

Medicines and Healthcare products Regulatory Agency

CERTIFICATE NUMBER : UK API 28255 Insp GMP 28255/123039-0013

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER(1),(2)

Part 1

Issued following an inspection in accordance with :
Regulation 331A of The Human Medicines Regulations 2012 (SI 2012/1916)

The competent authority of United Kingdom confirms the following :

The Manufacturer : RUTLAND BIODYNAMICS LIMITED

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

Is an active substance manufacturer that has been inspected in accordance with Regulation 327 of The Human Medicines Regulations 2012 (SI 2012/1916).

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on 31/08/2023 , it is considered that it complies with

- The principles of GMP for active substances referred to in Regulation B17 and C17 of the Human Medicines Regulations 2012 (SI 2012/1916)

This certificate reflects the status of the manufacturing site at the time of the inspection noted above and should not be relied upon to reflect the compliance status if more than three years have elapsed since the date of that inspection. However, this period of validity may be reduced or extended using regulatory risk management principles by an entry in the Restrictions or Clarifying remarks field. This certificate is valid only when presented with all pages and both Parts 1 and 2. The authenticity of this certificate may be verified in MHRA-GMDP. If it does not appear, please contact the issuing authority.

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- (1) *Guidance on the interpretation of this template can be found in the Help menu of MHRA-GMDP database.*
 - (2) *These requirements fulfil the GMP recommendations of WHO.*

Part 2

Human Medicinal Products

Manufacture of active substance. Names of substances subject to inspection :

- [3000018457] HYSSOPUS OFFICINALIS HERB
- [4000009543] COCILLANA EXTRACT
- [4000014422] ARCTIUM LAPPA ROOT
- [4000013679] GLYCYRRHIZA GLABRA ROOT
- [2000017650] CARAPICHEA IPECACUANHA ROOT
- [2000007910] PREPARED COAL TAR

- [4000014424] FUMARIA OFFICINALIS HERB
- [1000002754] EPHEDRINE
- [2000012996] SCUTELLARIA LATERIFLORA
- [1000007667] DRIMIA INDICA
- [1000004861] TOLU FLAVOUR
- [4000014430] MARRUBIUM VULGARE HERB
- [4000014429] MATRICARIA CHAMOMILLA FLOWERS
- [1000006847] CAMPHORATED OPIUM TINCTURE
- [3000004780] CHLOROFORM AND MORPHINE TINCTURE
- [2000011728] FUCUS VESICULOSUS
- [4000014427] POLYGALA SENEGA ROOT
- [4000014432] VITEX AGNUS-CASTUS FRUIT
- [2000011380] COAL TAR SOLUTION
- [4000014426] PAEONIA LACTIFLORA UNPEELED ROOT
- [4000014425] INULA HELENIUM ROOT
- [2000012458] PASSIFLORA INCARNATA
- [2000011388] GUAREA RUSBYI
- [2000016573] VALERIANA OFFICINALIS ROOT
- [2000012870] RHEUM PALMATUM
- [1000009783] AVENA SATIVA
- [1000006672] ECHINACEA
- [2000008503] LIQUIFIED PHENOL
- [4000011423] MELISSA OFFICINALIS QUANTIFIED DRY EXTRACT
- [2000011320] CIMICIFUGA RACEMOSA
- [2000008372] BELLADONNA TINCTURE
- [4000014216] COAL TAR SOLUTION STRONG
- [1000007633] LOBELIA INFLATA
- [4000014428] VERBENA OFFICINALIS HERB
- [2000008161] OPIUM TINCTURE
- [4000014423] COMMIPHORA MYRRHA RESIN
- [1000019859] BOSWELLIA SERRATA EXTRACT
- [1000006597] BAPTISIA TINCTORIA
- [4000010509] TOLU BALSAM SOLUTION
- [4000009545] COCILLANA LIQUID EXTRACT
- [4000010511] TOLU BALSAM TINCTURE
- [4000014431] THYMUS SERPYLLUM HERB
- [2000004001] TOLU-FLAVOUR SOLUTION
- [1000009310] TOLU BALSAM SYRUP
- [4000010114] ANISE OIL
- [2000011927] HYPERICUM PERFORATUM

3. MANUFACTURING OPERATIONS - ACTIVE SUBSTANCES

HYSSOPUS OFFICINALIS HERB

3.2 Processing Activities of Active Substance from Natural Sources

3.2.1 Plant Source Extraction

3.5 General Finishing Steps

3.5.1 Physical Processing Steps

Adjustment to final specification

3.5.2 Primary Packaging

3.5.3 Secondary Packaging

3.6 Quality Control Testing

3.6.1 Physical / Chemical testing

3.6.2 Microbiological testing (excluding sterility testing)

COCILLANA EXTRACT

3.2 Processing Activities of Active Substance from Natural Sources

3.2.1 Plant Source Extraction

3.5 General Finishing Steps

3.5.1 Physical Processing Steps
Adjustment to final specification

3.5.2 Primary Packaging

3.5.3 Secondary Packaging

3.6 Quality Control Testing

3.6.1 Physical / Chemical testing

3.6.2 Microbiological testing (excluding sterility testing)

ARCTIUM LAPPA ROOT

3.2 Processing Activities of Active Substance from Natural Sources

3.2.1 Plant Source Extraction

3.5 General Finishing Steps

3.5.1 Physical Processing Steps
Adjustment to final specification

3.5.2 Primary Packaging

3.5.3 Secondary Packaging

3.6 Quality Control Testing

3.6.1 Physical / Chemical testing

3.6.2 Microbiological testing (excluding sterility testing)

GLYCYRRHIZA GLABRA ROOT

3.2 Processing Activities of Active Substance from Natural Sources

3.2.1 Plant Source Extraction

3.5 General Finishing Steps

3.5.1 Physical Processing Steps

Adjustment to final specification

3.5.2 Primary Packaging

3.5.3 Secondary Packaging

3.6 Quality Control Testing

3.6.1 Physical / Chemical testing

3.6.2 Microbiological testing (excluding sterility testing)

CARAPICHEA IPECACUANHA ROOT

3.2 Processing Activities of Active Substance from Natural Sources

3.2.1 Plant Source Extraction

3.5 General Finishing Steps

3.5.1 Physical Processing Steps

Adjustment to final specification

3.5.2 Primary Packaging

3.5.3 Secondary Packaging

3.6 Quality Control Testing

3.6.1 Physical / Chemical testing

3.6.2 Microbiological testing (excluding sterility testing)

PREPARED COAL TAR

3.2 Processing Activities of Active Substance from Natural Sources

3.2.4 Mineral Source Extraction

3.5 General Finishing Steps

3.5.1 Physical Processing Steps

Solvation

3.5.2 Primary Packaging

3.6 Quality Control Testing

3.6.1 Physical / Chemical testing

3.6.2 Microbiological testing (excluding sterility testing)

FUMARIA OFFICINALIS HERB

- 3.2 Processing Activities of Active Substance from Natural Sources
 - 3.2.1 Plant Source Extraction

- 3.5 General Finishing Steps
 - 3.5.1 Physical Processing Steps
Adjustment to final specification
 - 3.5.2 Primary Packaging

 - 3.5.3 Secondary Packaging

- 3.6 Quality Control Testing
 - 3.6.1 Physical / Chemical testing

 - 3.6.2 Microbiological testing (excluding sterility testing)

EPHEDRINE

- 3.5 General Finishing Steps
 - 3.5.1 Physical Processing Steps
Mix Phenol and water. Adjust to final specification
 - 3.5.2 Primary Packaging

 - 3.5.3 Secondary Packaging

- 3.6 Quality Control Testing
 - 3.6.1 Physical / Chemical testing

 - 3.6.2 Microbiological testing (excluding sterility testing)

SCUTELLARIA LATERIFLORA

- 3.2 Processing Activities of Active Substance from Natural Sources
 - 3.2.1 Plant Source Extraction

- 3.5 General Finishing Steps
 - 3.5.1 Physical Processing Steps
Adjustment to final specification
 - 3.5.2 Primary Packaging

 - 3.5.3 Secondary Packaging

- 3.6 Quality Control Testing
 - 3.6.1 Physical / Chemical testing

3.6.2 Microbiological testing (excluding sterility testing)

DRIMIA INDICA

3.2 Processing Activities of Active Substance from Natural Sources

3.2.1 Plant Source Extraction

3.5 General Finishing Steps

3.5.1 Physical Processing Steps

Adjustment to final specification

3.5.2 Primary Packaging

3.5.3 Secondary Packaging

3.6 Quality Control Testing

3.6.1 Physical / Chemical testing

3.6.2 Microbiological testing (excluding sterility testing)

TOLU FLAVOUR

3.5 General Finishing Steps

3.5.1 Physical Processing Steps

Adjustment to final specification

3.5.2 Primary Packaging

3.5.3 Secondary Packaging

3.6 Quality Control Testing

3.6.1 Physical / Chemical testing

3.6.2 Microbiological testing (excluding sterility testing)

MARRUBIUM VULGARE HERB

3.2 Processing Activities of Active Substance from Natural Sources

3.2.1 Plant Source Extraction

3.5 General Finishing Steps

3.5.1 Physical Processing Steps

Adjustment to final specification

3.5.2 Primary Packaging

3.5.3 Secondary Packaging

3.6 Quality Control Testing

3.6.1 Physical / Chemical testing

3.6.2 Microbiological testing (excluding sterility testing)

MATRICARIA CHAMOMILLA FLOWERS

3.2 Processing Activities of Active Substance from Natural Sources

3.2.1 Plant Source Extraction

3.5 General Finishing Steps

3.5.1 Physical Processing Steps

Adjustment to final specification

3.5.2 Primary Packaging

3.5.3 Secondary Packaging

3.6 Quality Control Testing

3.6.1 Physical / Chemical testing

3.6.2 Microbiological testing (excluding sterility testing)

CAMPHORATED OPIUM TINCTURE

3.2 Processing Activities of Active Substance from Natural Sources

3.2.1 Plant Source Extraction

3.2.5 Modification of extracted substance

3.5 General Finishing Steps

3.5.1 Physical Processing Steps

Solvation

3.5.2 Primary Packaging

3.6 Quality Control Testing

3.6.1 Physical / Chemical testing

3.6.2 Microbiological testing (excluding sterility testing)

CHLOROFORM AND MORPHINE TINCTURE

3.2 Processing Activities of Active Substance from Natural Sources

3.2.1 Plant Source Extraction

3.2.5 Modification of extracted substance

3.5 General Finishing Steps

3.5.1 Physical Processing Steps

Solvation

3.5.2 Primary Packaging

3.6

Quality Control Testing

3.6.1 Physical / Chemical testing

3.6.2 Microbiological testing (excluding sterility testing)

FUCUS VESICULOSUS

3.2

Processing Activities of Active Substance from Natural Sources

3.2.1 Plant Source Extraction

3.5

General Finishing Steps

3.5.1 Physical Processing Steps

Adjustment to final specification

3.5.2 Primary Packaging

3.5.3 Secondary Packaging

3.6

Quality Control Testing

3.6.1 Physical / Chemical testing

3.6.2 Microbiological testing (excluding sterility testing)

POLYGALA SENEGA ROOT

3.2

Processing Activities of Active Substance from Natural Sources

3.2.1 Plant Source Extraction

3.5

General Finishing Steps

3.5.1 Physical Processing Steps

Adjustment to final specification

3.5.2 Primary Packaging

3.5.3 Secondary Packaging

3.6

Quality Control Testing

3.6.1 Physical / Chemical testing

3.6.2 Microbiological testing (excluding sterility testing)

VITEX AGNUS-CASTUS FRUIT

3.2

Processing Activities of Active Substance from Natural Sources

3.2.1 Plant Source Extraction

3.5 General Finishing Steps

3.5.1 Physical Processing Steps

Adjustment to final specification

3.5.2 Primary Packaging

3.5.3 Secondary Packaging

3.6 Quality Control Testing

3.6.1 Physical / Chemical testing

3.6.2 Microbiological testing (excluding sterility testing)

COAL TAR SOLUTION

3.2 Processing Activities of Active Substance from Natural Sources

3.2.4 Mineral Source Extraction

3.5 General Finishing Steps

3.5.1 Physical Processing Steps

Solvation

3.5.2 Primary Packaging

3.6 Quality Control Testing

3.6.1 Physical / Chemical testing

3.6.2 Microbiological testing (excluding sterility testing)

PAEONIA LACTIFLORA UNPEELED ROOT

3.2 Processing Activities of Active Substance from Natural Sources

3.2.1 Plant Source Extraction

3.5 General Finishing Steps

3.5.1 Physical Processing Steps

Adjustment to final specification

3.5.2 Primary Packaging

3.5.3 Secondary Packaging

3.6 Quality Control Testing

3.6.1 Physical / Chemical testing

3.6.2 Microbiological testing (excluding sterility testing)

INULA HELENIUM ROOT

- 3.2 Processing Activities of Active Substance from Natural Sources
 - 3.2.1 Plant Source Extraction

- 3.5 General Finishing Steps
 - 3.5.1 Physical Processing Steps
Adjustment to final specification
 - 3.5.2 Primary Packaging

 - 3.5.3 Secondary Packaging

- 3.6 Quality Control Testing
 - 3.6.1 Physical / Chemical testing

 - 3.6.2 Microbiological testing (excluding sterility testing)

PASSIFLORA INCARNATA

- 3.2 Processing Activities of Active Substance from Natural Sources
 - 3.2.1 Plant Source Extraction

- 3.5 General Finishing Steps
 - 3.5.1 Physical Processing Steps
Adjustment to final specification
 - 3.5.2 Primary Packaging

 - 3.5.3 Secondary Packaging

- 3.6 Quality Control Testing
 - 3.6.1 Physical / Chemical testing

 - 3.6.2 Microbiological testing (excluding sterility testing)

GUAREA RUSBYI

- 3.2 Processing Activities of Active Substance from Natural Sources
 - 3.2.1 Plant Source Extraction

- 3.5 General Finishing Steps
 - 3.5.1 Physical Processing Steps
Adjustment to final specification
 - 3.5.2 Primary Packaging

 - 3.5.3 Secondary Packaging

- 3.6 Quality Control Testing

3.6.1 Physical / Chemical testing

3.6.2 Microbiological testing (excluding sterility testing)

VALERIANA OFFICINALIS ROOT

3.2 Processing Activities of Active Substance from Natural Sources

3.2.1 Plant Source Extraction

3.5 General Finishing Steps

3.5.1 Physical Processing Steps

Adjustment to final specification

3.5.2 Primary Packaging

3.5.3 Secondary Packaging

3.6 Quality Control Testing

3.6.1 Physical / Chemical testing

3.6.2 Microbiological testing (excluding sterility testing)

RHEUM PALMATUM

3.2 Processing Activities of Active Substance from Natural Sources

3.2.1 Plant Source Extraction

3.5 General Finishing Steps

3.5.1 Physical Processing Steps

Adjustment to final specification

3.5.2 Primary Packaging

3.5.3 Secondary Packaging

3.6 Quality Control Testing

3.6.1 Physical / Chemical testing

3.6.2 Microbiological testing (excluding sterility testing)

AVENA SATIVA

3.2 Processing Activities of Active Substance from Natural Sources

3.2.1 Plant Source Extraction

3.5 General Finishing Steps

3.5.1 Physical Processing Steps

Adjustment to final specification

3.5.2 Primary Packaging

3.5.3 Secondary Packaging

3.6 Quality Control Testing

3.6.1 Physical / Chemical testing

3.6.2 Microbiological testing (excluding sterility testing)

ECHINACEA

3.2 Processing Activities of Active Substance from Natural Sources

3.2.1 Plant Source Extraction

3.5 General Finishing Steps

3.5.1 Physical Processing Steps
Adjustment to final specification

3.5.2 Primary Packaging

3.5.3 Secondary Packaging

3.6 Quality Control Testing

3.6.1 Physical / Chemical testing

3.6.2 Microbiological testing (excluding sterility testing)

LIQUIFIED PHENOL

3.5 General Finishing Steps

3.5.1 Physical Processing Steps
Mix Phenol and water. Adjust to final specification

3.5.2 Primary Packaging

3.5.3 Secondary Packaging

3.6 Quality Control Testing

3.6.1 Physical / Chemical testing

3.6.2 Microbiological testing (excluding sterility testing)

MELISSA OFFICINALIS QUANTIFIED DRY EXTRACT

3.2 Processing Activities of Active Substance from Natural Sources

3.2.1 Plant Source Extraction

3.5 General Finishing Steps

3.5.1 Physical Processing Steps

Adjustment to final specification

3.5.2 Primary Packaging

3.5.3 Secondary Packaging

3.6

Quality Control Testing

3.6.1 Physical / Chemical testing

3.6.2 Microbiological testing (excluding sterility testing)

CIMICIFUGA RACEMOSA

3.2

Processing Activities of Active Substance from Natural Sources

3.2.1 Plant Source Extraction

3.5

General Finishing Steps

3.5.1 Physical Processing Steps

Adjustment to final specification

3.5.2 Primary Packaging

3.5.3 Secondary Packaging

3.6

Quality Control Testing

3.6.1 Physical / Chemical testing

3.6.2 Microbiological testing (excluding sterility testing)

BELLADONNA TINCTURE

3.5

General Finishing Steps

3.5.1 Physical Processing Steps

Mix Phenol and water. Adjust to final specification

3.5.2 Primary Packaging

3.5.3 Secondary Packaging

3.6

Quality Control Testing

3.6.1 Physical / Chemical testing

3.6.2 Microbiological testing (excluding sterility testing)

COAL TAR SOLUTION STRONG

3.2

Processing Activities of Active Substance from Natural Sources

3.2.4 Mineral Source Extraction

- 3.5 General Finishing Steps
 - 3.5.1 Physical Processing Steps
 - Solvation
 - 3.5.2 Primary Packaging
- 3.6 Quality Control Testing
 - 3.6.1 Physical / Chemical testing
 - 3.6.2 Microbiological testing (excluding sterility testing)

LOBELIA INFLATA

- 3.2 Processing Activities of Active Substance from Natural Sources
 - 3.2.1 Plant Source Extraction
- 3.5 General Finishing Steps
 - 3.5.1 Physical Processing Steps
 - Adjustment to final specification
 - 3.5.2 Primary Packaging
 - 3.5.3 Secondary Packaging
- 3.6 Quality Control Testing
 - 3.6.1 Physical / Chemical testing
 - 3.6.2 Microbiological testing (excluding sterility testing)

VERBENA OFFICINALIS HERB

- 3.2 Processing Activities of Active Substance from Natural Sources
 - 3.2.1 Plant Source Extraction
- 3.5 General Finishing Steps
 - 3.5.1 Physical Processing Steps
 - Adjustment to final specification
 - 3.5.2 Primary Packaging
 - 3.5.3 Secondary Packaging
- 3.6 Quality Control Testing
 - 3.6.1 Physical / Chemical testing
 - 3.6.2 Microbiological testing (excluding sterility testing)

OPIUM TINCTURE

- 3.2 Processing Activities of Active Substance from Natural Sources

3.2.1 Plant Source Extraction

3.2.5 Modification of extracted substance

3.5 General Finishing Steps

3.5.1 Physical Processing Steps

Solvation

3.5.2 Primary Packaging

3.6 Quality Control Testing

3.6.1 Physical / Chemical testing

3.6.2 Microbiological testing (excluding sterility testing)

COMMIPHORA MYRRHA RESIN

3.2 Processing Activities of Active Substance from Natural Sources

3.2.1 Plant Source Extraction

3.5 General Finishing Steps

3.5.1 Physical Processing Steps

Adjustment to final specification

3.5.2 Primary Packaging

3.5.3 Secondary Packaging

3.6 Quality Control Testing

3.6.1 Physical / Chemical testing

3.6.2 Microbiological testing (excluding sterility testing)

BOSWELLIA SERRATA EXTRACT

3.2 Processing Activities of Active Substance from Natural Sources

3.2.1 Plant Source Extraction

3.2.5 Modification of extracted substance

3.5 General Finishing Steps

3.5.1 Physical Processing Steps

Solvation

3.5.2 Primary Packaging

3.6 Quality Control Testing

3.6.1 Physical / Chemical testing

3.6.2 Microbiological testing (excluding sterility testing)

BAPTISIA TINCTORIA

3.2 Processing Activities of Active Substance from Natural Sources

3.2.1 Plant Source Extraction

3.5 General Finishing Steps

3.5.1 Physical Processing Steps
Adjustment to final specification

3.5.2 Primary Packaging

3.5.3 Secondary Packaging

3.6 Quality Control Testing

3.6.1 Physical / Chemical testing

3.6.2 Microbiological testing (excluding sterility testing)

TOLU BALSAM SOLUTION

3.2 Processing Activities of Active Substance from Natural Sources

3.2.1 Plant Source Extraction

3.5 General Finishing Steps

3.5.1 Physical Processing Steps
Adjustment to final specification

3.5.2 Primary Packaging

3.5.3 Secondary Packaging

3.6 Quality Control Testing

3.6.1 Physical / Chemical testing

3.6.2 Microbiological testing (excluding sterility testing)

COCILLANA LIQUID EXTRACT

3.2 Processing Activities of Active Substance from Natural Sources

3.2.1 Plant Source Extraction

3.5 General Finishing Steps

3.5.1 Physical Processing Steps
Adjustment to final specification

3.5.2 Primary Packaging

3.5.3 Secondary Packaging

3.6 Quality Control Testing

3.6.1 Physical / Chemical testing

3.6.2 Microbiological testing (excluding sterility testing)

TOLU BALSAM TINCTURE

3.2 Processing Activities of Active Substance from Natural Sources

3.2.1 Plant Source Extraction

3.5 General Finishing Steps

3.5.1 Physical Processing Steps

Adjustment to final specification

3.5.2 Primary Packaging

3.5.3 Secondary Packaging

3.6 Quality Control Testing

3.6.1 Physical / Chemical testing

3.6.2 Microbiological testing (excluding sterility testing)

THYMUS SERPYLLUM HERB

3.2 Processing Activities of Active Substance from Natural Sources

3.2.1 Plant Source Extraction

3.5 General Finishing Steps

3.5.1 Physical Processing Steps

Adjustment to final specification

3.5.2 Primary Packaging

3.5.3 Secondary Packaging

3.6 Quality Control Testing

3.6.1 Physical / Chemical testing

3.6.2 Microbiological testing (excluding sterility testing)

TOLU-FLAVOUR SOLUTION

3.5 General Finishing Steps

3.5.1 Physical Processing Steps

Adjustment to final specification

3.5.2 Primary Packaging

3.5.3 Secondary Packaging

3.6 Quality Control Testing

3.6.1 Physical / Chemical testing

3.6.2 Microbiological testing (excluding sterility testing)

TOLU BALSAM SYRUP

3.2 Processing Activities of Active Substance from Natural Sources

3.2.1 Plant Source Extraction

3.5 General Finishing Steps

3.5.1 Physical Processing Steps
Adjustment to final specification

3.5.2 Primary Packaging

3.5.3 Secondary Packaging

3.6 Quality Control Testing

3.6.1 Physical / Chemical testing

3.6.2 Microbiological testing (excluding sterility testing)

ANISE OIL

3.2 Processing Activities of Active Substance from Natural Sources

3.2.1 Plant Source Extraction

3.5 General Finishing Steps

3.5.2 Primary Packaging

3.6 Quality Control Testing

3.6.1 Physical / Chemical testing

3.6.2 Microbiological testing (excluding sterility testing)

HYPERICUM PERFORATUM

3.2 Processing Activities of Active Substance from Natural Sources

3.2.1 Plant Source Extraction

3.5 General Finishing Steps

3.5.1 Physical Processing Steps
Adjustment to final specification

3.5.2 Primary Packaging

3.5.3 Secondary Packaging

3.6

Quality Control Testing

3.6.1 Physical / Chemical testing

3.6.2 Microbiological testing (excluding sterility testing)

13/10/2023	Name and signature of the authorised person of the Competent Authority of United Kingdom Confidential Medicines and Healthcare products Regulatory Agency Tel : Confidential
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