

Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number UK MIA(IMP) 39930

2: Name of authorisation holder PEPCEUTICALS LIMITED

3: Address(es) of manufacturing site(s) PEPCEUTICALS LIMITED, 4 FELDSPAR CLOSE,
ENDERBY, LEICESTER, LE19 4JS, UNITED KINGDOM

4: Legally registered address of authorisation holder PEPCEUTICALS LIMITED, 4 FELDSPAR CLOSE,
ENDERBY, LEICESTER, LE19 4JS, 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 26/06/2024

9: Annexes attached Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 2

Name and address of the site:

PEPCEUTICALS LIMITED, 4 FELDSPAR CLOSE, ENDERBY, LEICESTER, LE19 4JS, 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) [1.2.1.4] Impregnated matrices [1.2.1.5] Liquids for external use [1.2.1.6] Liquids for internal use [1.2.1.11] Semi-solids [1.2.2] Batch certification [1.6] Quality control testing [1.6.3] Chemical/Physical