

# Medicines and Healthcare products Regulatory Agency

## MANUFACTURER'S AUTHORISATION

**1: Authorisation Number** UK MIA 327

**2: Name of authorisation holder** CROOKES HEALTHCARE LIMITED

**3: Address(es) of manufacturing site(s)** RECKITT BENCKISER HEALTHCARE INTERNATIONAL LIMITED,  
NOTTINGHAM SITE, THANE ROAD, NOTTINGHAM, NG90 2DB,  
UNITED KINGDOM

**4: Legally registered address of authorisation holder** CROOKES HEALTHCARE LIMITED, THANE ROAD,  
NOTTINGHAM, NG90 2DB, 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** 06/03/2018

**9: Annexes attached** 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> <b>[ 1.1 ] Sterile Products</b> [ 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 <b>[ 1.2 ] Non-sterile products</b> [ 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

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

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

[ 1.4.2.1 ] Filtration

[ 1.4.2.2 ] Dry heat

[ 1.4.2.3 ] Moist heat

**[ 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-dose forms-capsules

[ 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**

[ 2.1.1 ] Microbiological: sterility

[ 2.1.2 ] Microbiological: non-sterility

[ 2.1.3 ] Chemical/Physical

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

[ 2.2.2 ] Non-sterile products