

Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number UK MIA 8596

2: Name of authorisation holder HVL PHARMA UK LTD

3: Address(es) of manufacturing site(s) HVL PHARMA UK LTD, 37 HOLLANDS ROAD,
HAVERHILL, CB9 8PU, UNITED KINGDOM

4: Legally registered address of authorisation holder HVL PHARMA UK LTD, 37 HOLLANDS ROAD,
HAVERHILL, CB9 8PU, 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 09/12/2025

9: Annexes attached Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

HVL PHARMA UK LTD, 37 HOLLANDS ROAD, HAVERHILL, CB9 8PU, UNITED KINGDOM

Human Medicinal Products
Authorised Operations
MANUFACTURING OPERATIONS (according to part 1)
Part 1 - MANUFACTURING OPERATIONS [1.1] Sterile Products [1.1.3] Batch certification [1.2] Non-sterile products [1.2.2] Batch certification [1.3] Biological medicinal products [1.3.2] Batch certification [1.3.2.2] Immunological products [1.3.2.3] Cell therapy products [1.3.2.5] Biotechnology products

[1.3.2.6] Human or animal extracted products

[1.5] Packaging

[1.5.1] Primary packaging

[1.5.1.6] Liquids for internal use

[1.5.2] Secondary packaging

[1.6] Quality control testing

[1.6.2] Microbiological: non-sterility

[1.6.3] Chemical/Physical

[1.6.4] Biological