

Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number UK MIA(IMP) 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 Part 6 of The Medicines for Human Use (Clinical
Trials) Regulations 2004 [SI 2004/1031]

**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 2

Name and address of the site:

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

Human Investigational Medicinal Products
Authorised Operations
MANUFACTURING OPERATIONS (according to part 1)
Part 1 - MANUFACTURING OPERATIONS [1.2] Non-sterile investigational medicinal products [1.2.1] Non-Sterile Products (processing operations for the following dosage forms) [1.2.1.15] Other non-sterile medicinal products Partial manufacture only: formulation & spray-drying only [1.6] Quality control testing [1.6.2] Microbiological: non-sterility [1.6.3] Chemical/Physical