Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

UK MIA 28255 1: Authorisation Number

RUTLAND BIODYNAMICS LIMITED 2: Name of authorisation holder

RUTLAND BIODYNAMICS LIMITED, TOWN PARK FARM, OAKHAM ROAD, BROOKE, OAKHAM, LE15 8DG, UNITED 3: Address(es) of manufacturing site(s)

KINGDOM

RUTLAND BIODYNAMICS LIMITED, TOWN PARK FARM, 4: Legally registered address of authorisation holder

OAKHAM ROAD, BROOKE, OAKHAM, LE15 8DG, UNITED

KINGDOM

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

Regulation 17 of The Human Medicines Regulations 2012 (SI 6: Legal Basis of authorisation

2012/1916)

7: Name of responsible officer of the competent authority of the

member state granting the manufacturing authorisation

Confidential

8: Authorisation Date 23/04/2024

9: Annexes attached Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

RUTLAND BIODYNAMICS LIMITED, TOWN PARK FARM, OAKHAM ROAD, BROOKE, OAKHAM, LE15 8DG, 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

[1.1.3] 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

[1.2.1.11] Semi-solids

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[1.2.2] Batch certification [1.4] Other products or manufacturing activity [1.4.1] Manufacture of: [1.4.1.1] Herbal products [1.4.1.3] Other Manufacture API's [1.5] Packaging [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

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