Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number UK MIA(IMP) 44400

2: Name of authorisation holder L M MANUFACTURING LIMITED

L M MANUFACTURING LIMITED, SANDRETTO BUILDING, CAVALRY

3: Address(es) of manufacturing site(s) HILL INDUSTRIAL PARK, WEEDON, NORTHAMPTON, NN7 4PP,

UNITED KINGDOM

L M MANUFACTURING LIMITED, SANDRETTO BUILDING, CAVALRY

4: Legally registered address of authorisation holder HILL INDUSTRIAL PARK, WEEDON, NORTHAMPTON, NN7 4PP,

UNITED KINGDOM

5: Scope of authorisation and dosage forms ANNEX 1 and/ or ANNEX 2

6: Legal Basis of authorisation

Part 6 of The Medicines for Human Use (Clinical Trials) Regulations 2004

[SI 2004/1031]

7: Name of responsible officer of the competent

authority of the member state granting the

manufacturing authorisation

Confidential

8: Authorisation Date 27/04/2023

9: Annexes attached Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 2

Name and address of the site:

L M MANUFACTURING LIMITED, SANDRETTO BUILDING, CAVALRY HILL INDUSTRIAL PARK, WEEDON, NORTHAMPTON, NN7 4PP, 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)

[1.2.1.6] Liquids for internal use

Special Requirements

Cytotoxic, Cytostatic, Narcotic /Psychotropic materials.

[1.2.2] Batch certification

[1.5] Packaging

Issue Date: 27 Apr 2023

[1.5.1] Primary packaging

[1.5.1.6] Liquids for internal use

[1.5.2] Secondary packaging

[1.6] Quality control testing

[1.6.2] Microbiological: non-sterility

[1.6.3] Chemical/Physical

