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	06/05/2026
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

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[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

MHRA-GMDP MHRA MHRA-GMDP MHRA