

# Medicines and Healthcare products Regulatory Agency

## MANUFACTURER'S AUTHORISATION

**1: Authorisation Number** UK MIA 15632

**2: Name of authorisation holder** PHARMAPAC (UK) LIMITED

**3: Address(es) of manufacturing site(s)** PHARMAPAC (UK) LIMITED, UNITS 20 TO 24 AND 29 AND 30, VALLEY ROAD BUSINESS PARK, BIRKENHEAD, CH41 7EL, UNITED KINGDOM

**4: Legally registered address of authorisation holder** PHARMAPAC (UK) LIMITED, UNIT 22, VALLEY ROAD BUSINESS PARK, BIDSTON, WIRRAL, MERSEYSIDE, CH41 7EL, 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** 31/03/2025

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

### SCOPE OF AUTHORISATION

#### Annex 1

Name and address of the site:

**PHARMAPAC (UK) LIMITED**, UNITS 20 TO 24 AND 29 AND 30, VALLEY ROAD BUSINESS PARK, BIRKENHEAD, CH41 7EL, UNITED KINGDOM

|                                                                                                                                                                                                                                                                                                                                                                          |
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| Human Medicinal Products                                                                                                                                                                                                                                                                                                                                                 |
| Authorised Operations                                                                                                                                                                                                                                                                                                                                                    |
| MANUFACTURING OPERATIONS (according to part 1)                                                                                                                                                                                                                                                                                                                           |
| <b>Part 1 - MANUFACTURING OPERATIONS</b><br><b>[ 1.2 ] Non-sterile products</b><br>[ 1.2.1 ] Non-Sterile Products (processing operations for the following dosage forms)<br>[ 1.2.1.8 ] Other solid dosage forms<br>[ 1.2.2 ] Batch certification<br><b>[ 1.4 ] Other products or manufacturing activity</b><br>[ 1.4.1 ] Manufacture of:<br>[ 1.4.1.1 ] Herbal products |

## [ 1.5 ] Packaging

### [ 1.5.1 ] Primary packaging

[ 1.5.1.1 ] Capsules, hard shell

[ 1.5.1.2 ] Capsules, soft shell

[ 1.5.1.3 ] Chewing gums

[ 1.5.1.5 ] Liquids for external use

[ 1.5.1.8 ] Other solid dosage forms

[ 1.5.1.11 ] Semi-solids

[ 1.5.1.12 ] Suppositories

[ 1.5.1.13 ] Tablets

[ 1.5.1.17 ] Other non-sterile medicinal products

Assembly of medical devices, THR blended powder for filling into sachets. Homeopathic powder for filling into sachets

### [ 1.5.2 ] Secondary packaging

#### **Any restrictions or clarifying remarks**

Ointment manufacturing is included to cover cGMP requirements for the Canadian Authority for one product which is classified as a medicinal product in Canada and not a medical device.