

Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number UK MIA 3436

2: Name of authorisation holder KL PHARMACEUTICAL LIMITED

3: Address(es) of manufacturing site(s) KL PHARMACEUTICAL LIMITED, 21 MACADAM PLACE,
SOUTH NEWMOOR, IRVINE, KA11 4HP, UNITED KINGDOM

4: Legally registered address of authorisation holder KL PHARMACEUTICAL LIMITED, 21 MACADAM PLACE,
SOUTH NEWMOOR, IRVINE, KA11 4HP, 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 07/05/2024

9: Annexes attached Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

KL PHARMACEUTICAL LIMITED, 21 MACADAM PLACE, SOUTH NEWMOOR, IRVINE, KA11 4HP, UNITED KINGDOM

Human Medicinal Products
Authorised Operations
MANUFACTURING OPERATIONS (according to part 1)
Part 1 - MANUFACTURING OPERATIONS [1.2] Non-sterile products [1.2.1] Non-Sterile Products (processing operations for the following dosage forms) [1.2.1.5] Liquids for external use [1.2.1.11] Semi-solids [1.2.2] Batch certification [1.5] Packaging [1.5.2] Secondary packaging