

Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number UK MIA 49794

2: Name of authorisation holder FLEXIPHARM AUSTRADING LIMITED

3: Address(es) of manufacturing site(s) FLEXIPHARM AUSTRADING LIMITED, ATI HOUSE, 6 BOSTON DRIVE, BOURNE END, SL8 5YS, UNITED KINGDOM

4: Legally registered address of authorisation holder FLEXIPHARM AUSTRADING LIMITED, ATI HOUSE, 6 BOSTON DRIVE, BOURNE END, SL8 5YS, 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 12/12/2022

9: Annexes attached Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

FLEXIPHARM AUSTRADING LIMITED, ATI HOUSE, 6 BOSTON DRIVE, BOURNE END, SL8 5YS, UNITED KINGDOM

Human Medicinal Products
Authorised Operations
IMPORTATION OF MEDICINAL PRODUCTS (according to part 2)
Part 2 - IMPORTATION OF MEDICINAL PRODUCTS [2.2] Batch certification of imported medicinal products [2.2.1] Sterile Products [2.2.1.2] Terminally sterilised [2.2.2] Non-sterile products [2.3] Other Importation Activities [2.3.4] Products authorised under regulation 174 (supply in response to spread of pathogenic agents etc) Authorised importation activities without manufacturing activity. Site of operations, not site of physical importation. Storage of retention samples