

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