# Medicines and Healthcare products Regulatory Agency

# MANUFACTURER'S AUTHORISATION

1: Authorisation Number UK ManA 39427

2: Name of authorisation holder NEMAURA PHARMA LIMITED

NEMAURA PHARMA LIMITED, ADVANCED TECHNOLOGY AND INNOVATION

3: Address(es) of manufacturing site(s) CENTRE, LOUGHBOROUGH UNIVERSITY SCIENCE AND ENTERPRISE PARK, 5

OAKWOOD DRIVE, LOUGHBOROUGH, LE11 3QF, UNITED KINGDOM

4: Legally registered address of authorisation

holder

NEMAURA PHARMA LIMITED, ADVANCED TECHNOLOGY AND INNOVATION CENTRE, LOUGHBOROUGH UNIVERSITY SCIENCE AND ENTERPRISE PARK, 5

OAKWOOD DRIVE, LOUGHBOROUGH, LE11 3QF, UNITED KINGDOM

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

**6: Legal Basis of authorisation** Regulation 5 of the current Veterinary Medicines Regulations

7: Name of responsible officer of the

competent authority of the member state granting the manufacturing authorisation

Confidential

8: Authorisation Date 20/10/2023

**9: Annexes attached** Annex 1 and/or Annex 2

## SCOPE OF AUTHORISATION

#### Annex 1

Name and address of the site:

NEMAURA PHARMA LIMITED, ADVANCED TECHNOLOGY AND INNOVATION CENTRE, LOUGHBOROUGH UNIVERSITY SCIENCE AND ENTERPRISE PARK, 5 OAKWOOD DRIVE, LOUGHBOROUGH, LE11 3QF, UNITED KINGDOM

Veterinary Medicinal Products

**Authorised Operations** 

MANUFACTURING OPERATIONS (according to part 1)

# Part 1 - MANUFACTURING OPERATIONS

1. MANUFACTURING OPERATIONS

### [ 1.1 ] Sterile Products

[ 1.1.1 ] Aseptically prepared (processing operations for the following dosage forms)

[1.1.1.4] Small volume liquids

[1.1.1.5] Solids and implants

[1.1.2] Terminally Sterilised (processing operations for the following dosage forms)

[1.1.2.2] Semi-solids

[1.1.2.3] Small volume liquids

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[1.1.2.4] Solids and implants [ 1.2 ] Non-sterile products [ 1.2.1 ] Non-Sterile Products (processing operations for the following dosage forms) [1.2.1.11] Semi-solids [1.2.1.14] Transdermal patches [ 1.2.1.17 ] Other non-sterile medicinal products Topical gels [ 1.2.2 ] Batch certification [ 1.5 ] Packaging [1.5.1] Primary packaging [ 1.5.1.11 ] Semi-solids [ 1.5.1.14 ] Transdermal patches [ 1.5.1.17 ] Other non-sterile medicinal products Topical gels [ 1.6 ] Quality control testing [ 1.6.2 ] Microbiological: non-sterility [ 1.6.3 ] Chemical/Physical [1.6.4] Biological

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