

Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number	UK ManA 39427
2: Name of authorisation holder	NEMAURA PHARMA LIMITED
3: Address(es) of manufacturing site(s)	NEMAURA PHARMA LIMITED, ADVANCED TECHNOLOGY AND INNOVATION 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)
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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

[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