

Medicines and Healthcare products Regulatory Agency

REGISTRATION OF MANUFACTURER, IMPORTER OR DISTRIBUTOR OF ACTIVE SUBSTANCES TO BE USED AS STARTING MATERIALS IN MEDICINAL PRODUCTS FOR HUMAN USE

Registrant Details

1. Registration Number
UK API 28255
2. Name or corporate name of registrant
RUTLAND BIODYNAMICS LIMITED
3. Permanent or legal address of registrant
RUTLAND BIODYNAMICS LIMITED, TOWN PARK FARM, OAKHAM
ROAD, BROOKE, OAKHAM, LE15 8DG, UNITED KINGDOM
4. Address(es) of site(s) where registered activities take place
RUTLAND BIODYNAMICS LIMITED, TOWN PARK FARM, OAKHAM
ROAD, BROOKE, OAKHAM, LE15 8DG, UNITED KINGDOM
5. National legal basis of registration
Regulation 327 of The Human Medicines Regulations 2012 (SI 2012/1916)
6. Name of responsible officer of the competent authority
of the member state validating the registration
Confidential
7. Date
17/04/2024

This registration form is valid only when presented with all pages. The authenticity of this registration form may be verified in MHRA-GMDP.

The registration holder referred to in section 2 shall communicate annually to the competent authority an inventory of the changes which have taken place as regards the information provided in this registration form. Any changes that may have an impact on the quality or safety of the listed active substances must be notified immediately.

SCOPE OF REGISTRATION

Name and address of the site

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

1. MANUFACTURING OPERATIONS

Active substance

SCUTELLARIA LATERIFLORA
2000012996

B	Extraction of Active Substance from Natural Sources
	B.1 Plant Source Extraction
E	General Finishing Steps

	E.1 Physical Processing Steps Adjustment to final specification
	E.2 Primary Packaging
	E.3 Secondary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing
	F.2 Microbiological testing (excluding sterility testing)

Active substance

HYPERICUM PERFORATUM

2000011927

B	Extraction of Active Substance from Natural Sources
	B.1 Plant Source Extraction
E	General Finishing Steps
	E.1 Physical Processing Steps Adjustment to final specification
	E.2 Primary Packaging
	E.3 Secondary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing
	F.2 Microbiological testing (excluding sterility testing)

Active substance

DRIMIA INDICA

1000007667

B	Extraction of Active Substance from Natural Sources
	B.1 Plant Source Extraction
E	General Finishing Steps
	E.1 Physical Processing Steps Adjustment to final specification
	E.2 Primary Packaging
	E.3 Secondary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing

	F.2 Microbiological testing (excluding sterility testing)
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Active substance

PASSIFLORA INCARNATA

2000012458

B	Extraction of Active Substance from Natural Sources
	B.1 Plant Source Extraction
E	General Finishing Steps
	E.1 Physical Processing Steps Adjustment to final specification
	E.2 Primary Packaging
	E.3 Secondary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing
	F.2 Microbiological testing (excluding sterility testing)

Active substance

FUCUS VESICULOSUS

2000011728

B	Extraction of Active Substance from Natural Sources
	B.1 Plant Source Extraction
E	General Finishing Steps
	E.1 Physical Processing Steps Adjustment to final specification
	E.2 Primary Packaging
	E.3 Secondary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing
	F.2 Microbiological testing (excluding sterility testing)

Active substance

GUAREA RUSBYI

2000011388

B	Extraction of Active Substance from Natural Sources
	B.1 Plant Source Extraction

E	General Finishing Steps
	E.1 Physical Processing Steps Adjustment to final specification
	E.2 Primary Packaging
	E.3 Secondary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing
	F.2 Microbiological testing (excluding sterility testing)

Active substance

BELLADONNA TINCTURE

2000008372

E	General Finishing Steps
	E.1 Physical Processing Steps Mix Phenol and water. Adjust to final specification
	E.2 Primary Packaging
	E.3 Secondary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing
	F.2 Microbiological testing (excluding sterility testing)

Active substance

MELISSA OFFICINALIS QUANTIFIED DRY EXTRACT

4000011423

B	Extraction of Active Substance from Natural Sources
	B.1 Plant Source Extraction
E	General Finishing Steps
	E.1 Physical Processing Steps Adjustment to final specification
	E.2 Primary Packaging
	E.3 Secondary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing
	F.2 Microbiological testing (excluding sterility testing)

Active substance

EPHEDRINE

1000002754

E	General Finishing Steps
	E.1 Physical Processing Steps Mix Phenol and water. Adjust to final specification
	E.2 Primary Packaging
	E.3 Secondary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing
	F.2 Microbiological testing (excluding sterility testing)

Active substance

LIQUIFIED PHENOL

2000008503

E	General Finishing Steps
	E.1 Physical Processing Steps Mix Phenol and water. Adjust to final specification
	E.2 Primary Packaging
	E.3 Secondary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing
	F.2 Microbiological testing (excluding sterility testing)

Active substance

TOLU FLAVOUR

1000004861

E	General Finishing Steps
	E.1 Physical Processing Steps Adjustment to final specification
	E.2 Primary Packaging
	E.3 Secondary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing
	F.2 Microbiological testing (excluding sterility testing)

Active substance

COAL TAR SOLUTION

2000011380

B	Extraction of Active Substance from Natural Sources
	B.4 Mineral Source Extraction
E	General Finishing Steps
	E.1 Physical Processing Steps Solvation
	E.2 Primary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing
	F.2 Microbiological testing (excluding sterility testing)

Active substance

POLYGALA SENEGA ROOT

4000014427

B	Extraction of Active Substance from Natural Sources
	B.1 Plant Source Extraction
E	General Finishing Steps
	E.1 Physical Processing Steps Adjustment to final specification
	E.2 Primary Packaging
	E.3 Secondary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing
	F.2 Microbiological testing (excluding sterility testing)

Active substance

COAL TAR SOLUTION STRONG

4000014216

B	Extraction of Active Substance from Natural Sources
	B.4 Mineral Source Extraction
E	General Finishing Steps
	E.1 Physical Processing Steps Solvation

	E.2 Primary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing
	F.2 Microbiological testing (excluding sterility testing)

Active substance

MATRICARIA CHAMOMILLA FLOWERS
4000014429

B	Extraction of Active Substance from Natural Sources
	B.1 Plant Source Extraction
E	General Finishing Steps
	E.1 Physical Processing Steps Adjustment to final specification
	E.2 Primary Packaging
	E.3 Secondary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing
	F.2 Microbiological testing (excluding sterility testing)

Active substance

BOSWELLIA SERRATA EXTRACT
1000019859

B	Extraction of Active Substance from Natural Sources
	B.1 Plant Source Extraction
	B.5 Modification of Extracted Substance
E	General Finishing Steps
	E.1 Physical Processing Steps Solvation
	E.2 Primary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing
	F.2 Microbiological testing (excluding sterility testing)

Active substance

CHLOROFORM AND MORPHINE TINCTURE

3000004780

B	Extraction of Active Substance from Natural Sources
	B.1 Plant Source Extraction
	B.5 Modification of Extracted Substance
E	General Finishing Steps
	E.1 Physical Processing Steps Solvation
	E.2 Primary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing
	F.2 Microbiological testing (excluding sterility testing)

Active substance

INULA HELENIUM ROOT

4000014425

B	Extraction of Active Substance from Natural Sources
	B.1 Plant Source Extraction
E	General Finishing Steps
	E.1 Physical Processing Steps Adjustment to final specification
	E.2 Primary Packaging
	E.3 Secondary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing
	F.2 Microbiological testing (excluding sterility testing)

Active substance

ECHINACEA

1000006672

B	Extraction of Active Substance from Natural Sources
	B.1 Plant Source Extraction
E	General Finishing Steps
	E.1 Physical Processing Steps Adjustment to final specification

	E.2 Primary Packaging
	E.3 Secondary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing
	F.2 Microbiological testing (excluding sterility testing)

Active substance

LOBELIA INFLATA

1000007633

B	Extraction of Active Substance from Natural Sources
	B.1 Plant Source Extraction
E	General Finishing Steps
	E.1 Physical Processing Steps Adjustment to final specification
	E.2 Primary Packaging
	E.3 Secondary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing
	F.2 Microbiological testing (excluding sterility testing)

Active substance

VERBENA OFFICINALIS HERB

4000014428

B	Extraction of Active Substance from Natural Sources
	B.1 Plant Source Extraction
E	General Finishing Steps
	E.1 Physical Processing Steps Adjustment to final specification
	E.2 Primary Packaging
	E.3 Secondary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing
	F.2 Microbiological testing (excluding sterility testing)

Active substance

GLYCYRRHIZA GLABRA ROOT
4000013679

B	Extraction of Active Substance from Natural Sources
	B.1 Plant Source Extraction
E	General Finishing Steps
	E.1 Physical Processing Steps Adjustment to final specification
	E.2 Primary Packaging
	E.3 Secondary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing
	F.2 Microbiological testing (excluding sterility testing)

Active substance
TOLU-FLAVOUR SOLUTION
2000004001

E	General Finishing Steps
	E.1 Physical Processing Steps Adjustment to final specification
	E.2 Primary Packaging
	E.3 Secondary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing
	F.2 Microbiological testing (excluding sterility testing)

Active substance
ARCTIUM LAPPA ROOT
4000014422

B	Extraction of Active Substance from Natural Sources
	B.1 Plant Source Extraction
E	General Finishing Steps
	E.1 Physical Processing Steps Adjustment to final specification
	E.2 Primary Packaging
	E.3 Secondary Packaging

F	Quality Control Testing
	F.1 Physical / Chemical testing
	F.2 Microbiological testing (excluding sterility testing)

Active substance

TOLU BALSAM SYRUP

1000009310

B	Extraction of Active Substance from Natural Sources
	B.1 Plant Source Extraction
E	General Finishing Steps
	E.1 Physical Processing Steps Adjustment to final specification
	E.2 Primary Packaging
	E.3 Secondary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing
	F.2 Microbiological testing (excluding sterility testing)

Active substance

RHEUM PALMATUM

2000012870

B	Extraction of Active Substance from Natural Sources
	B.1 Plant Source Extraction
E	General Finishing Steps
	E.1 Physical Processing Steps Adjustment to final specification
	E.2 Primary Packaging
	E.3 Secondary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing
	F.2 Microbiological testing (excluding sterility testing)

Active substance

COCILLANA EXTRACT

4000009543

B	Extraction of Active Substance from Natural Sources
	B.1 Plant Source Extraction
E	General Finishing Steps
	E.1 Physical Processing Steps Adjustment to final specification
	E.2 Primary Packaging
	E.3 Secondary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing
	F.2 Microbiological testing (excluding sterility testing)

Active substance

CIMICIFUGA RACEMOSA

2000011320

B	Extraction of Active Substance from Natural Sources
	B.1 Plant Source Extraction
E	General Finishing Steps
	E.1 Physical Processing Steps Adjustment to final specification
	E.2 Primary Packaging
	E.3 Secondary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing
	F.2 Microbiological testing (excluding sterility testing)

Active substance

COMMIPHORA MYRRHA RESIN

4000014423

B	Extraction of Active Substance from Natural Sources
	B.1 Plant Source Extraction
E	General Finishing Steps
	E.1 Physical Processing Steps Adjustment to final specification
	E.2 Primary Packaging

	E.3 Secondary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing
	F.2 Microbiological testing (excluding sterility testing)

Active substance

MARRUBIUM VULGARE HERB

4000014430

B	Extraction of Active Substance from Natural Sources
	B.1 Plant Source Extraction
E	General Finishing Steps
	E.1 Physical Processing Steps Adjustment to final specification
	E.2 Primary Packaging
	E.3 Secondary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing
	F.2 Microbiological testing (excluding sterility testing)

Active substance

BAPTISIA TINCTORIA

1000006597

B	Extraction of Active Substance from Natural Sources
	B.1 Plant Source Extraction
E	General Finishing Steps
	E.1 Physical Processing Steps Adjustment to final specification
	E.2 Primary Packaging
	E.3 Secondary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing
	F.2 Microbiological testing (excluding sterility testing)

Active substance

TOLU BALSAM SOLUTION

4000010509

B	Extraction of Active Substance from Natural Sources
	B.1 Plant Source Extraction
E	General Finishing Steps
	E.1 Physical Processing Steps Adjustment to final specification
	E.2 Primary Packaging
	E.3 Secondary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing
	F.2 Microbiological testing (excluding sterility testing)

Active substance

FUMARIA OFFICINALIS HERB

4000014424

B	Extraction of Active Substance from Natural Sources
	B.1 Plant Source Extraction
E	General Finishing Steps
	E.1 Physical Processing Steps Adjustment to final specification
	E.2 Primary Packaging
	E.3 Secondary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing
	F.2 Microbiological testing (excluding sterility testing)

Active substance

VITEX AGNUS-CASTUS FRUIT

4000014432

B	Extraction of Active Substance from Natural Sources
	B.1 Plant Source Extraction
E	General Finishing Steps
	E.1 Physical Processing Steps Adjustment to final specification

	E.2 Primary Packaging
	E.3 Secondary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing
	F.2 Microbiological testing (excluding sterility testing)

Active substance

HYSSOPUS OFFICINALIS HERB

3000018457

B	Extraction of Active Substance from Natural Sources
	B.1 Plant Source Extraction
E	General Finishing Steps
	E.1 Physical Processing Steps Adjustment to final specification
	E.2 Primary Packaging
	E.3 Secondary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing
	F.2 Microbiological testing (excluding sterility testing)

Active substance

CAMPHORATED OPIUM TINCTURE

1000006847

B	Extraction of Active Substance from Natural Sources
	B.1 Plant Source Extraction
	B.5 Modification of Extracted Substance
E	General Finishing Steps
	E.1 Physical Processing Steps Solvation
	E.2 Primary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing
	F.2 Microbiological testing (excluding sterility testing)

Active substance

PREPARED COAL TAR
2000007910

B	Extraction of Active Substance from Natural Sources
	B.4 Mineral Source Extraction
E	General Finishing Steps
	E.1 Physical Processing Steps Solvation
	E.2 Primary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing
	F.2 Microbiological testing (excluding sterility testing)

Active substance
OPIUM TINCTURE
2000008161

B	Extraction of Active Substance from Natural Sources
	B.1 Plant Source Extraction
	B.5 Modification of Extracted Substance
E	General Finishing Steps
	E.1 Physical Processing Steps Solvation
	E.2 Primary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing
	F.2 Microbiological testing (excluding sterility testing)

Active substance
TOLU BALSAM TINCTURE
4000010511

B	Extraction of Active Substance from Natural Sources
	B.1 Plant Source Extraction
E	General Finishing Steps
	E.1 Physical Processing Steps Adjustment to final specification
	E.2 Primary Packaging

	E.3 Secondary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing
	F.2 Microbiological testing (excluding sterility testing)

Active substance

COCILLANA LIQUID EXTRACT
4000009545

B	Extraction of Active Substance from Natural Sources
	B.1 Plant Source Extraction
E	General Finishing Steps
	E.1 Physical Processing Steps Adjustment to final specification
	E.2 Primary Packaging
	E.3 Secondary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing
	F.2 Microbiological testing (excluding sterility testing)

Active substance

AVENA SATIVA
1000009783

B	Extraction of Active Substance from Natural Sources
	B.1 Plant Source Extraction
E	General Finishing Steps
	E.1 Physical Processing Steps Adjustment to final specification
	E.2 Primary Packaging
	E.3 Secondary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing
	F.2 Microbiological testing (excluding sterility testing)

Active substance

THYMUS SERPYLLUM HERB

4000014431

B	Extraction of Active Substance from Natural Sources
	B.1 Plant Source Extraction
E	General Finishing Steps
	E.1 Physical Processing Steps Adjustment to final specification
	E.2 Primary Packaging
	E.3 Secondary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing
	F.2 Microbiological testing (excluding sterility testing)

Active substance

PAEONIA LACTIFLORA UNPEELED ROOT

4000014426

B	Extraction of Active Substance from Natural Sources
	B.1 Plant Source Extraction
E	General Finishing Steps
	E.1 Physical Processing Steps Adjustment to final specification
	E.2 Primary Packaging
	E.3 Secondary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing
	F.2 Microbiological testing (excluding sterility testing)

Active substance

ANISE OIL

4000010114

B	Extraction of Active Substance from Natural Sources
	B.1 Plant Source Extraction
E	General Finishing Steps
	E.2 Primary Packaging
F	Quality Control Testing

	F.1 Physical / Chemical testing
	F.2 Microbiological testing (excluding sterility testing)

Active substance

CARAPICHEA IPECACUANHA ROOT

2000017650

B	Extraction of Active Substance from Natural Sources
	B.1 Plant Source Extraction
E	General Finishing Steps
	E.1 Physical Processing Steps Adjustment to final specification
	E.2 Primary Packaging
	E.3 Secondary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing
	F.2 Microbiological testing (excluding sterility testing)

Active substance

VALERIANA OFFICINALIS ROOT

2000016573

B	Extraction of Active Substance from Natural Sources
	B.1 Plant Source Extraction
E	General Finishing Steps
	E.1 Physical Processing Steps Adjustment to final specification
	E.2 Primary Packaging
	E.3 Secondary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing
	F.2 Microbiological testing (excluding sterility testing)

2. IMPORTATION AND DISTRIBUTION OPERATIONS

B Distribution

SCUTELLARIA LATERIFLORA (2000012996)

HYPERICUM PERFORATUM (2000011927)

DRIMIA INDICA (1000007667)

PASSIFLORA INCARNATA (2000012458)
FUCUS VESICULOSUS (2000011728)
GUAREA RUSBYI (2000011388)
BELLADONNA TINCTURE (2000008372)
MELISSA OFFICINALIS QUANTIFIED DRY EXTRACT (4000011423)
EPHEDRINE (1000002754)
LIQUIFIED PHENOL (2000008503)
TOLU FLAVOUR (1000004861)
COAL TAR SOLUTION (2000011380)
POLYGALA SENEGA ROOT (4000014427)
COAL TAR SOLUTION STRONG (4000014216)
MATRICARIA CHAMOMILLA FLOWERS (4000014429)
BOSWELLIA SERRATA EXTRACT (1000019859)
CHLOROFORM AND MORPHINE TINCTURE (3000004780)
INULA HELENIUM ROOT (4000014425)
ECHINACEA (1000006672)
LOBELIA INFLATA (1000007633)
VERBENA OFFICINALIS HERB (4000014428)
GLYCYRRHIZA GLABRA ROOT (4000013679)
TOLU-FLAVOUR SOLUTION (2000004001)
ARCTIUM LAPPA ROOT (4000014422)
TOLU BALSAM SYRUP (1000009310)
RHEUM PALMATUM (2000012870)
COCILLANA EXTRACT (4000009543)
CIMICIFUGA RACEMOSA (2000011320)
COMMIPHORA MYRRHA RESIN (4000014423)
MARRUBIUM VULGARE HERB (4000014430)
BAPTISIA TINCTORIA (1000006597)
TOLU BALSAM SOLUTION (4000010509)
FUMARIA OFFICINALIS HERB (4000014424)
VITEX AGNUS-CASTUS FRUIT (4000014432)
HYSSOPUS OFFICINALIS HERB (3000018457)
CAMPHORATED OPIUM TINCTURE (1000006847)
PREPARED COAL TAR (2000007910)
OPIUM TINCTURE (2000008161)
TOLU BALSAM TINCTURE (4000010511)
COCILLANA LIQUID EXTRACT (4000009545)
AVENA SATIVA (1000009783)
THYMUS SERPYLLUM HERB (4000014431)
PAEONIA LACTIFLORA UNPEELED ROOT (4000014426)
ANISE OIL (4000010114)

CARAPICHEA IPECACUANHA ROOT (2000017650)

VALERIANA OFFICINALIS ROOT (2000016573)

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