

# 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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