Medicines and Healthcare products Regulatory Agency

CERTIFICATE NUMBER : UK API 28255 Insp GMP 28255/123039-0014

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.

- *(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 :

- [2000008503] LIQUIFIED PHENOL
- [4000010509] TOLU BALSAM SOLUTION
- [2000012870] RHEUM PALMATUM
- [1000019859] BOSWELLIA SERRATA EXTRACT
- [2000011320] CIMICIFUGA RACEMOSA
- [3000018457] HYSSOPUS OFFICINALIS HERB

MHRA-GMDP MHRA-GMDP MHRA-GMDP MHRA

- [4000009545] COCILLANA LIQUID EXTRACT
- [4000014426] PAEONIA LACTIFLORA UNPEELED ROOT
- [1000007667] DRIMIA INDICA
- [4000014423] COMMIPHORA MYRRHA RESIN
- [4000014428] VERBENA OFFICINALIS HERB
- [4000014422] ARCTIUM LAPPA ROOT
- [4000010511] TOLU BALSAM TINCTURE
- [1000006597] BAPTISIA TINCTORIA
- [4000014430] MARRUBIUM VULGARE HERB
- [2000012996] SCUTELLARIA LATERIFLORA
- [2000008161] OPIUM TINCTURE
- [1000006847] CAMPHORATED OPIUM TINCTURE
- [3000004780] CHLOROFORM AND MORPHINE TINCTURE
- [4000014431] THYMUS SERPYLLUM HERB
- [4000011423] MELISSA OFFICINALIS QUANTIFIED DRY EXTRACT
- [2000011380] COAL TAR SOLUTION
- [2000017650] CARAPICHEA IPECACUANHA ROOT
- [1000007633] LOBELIA INFLATA
- [4000014424] FUMARIA OFFICINALIS HERB
- [2000011927] HYPERICUM PERFORATUM
- [4000014432] VITEX AGNUS-CASTUS FRUIT
- [4000014427] POLYGALA SENEGA ROOT
- [2000016573] VALERIANA OFFICINALIS ROOT
- [1000002754] EPHEDRINE
- [2000011728] FUCUS VESICULOSUS
- [4000009543] COCILLANA EXTRACT
- [1000004861] TOLU FLAVOUR
- [2000011388] GUAREA RUSBYI
- [4000010114] ANISE OIL
- [2000004001] TOLU-FLAVOUR SOLUTION
- [2000008372] BELLADONNA TINCTURE
- [2000007910] PREPARED COAL TAR
- [4000013679] GLYCYRRHIZA GLABRA ROOT
- [1000009783] AVENA SATIVA
- [1000006672] ECHINACEA
- [4000014429] MATRICARIA CHAMOMILLA FLOWERS
- [4000014425] INULA HELENIUM ROOT
- [2000012458] PASSIFLORA INCARNATA
- [1000009310] TOLU BALSAM SYRUP
- [4000014216] COAL TAR SOLUTION STRONG

3. MANUFACTURING OPERATIONS - ACTIVE SUBSTANCES

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

MHRA-GMDP

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)

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)

BOSWELLIA SERRATA EXTRACT

3.2 Processing Activities of Active Substance from Natural Sources

3.2.1 Plant Source Extraction

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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)

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)

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)

MHRA-GMDP

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)

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)

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

MHRA-GMDP

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)

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)

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

MHRA-GMDP

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)

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)

MARRUBIUM VULGARE HERB

3.2 Processing Activities of Active Substance from Natural Sources

MHRA-GMDP

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)

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)

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

MHRA-GMDP

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)

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

MHRA-GMDP MHRA MHRA-GMDP MHRA

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)

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)

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

MHRA-GMDP

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)

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)

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)

HYPERICUM PERFORATUM

3.2 Processing Activities of Active Substance from Natural Sources

MHRA-GMDP

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)

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

MHRA-GMDP

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)

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)

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

MHRA-GMDP

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)

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)

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

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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)

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)

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)

PREPARED COAL TAR

MHRA-GMDP

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)

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)

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

MHRA-GMDP

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)

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)

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

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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)

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)

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

MHRA-GMDP

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)

06/07/2026	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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