

Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number UK MIA 49690

2: Name of authorisation holder QUEST PHARM LIMITED

3: Address(es) of manufacturing site(s) QUEST PHARM LIMITED, UNIT 5, MOUNT STREET BUSINESS PARK, MOUNT STREET, NECHELLS, BIRMINGHAM, B7 5QU, UNITED KINGDOM

4: Legally registered address of authorisation holder QUEST PHARM LIMITED, UNIT 5, MOUNT STREET BUSINESS PARK, NECHELLS, BIRMINGHAM, B7 5QU, 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 10/09/2018

9: Annexes attached Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

QUEST PHARM LIMITED, UNIT 5, MOUNT STREET BUSINESS PARK, MOUNT STREET, NECHELLS, BIRMINGHAM, B7 5QU, UNITED KINGDOM

Human Medicinal Products
Authorised Operations
MANUFACTURING OPERATIONS (according to part 1)

Part 1 - MANUFACTURING OPERATIONS

[1.2] Non-sterile products

[1.2.1] Non-Sterile Products (processing operations for the following dosage forms)

[1.2.1.6] Liquids for internal use

[1.5] Packaging

[1.5.1] Primary packaging

[1.5.1.6] Liquids for internal use

[1.5.2] Secondary packaging

[1.6] Quality control testing

MHRA-GMDP

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