

# Medicines and Healthcare products Regulatory Agency

## MANUFACTURER'S AUTHORISATION

<b>1: Authorisation Number</b>	UK MIA 12862
<b>2: Name of authorisation holder</b>	RECKITT BENCKISER HEALTHCARE INTERNATIONAL LIMITED RECKITT BENCKISER HEALTHCARE INTERNATIONAL LIMITED, NOTTINGHAM SITE, THANE ROAD, NOTTINGHAM, NG90 2DB, UNITED KINGDOM
<b>3: Address(es) of manufacturing site(s)</b>	PHARMAPAC (UK) LIMITED, UNITS 20 TO 24 AND 29 AND 30, VALLEY ROAD BUSINESS PARK, BIRKENHEAD, CH41 7EL, UNITED KINGDOM  KFM CO-PACKER LIMITED, EAGLE BUSINESS CENTRE, 49 CLEVELAND STREET, HULL, HU8 7AU, UNITED KINGDOM
<b>4: Legally registered address of authorisation holder</b>	RECKITT BENCKISER HEALTHCARE INTERNATIONAL LIMITED, NOTTINGHAM SITE, THANE ROAD, NOTTINGHAM, NG90 2DB, UNITED KINGDOM
<b>5: Scope of authorisation and dosage forms</b>	ANNEX 1 and/ or ANNEX 2
<b>6: Legal Basis of authorisation</b>	Regulation 17 of The Human Medicines Regulations 2012 (SI 2012/1916)
<b>7: Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation</b>	Confidential
<b>8: Authorisation Date</b>	14/11/2024
<b>9: Annexes attached</b>	Annex 1 and/or Annex 2

### SCOPE OF AUTHORISATION

#### Annex 1

Name and address of the site:

**RECKITT BENCKISER HEALTHCARE INTERNATIONAL LIMITED**, NOTTINGHAM SITE, THANE ROAD, NOTTINGHAM, NG90 2DB,  
UNITED KINGDOM

Human Medicinal Products
Authorised Operations
MANUFACTURING OPERATIONS (according to part 1) IMPORTATION OF MEDICINAL PRODUCTS (according to part 2)
<b>Part 1 - MANUFACTURING OPERATIONS</b>

**[ 1.1 ] Sterile Products**

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

[ 1.1.1.1 ] Large volume liquids

[ 1.1.1.4 ] Small volume liquids

[ 1.1.3 ] Batch certification

**[ 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

[ 1.2.1.13 ] Tablets

[ 1.2.1.17 ] Other non-sterile medicinal products

Medicated Lozenges

[ 1.2.2 ] Batch certification

**[ 1.4 ] Other products or manufacturing activity**

[ 1.4.2 ] Sterilisation of active substances/excipients/finished products:

[ 1.4.2.1 ] Filtration

**[ 1.5 ] Packaging**

[ 1.5.1 ] Primary packaging

[ 1.5.1.2 ] Capsules, soft shell

[ 1.5.1.17 ] Other non-sterile medicinal products

Solid non-sterile unit dosage forms: capsules. Medicated Lozenges

[ 1.5.2 ] Secondary packaging

**[ 1.6 ] Quality control testing**

[ 1.6.1 ] Microbiological: sterility

[ 1.6.2 ] Microbiological: non-sterility

[ 1.6.3 ] Chemical/Physical

**Part 2 - IMPORTATION OF MEDICINAL PRODUCTS**

**[ 2.1 ] Quality control testing of imported medicinal products**

[ 2.1.2 ] Microbiological: non-sterility

[ 2.1.3 ] Chemical/Physical

**[ 2.2 ] Batch certification of imported medicinal products**

[ 2.2.1 ] Sterile Products

[ 2.2.1.1 ] Aseptically prepared

[ 2.2.2 ] Non-sterile products

**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**

**[ 1.5 ] Packaging**

[ 1.5.1 ] Primary packaging

[ 1.5.1.2 ] Capsules, soft shell

[ 1.5.1.8 ] Other solid dosage forms

[ 1.5.2 ] Secondary packaging

**SCOPE OF AUTHORISATION**

**Annex 1**

Name and address of the site:

**KFM CO-PACKER LIMITED**, EAGLE BUSINESS CENTRE, 49 CLEVELAND STREET, HULL, HU8 7AU, UNITED KINGDOM

Human Medicinal Products

Authorised Operations

MANUFACTURING OPERATIONS (according to part 1)

**Part 1 - MANUFACTURING OPERATIONS**

**[ 1.5 ] Packaging**

[ 1.5.2 ] Secondary packaging