Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number UK MIA 35533

2: Name of authorisation holder ASPIRE PHARMA LIMITED

ASPIRE PHARMA LIMITED, UNIT 4, ROTHERBROOK COURT, BEDFORD ROAD, PETERSFIELD, GU32 3QG, UNITED KINGDOM

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

ASPIRE PHARMA LIMITED, SECOND FLOOR, BOSS COURT, 7

BARTON CLOSE, GROVE PARK, LEICESTER, LE19 1SJ, UNITED

KINGDOM

4: Legally registered address of authorisation holder

BEDFORD ROAD, PETERSFIELD, GU32 3QG, 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 30/10/2024

9: Annexes attached Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

ASPIRE PHARMA LIMITED, UNIT 4, ROTHERBROOK COURT, BEDFORD ROAD, PETERSFIELD, GU32 3QG, 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

Issue Date: 30 Oct 2024

SCOPE OF AUTHORISATION

Annex 1

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MHRA: GMDY MHRA

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