

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)
Part 1 - MANUFACTURING OPERATIONS [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 [1.2] 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

[1.4] 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