Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number

2: Name of authorisation holder FLEXIPHARM AUSTRADING LIMITED

FLEXIPHARM AUSTRADING LIMITED, ATI HOUSE, 6

3: Address(es) of manufacturing site(s)

BOSTON DRIVE, BOURNE END, SL8 5YS, UNITED KINGDOM

4: Legally registered address of authorisation holder

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 Regulations 2012 (SI

2012/1916)

UK MIA 49794

7: Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation

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

Manufacturer's Authorisation: UK MIA 49794 Page 1 of 1 Issue Date: 12 Dec 2022