

# Medicines and Healthcare products Regulatory Agency

## MANUFACTURER'S AUTHORISATION

1: Authorisation Number	UK MIA 6719
2: Name of authorisation holder	GALPHARM INTERNATIONAL LIMITED
3: Address(es) of manufacturing site(s)	GALPHARM INTERNATIONAL LIMITED, ELMHIRST PARK, MIDDLE FIELD ROAD, SILKSTONE, BARNSELEY, S75 4LS, UNITED KINGDOM
4: Legally registered address of authorisation holder	GALPHARM INTERNATIONAL LIMITED, WRAFTON, BRAUNTON, EX33 2DL, 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	22/03/2024
9: Annexes attached	Annex 1 and/or Annex 2

### SCOPE OF AUTHORISATION

#### Annex 1

Name and address of the site:

**GALPHARM INTERNATIONAL LIMITED**, ELMHIRST PARK, MIDDLE FIELD ROAD, SILKSTONE, BARNSELEY, S75 4LS, UNITED KINGDOM

Human Medicinal Products
Authorised Operations
MANUFACTURING OPERATIONS (according to part 1) IMPORTATION OF MEDICINAL PRODUCTS (according to part 2)
<b>Part 1 - MANUFACTURING OPERATIONS</b> <b>[ 1.2 ] Non-sterile products</b> [ 1.2.2 ] Batch certification <b>Part 2 - IMPORTATION OF MEDICINAL PRODUCTS</b> <b>[ 2.2 ] Batch certification of imported medicinal products</b> [ 2.2.2 ] Non-sterile products <b>[ 2.3 ] Other Importation Activities</b> [ 2.3.1 ] Site of Physical Importation