

Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number UK MIA 1883

2: Name of authorisation holder MACARTHYS LABORATORIES LIMITED

3: Address(es) of manufacturing site(s) MACARTHYS LABORATORIES LIMITED T/A MARTINDALE PHARMA, BAMPTON ROAD, HAROLD HILL, ROMFORD, RM3 8UG, UNITED KINGDOM

4: Legally registered address of authorisation holder MACARTHYS LABORATORIES LIMITED, MERCURY PARK, WYCOMBE LANE, WOOBURN GREEN, HIGH WYCOMBE, HP10 0HH, UNITED KINGDOM

5: Scope of authorisation and dosage forms MACARTHYS LABORATORIES LIMITED T/A MARTINDALE PHARMA, HUBERT ROAD, BRENTWOOD, CM14 4JY, UNITED KINGDOM

6: Legal Basis of authorisation ANNEX 1 and/ or ANNEX 2

7: Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation Regulation 17 of The Human Medicines Regulations 2012 (SI 2012/1916)

8: Authorisation Date Confidential

9: Annexes attached 29/01/2025

Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

MACARTHYS LABORATORIES LIMITED T/A MARTINDALE PHARMA, BAMPTON ROAD, HAROLD HILL, ROMFORD, RM3 8UG, 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)
 - [1.1.1.4] Small volume liquids
- [1.1.2] Terminally Sterilised (processing operations for the following dosage forms)
 - [1.1.2.3] Small volume liquids
- [1.1.3] Batch certification

[1.2] Non-sterile products

- [1.2.1] Non-Sterile Products (processing operations for the following dosage forms)
 - [1.2.1.5] Liquids for external use
 - [1.2.1.6] Liquids for internal use
- [1.2.2] Batch certification

[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
 - [1.5.1.5] Liquids for external use
 - [1.5.1.6] Liquids for internal use
- [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

SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

MACARTHYS LABORATORIES LIMITED, MERCURY PARK, WYCOMBE LANE, WOOBURN GREEN, HIGH WYCOMBE, HP10 0HH,
UNITED KINGDOM

Human Medicinal Products

Authorised Operations
MANUFACTURING OPERATIONS (according to part 1)

Part 1 - MANUFACTURING OPERATIONS [1.1] Sterile Products [1.1.3] Batch certification [1.2] Non-sterile products [1.2.2] Batch certification
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SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

MACARTHYS LABORATORIES LIMITED T/A MARTINDALE PHARMA, HUBERT ROAD, BRENTWOOD, CM14 4JY, UNITED KINGDOM

Human Medicinal Products

Authorised Operations
IMPORTATION OF MEDICINAL PRODUCTS (according to part 2)

Part 2 - IMPORTATION OF MEDICINAL PRODUCTS [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
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