

Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number UK MIA 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 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 28/04/2025

9: Annexes attached Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

RECKITT BENCKISER HEALTHCARE (UK) LIMITED, DANSOM LANE, HULL, HU8 7DS, 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 [1.2] Non-sterile products [1.2.1] Non-Sterile Products (processing operations for the following dosage forms) [1.2.1.1] Capsules, hard shell [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 [1.2.2] Batch certification

[1.4] Other products or manufacturing activity

[1.4.1] Manufacture of:

[1.4.1.3] Other

1) Standardised Senna, 2) Isphagula sphagula Husk, Powdered

[1.5] Packaging

[1.5.1] Primary packaging

[1.5.1.1] Capsules, hard shell

[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

[1.5.2] 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

[2.2.2] Non-sterile products