Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number

2: Name of authorisation holder

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

4: Legally registered address of authorisation holder

5: Scope of authorisation and dosage forms

6: Legal Basis of authorisation

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

8: Authorisation Date

9: Annexes attached

UK MIA(IMP) 47357

APOLLO PHARMA LIMITED

APOLLO PHARMA LIMITED, UNIT 1, IRWELL WORKS, LOWER WOODHILL ROAD, BURY, BL8 1AA, UNITED KINGDOM

APOLLO PHARMA LIMITED, UNIT 1, IRWELL WORKS, LOWER WOODHILL ROAD, BURY, BL8 1AA, UNITED

KINGDOM

ANNEX 1 and/ or ANNEX 2

Part 6 of The Medicines for Human Use (Clinical Trials)

Regulations 2004 [SI 2004/1031]

Confidential

01/04/2021

Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 2

Name and address of the site:

APOLLO PHARMA LIMITED, UNIT 1, IRWELL WORKS, LOWER WOODHILL ROAD, BURY, BL8 1AA, 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)

[1.2.1.5] Liquids for external use

[1.2.1.6] Liquids for internal use

[1.2.1.8] Other solid dosage forms

[1.2.1.11] Semi-solids

[1.6] Quality control testing

[1.6.3] Chemical/Physical

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