterile products

MHRA-GMDP

MHRA

MHRA-GMDP

MHRA