

Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number UK MIA(IMP) 63

2: Name of authorisation holder RECKITT BENCKISER HEALTHCARE (UK) LIMITED

3: Address(es) of manufacturing site(s) RECKITT BENCKISER HEALTHCARE (UK) LIMITED,
DANSOM LANE, HULL, HU8 7DS, UNITED KINGDOM

4: Legally registered address of authorisation holder RECKITT BENCKISER HEALTHCARE (UK) LIMITED,
DANSOM LANE, HULL, HU8 7DS, UNITED KINGDOM

5: Scope of authorisation and dosage forms ANNEX 1 and/ or ANNEX 2

6: Legal Basis of authorisation Part 6 of The Medicines for Human Use (Clinical Trials)
Regulations 2004 [SI 2004/1031]

7: Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation Confidential

8: Authorisation Date 02/12/2024

9: Annexes attached Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 2

Name and address of the site:

RECKITT BENCKISER HEALTHCARE (UK) LIMITED, DANSOM LANE, HULL, HU8 7DS, UNITED KINGDOM

Human Investigational 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 Investigational Medicinal Products [1.1.3] Batch certification [1.2] Non-sterile investigational medicinal products [1.2.1] Non-Sterile Products (processing operations for the following dosage forms) [1.2.1.1] Capsules, hard shell [1.2.1.3] Chewing gums [1.2.1.5] Liquids for external use [1.2.1.6] Liquids for internal use [1.2.1.8] Other solid dosage forms

- [1.2.1.11] Semi-solids
- [1.2.1.13] Tablets
- [1.2.1.15] Other non-sterile medicinal products
- Powders

- [1.2.2] Batch certification

[1.4] Other investigational medicinal products or manufacturing activity

- [1.4.1] Manufacture of:
 - [1.4.1.3] Other
 - Standardised Senna

[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
 - [1.5.1.6] Liquids for internal use
 - [1.5.1.8] Other solid dosage forms
 - [1.5.1.11] Semi-solids
 - [1.5.1.13] Tablets
 - [1.5.1.15] Other non-sterile medicinal products
 - Powder and Granules
- [1.5.2] Secondary packaging

[1.6] Quality control testing

- [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
 - [2.2.1.2] Terminally sterilised
- [2.2.2] Non-sterile products

[2.3] Other Importation Activities

- [2.3.1] Site of Physical Importation
- [2.3.2] Importation of Intermediate which undergoes further processing