

Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number UK MIA(IMP) 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, BAMPTON ROAD, HAROLD HILL, ROMFORD, RM3 8UG, 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 26/07/2024

9: Annexes attached Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 2

Name and address of the site:

MACARTHYS LABORATORIES LIMITED T/A MARTINDALE PHARMA, BAMPTON ROAD, HAROLD HILL, ROMFORD, RM3 8UG, UNITED KINGDOM

Human Investigational Medicinal Products
Authorised Operations
MANUFACTURING OPERATIONS (according to part 1)
Part 1 - MANUFACTURING OPERATIONS [1.1] Sterile Investigational Medicinal Products [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 investigational medicinal products [1.2.1] Non-Sterile Products (processing operations for the following dosage forms) [1.2.1.6] Liquids for internal use [1.2.2] Batch certification

[1.4] Other investigational medicinal products or manufacturing activity

[1.4.2] Sterilisation of active substances/excipients/finished products:

[1.4.2.3] Moist heat

[1.5] Packaging

[1.5.1] Primary packaging

[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