

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 17/06/2025

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

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