

# Medicines and Healthcare products Regulatory Agency

## MANUFACTURER'S AUTHORISATION

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| 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

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| Veterinary Medicinal Products  |
| Authorised Operations  |
| MANUFACTURING OPERATIONS (according to part 1)   |
| <b>Part 1 - MANUFACTURING OPERATIONS</b><br>1. MANUFACTURING OPERATIONS<br><b>[ 1.1 ] Sterile Products</b><br>[ 1.1.1 ] Aseptically prepared (processing operations for the following dosage forms)<br>[ 1.1.1.4 ] Small volume liquids<br>[ 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