

# Medicines and Healthcare products Regulatory Agency

CERTIFICATE NUMBER : UK API 39937 Insp GMP/GDP 39937/345063-0011

## 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 : RANSOM NATURALS LIMITED

Site address : RANSOM NATURALS LIMITED, 51-55 BURY MEAD ROAD, HITCHIN, SG5 1RT, 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 30/06/2020 , 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 :

- [2000018536] WHITE PINE COMPOUND
- [1000001979] GENTIAN TINCTURE, COMPOUND
- [1000001731] LAVENDER EXTRACT
- [4000013316] WILD LETTUCE AQUEOUS EXTRACT
- [1000002130] BENZOIN EXTRACT
- [4000014968] BITTER ORANGE PEEL EXTRACT
- [4000010071] PEPPERMINT OIL

- [1000008237] WILD CHERRY EXTRACT
- [4000010162] SENEGA LIQUID EXTRACT
- [2000008200] CAPSICUM OLEORESIN
- [4000014966] PASSIFLORA INCARNATA AQUEOUS POWDERED EXTRACT
- [2000007426] GINGER TINCTURE,STRONG
- [2000008366] BENZOIN TINCTURE
- [4000014967] UVA URSI AQUEOUS POWDERED EXTRACT
- [4000009560] MYRRH TINCTURE
- [2000008628] IPECACUANHA TINCTURE
- [2000018537] SQUILL ALCOHOLIC SOFT EXTRACT
- [3000006351] ACETYLSALICYLIC ACID
- [2000006531] EUPHORBIA EXTRACT
- [1000001652] CONCENTRATED PEPPERMINT WATER
- [2000018538] BENZOIN EXTRACT COMPOUND
- [1000002112] CINCHONA EXTRACT
- [2000018534] VALERIAN AQUEOUS POWDERED EXTRACT
- [4000009349] BENZOIN TINCTURE,COMPOUND
- [2000016877] KRAMERIA TINCTURE
- [2000005975] STRONG AMMONIUM ACETATE SOLUTION
- [4000013471] BUCHU DRY EXTRACT
- [2000008630] IPECACUANHA LIQUID EXTRACT
- [2000019133] HEDERA LIQUID EXTRACT
- [2000007466] SQUILL TINCTURE
- [2000007933] COMPOUND RHUBARB TINCTURE
- [4000002022] SENEGA EXTRACT
- [4000014960] CAPSICUM OLEORESIN 8.4%, REFINED AND STANDARDISED
- [2000005978] SQUILL AQUEOUS SOFT EXTRACT
- [4000015176] COMFREY LIQUID EXTRACT
- [2000006864] EUPHORBIA LIQUID EXTRACT
- [1000001992] WILD CHERRY SYRUP
- [4000014969] CAPSICUM OLEORESIN 12.6%, REFINED AND STANDARDISED
- [1000009710] SALICYLIC ACID
- [2000018533] SQUILL ELIXIR
- [1000009648] ARACHIS OIL
- [2000018535] QUASSIA LIQUID EXTRACT
- [2000007465] SQUILL VINEGAR
- [2000019404] CAPSICUM SOFT EXTRACT
- [1000009540] SODIUM BICARBONATE
- [2000008450] ARNICA FLOWER TINCTURE
- [4000010910] WHITE HOREHOUND LIQUID EXTRACT
- [2000019132] PELARGONIUM SIDOIDES AQUEOUS EXTRACT
- [4000013475] BUCHU LIQUID EXTRACT
- [1000008905] ICHTHAMMOL
- [1000002372] ORANGE TINCTURE
- [4000000344] CARDAMOM TINCTURE,COMPOUND
- [2000006524] GENTIAN EXTRACT
- [4000000783] VALERIAN TINCTURE
- [2000007807] RHUBARB EXTRACT
- [2000013194] SQUILL OXYMEL
- [2000007467] SQUILL LIQUID EXTRACT

- [4000014965] LETTUCE AQUEOUS POWDERED EXTRACT
- [2000008501] LIQUORICE LIQUID EXTRACT
- [4000009545] COCILLANA LIQUID EXTRACT
- [4000013876] SLIPPERY ELM BARK EXTRACT
- [1000009818] POTASSIUM CHLORIDE
- [4000006486] LIQUID PARAFFIN
- [4000014970] CAPSICUM OLEORESIN 2.0%, REFINED AND STANDARDISED
- [4000010163] SENEGA ROOT CONCENTRATED INFUSION
- [4000009543] COCILLANA EXTRACT
- [4000010507] PERU BALSAM
- [2000008199] CAPSICUM TINCTURE
- [2000011760] GINGER EXTRACT
- [1000006847] CAMPHORATED OPIUM TINCTURE
- [4000009923] MAGNESIUM SULFATE HEPTAHYDRATE
- [2000008486] VALERIAN EXTRACT
- [1000002361] SENEGA TINCTURE
- [2000008631] IPECACUANHA EXTRACT
- [2000008372] BELLADONNA TINCTURE
- [2000008399] ZINC OXIDE

### 3. MANUFACTURING OPERATIONS - ACTIVE SUBSTANCES

#### WHITE PINE COMPOUND

- 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
    - Filtration, Separation, Evaporation under vacuum, Blending/mixing
  - 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)

#### GENTIAN TINCTURE, COMPOUND

- 3.2 Processing Activities of Active Substance from Natural Sources
  - 3.2.1 Plant Source Extraction
  - 3.2.6 Purification of extracted substance
- 3.5 General Finishing Steps
  - 3.5.1 Physical Processing Steps
    - Filtration, Evaporation under vacuum, Blending/mixing

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)

LAVENDER 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

Blending/mixing

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)

WILD LETTUCE AQUEOUS EXTRACT

3.2 Processing Activities of Active Substance from Natural Sources

3.2.1 Plant Source Extraction

3.2.6 Purification of extracted substance

3.5 General Finishing Steps

3.5.1 Physical Processing Steps

Filtration, Evaporation under vacuum, Blending/mixing

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)

BENZOIN 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

Filtration, Evaporation under vacuum, Blending/mixing

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)

BITTER ORANGE PEEL 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

Filtration, Evaporation under vacuum, Blending/mixing

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)

PEPPERMINT OIL

3.5 General Finishing Steps

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)

WILD CHERRY 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

Filtration, Evaporation under vacuum, Blending/mixing

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)

SENEGA LIQUID EXTRACT

3.2 Processing Activities of Active Substance from Natural Sources

3.2.1 Plant Source Extraction

3.2.6 Purification of extracted substance

3.5 General Finishing Steps

3.5.1 Physical Processing Steps

Filtration, Evaporation under vacuum, Blending/mixing

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)

CAPSICUM OLEORESIN

3.2 Processing Activities of Active Substance from Natural Sources

3.2.1 Plant Source Extraction

3.2.6 Purification of extracted substance

3.5 General Finishing Steps

3.5.1 Physical Processing Steps

Filtration, Separation, Evaporation under vacuum, Blending/mixing

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 AQUEOUS POWDERED EXTRACT

3.5 General Finishing Steps

3.5.3 Secondary Packaging

3.6 Quality Control Testing

3.6.1 Physical / Chemical testing

3.6.2 Microbiological testing (excluding sterility testing)

GINGER TINCTURE,STRONG

3.2 Processing Activities of Active Substance from Natural Sources

3.2.1 Plant Source Extraction

3.2.6 Purification of extracted substance

3.5 General Finishing Steps

3.5.1 Physical Processing Steps

Filtration, Evaporation under vacuum, Blending/mixing

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)

BENZOIN 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

Filtration

3.5.2 Primary Packaging



3.5.3 Secondary Packaging

3.6 Quality Control Testing

3.6.1 Physical / Chemical testing

UVA URSI AQUEOUS POWDERED EXTRACT

3.5 General Finishing Steps

3.5.3 Secondary Packaging

3.6 Quality Control Testing

3.6.1 Physical / Chemical testing

3.6.2 Microbiological testing (excluding sterility testing)

MYRRH 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

Filtration, Mixing/blending

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)

IPECACUANHA TINCTURE

3.2 Processing Activities of Active Substance from Natural Sources

3.2.1 Plant Source Extraction

3.2.6 Purification of extracted substance

3.5 General Finishing Steps

3.5.1 Physical Processing Steps

Filtration, Evaporation under vacuum, Blending/mixing

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)

#### SQUILL ALCOHOLIC SOFT EXTRACT

3.2 Processing Activities of Active Substance from Natural Sources

3.2.1 Plant Source Extraction

3.2.6 Purification of extracted substance

3.5 General Finishing Steps

3.5.1 Physical Processing Steps

Filtration, Evaporation under vacuum, Blending/mixing

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)

#### ACETYLSALICYLIC ACID

3.5 General Finishing Steps

3.5.2 Primary Packaging

3.5.3 Secondary Packaging

3.6 Quality Control Testing

3.6.1 Physical / Chemical testing

#### EUPHORBIA EXTRACT

3.2 Processing Activities of Active Substance from Natural Sources

3.2.1 Plant Source Extraction

3.2.6 Purification of extracted substance

3.5 General Finishing Steps

3.5.1 Physical Processing Steps

Filtration, Evaporation under vacuum, Blending/mixing

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)

#### CONCENTRATED PEPPERMINT WATER

- 3.2 Processing Activities of Active Substance from Natural Sources
  - 3.2.7 OtherMixture prepared from bought in materials to BP 1973 monograph
- 3.5 General Finishing Steps
  - 3.5.1 Physical Processing StepsFiltration, Mixing/blending
- 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)

#### BENZOIN EXTRACT COMPOUND

- 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 StepsFiltration, Evaporation under vacuum, Blending/mixing
- 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)

#### CINCHONA 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 StepsFiltration, Evaporation under vacuum, Blending/mixing

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)

#### VALERIAN AQUEOUS POWDERED EXTRACT

3.5 General Finishing Steps

3.5.3 Secondary Packaging

3.6 Quality Control Testing

3.6.1 Physical / Chemical testing

3.6.2 Microbiological testing (excluding sterility testing)

#### BENZOIN TINCTURE, COMPOUND

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

Filtration, blending/mixing

3.5.2 Primary Packaging

3.5.3 Secondary Packaging

3.6 Quality Control Testing

3.6.1 Physical / Chemical testing

#### KRAMERIA 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

Filtration

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)

#### STRONG AMMONIUM ACETATE SOLUTION

- 3.1 Manufacture of Active Substance by Chemical Synthesis
  - 3.1.3 Salt Formation/Purification steps (eg. Crystallisation)
- Formulation to BP monograph
- 3.5 General Finishing Steps
  - 3.5.1 Physical Processing Steps
  - Filtration
  - 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)

#### BUCHU DRY EXTRACT

- 3.5 General Finishing Steps
  - 3.5.3 Secondary Packaging
- 3.6 Quality Control Testing
  - 3.6.1 Physical / Chemical testing
  - 3.6.2 Microbiological testing (excluding sterility testing)

#### IPECACUANHA LIQUID EXTRACT

- 3.2 Processing Activities of Active Substance from Natural Sources
  - 3.2.1 Plant Source Extraction
  - 3.2.6 Purification of extracted substance
- 3.5 General Finishing Steps
  - 3.5.1 Physical Processing Steps
  - Filtration, Evaporation under vacuum, Blending/mixing
  - 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)

#### HEDERA LIQUID EXTRACT

3.2 Processing Activities of Active Substance from Natural Sources

3.2.1 Plant Source Extraction

3.2.6 Purification of extracted substance

3.5 General Finishing Steps

3.5.1 Physical Processing Steps

Filtration, Evaporation under vacuum, Blending/mixing

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)

#### SQUILL 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

Filtration, Evaporation under vacuum, Blending/mixing

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)

#### COMPOUND RHUBARB TINCTURE

3.2 Processing Activities of Active Substance from Natural Sources

3.2.1 Plant Source Extraction

3.2.6 Purification of extracted substance

- 3.5 General Finishing Steps
- 3.5.1 Physical Processing Steps  
Filtration, Evaporation under vacuum, Blending/mixing
- 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)

#### SENEGA EXTRACT

- 3.2 Processing Activities of Active Substance from Natural Sources
- 3.2.1 Plant Source Extraction
- 3.2.6 Purification of extracted substance
- 3.5 General Finishing Steps
- 3.5.1 Physical Processing Steps  
Filtration, Evaporation under vacuum, Blending/mixing
- 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)

#### CAPSICUM OLEORESIN 8.4%, REFINED AND STANDARDISED

- 3.2 Processing Activities of Active Substance from Natural Sources
- 3.2.1 Plant Source Extraction
- 3.2.6 Purification of extracted substance
- 3.5 General Finishing Steps
- 3.5.1 Physical Processing Steps  
Filtration, Separation, Evaporation under vacuum, Blending/mixing
- 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)

#### SQUILL AQUEOUS SOFT EXTRACT

3.2 Processing Activities of Active Substance from Natural Sources

3.2.1 Plant Source Extraction

3.2.6 Purification of extracted substance

3.5 General Finishing Steps

3.5.1 Physical Processing Steps

Filtration, Evaporation under vacuum, Blending/mixing

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)

#### COMFREY LIQUID EXTRACT

3.2 Processing Activities of Active Substance from Natural Sources

3.2.1 Plant Source Extraction

3.2.6 Purification of extracted substance

3.5 General Finishing Steps

3.5.1 Physical Processing Steps

Filtration, Evaporation under vacuum, Blending/mixing

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)

#### EUPHORBIA LIQUID EXTRACT

3.2 Processing Activities of Active Substance from Natural Sources

3.2.1 Plant Source Extraction



3.2.6 Purification of extracted substance

3.5

General Finishing Steps

3.5.1 Physical Processing Steps

Filtration, Evaporation under vacuum, Blending/mixing

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)

WILD CHERRY 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

Filtration, Blending/mixing

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)

CAPSICUM OLEORESIN 12.6%, REFINED AND STANDARDISED

3.2

Processing Activities of Active Substance from Natural Sources

3.2.1 Plant Source Extraction

3.2.6 Purification of extracted substance

3.5

General Finishing Steps

3.5.1 Physical Processing Steps

Filtration, Separation, Evaporation under vacuum, Blending/mixing

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)

#### SALICYLIC ACID

3.5 General Finishing Steps

3.5.2 Primary Packaging

3.5.3 Secondary Packaging

3.6 Quality Control Testing

3.6.1 Physical / Chemical testing

#### SQUILL ELIXIR

3.2 Processing Activities of Active Substance from Natural Sources

3.2.1 Plant Source Extraction

3.2.6 Purification of extracted substance

3.5 General Finishing Steps

3.5.1 Physical Processing Steps

Filtration, Evaporation under vacuum, Blending/mixing

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)

#### ARACHIS OIL

3.5 General Finishing Steps

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)

#### QUASSIA LIQUID EXTRACT

3.2 Processing Activities of Active Substance from Natural Sources

3.2.1 Plant Source Extraction

3.2.6 Purification of extracted substance

3.5 General Finishing Steps

3.5.1 Physical Processing Steps

Filtration, Evaporation under vacuum, Blending/mixing

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)

SQUILL VINEGAR

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

Filtration, Evaporation under vacuum, Blending/mixing

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)

CAPSICUM SOFT EXTRACT

3.2 Processing Activities of Active Substance from Natural Sources

3.2.1 Plant Source Extraction

3.2.6 Purification of extracted substance

3.5 General Finishing Steps

3.5.1 Physical Processing Steps

Filtration, Evaporation under vacuum, Blending/mixing

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)

SODIUM BICARBONATE

3.5 General Finishing Steps

3.5.2 Primary Packaging

3.5.3 Secondary Packaging

3.6 Quality Control Testing

3.6.1 Physical / Chemical testing

ARNICA FLOWER 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

Filtration

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)

WHITE HOREHOUND LIQUID EXTRACT

3.2 Processing Activities of Active Substance from Natural Sources

3.2.1 Plant Source Extraction

3.2.6 Purification of extracted substance

3.5 General Finishing Steps

3.5.1 Physical Processing Steps

Filtration, Evaporation under vacuum, Blending/mixing

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)

## PELARGONIUM SIDOIDES AQUEOUS EXTRACT

## 3.2 Processing Activities of Active Substance from Natural Sources

### 3.2.1 Plant Source Extraction

### 3.2.6 Purification of extracted substance

## 3.5 General Finishing Steps

### 3.5.1 Physical Processing Steps

Filtration, Blending/mixing

### 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)

## BUCHU LIQUID EXTRACT

## 3.2 Processing Activities of Active Substance from Natural Sources

### 3.2.1 Plant Source Extraction

### 3.2.6 Purification of extracted substance

## 3.5 General Finishing Steps

### 3.5.1 Physical Processing Steps

Filtration, Evaporation under vacuum, Blending/mixing

### 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)

## ICHTHAMMOL

- 3.5 General Finishing Steps
  - 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)

#### ORANGE 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
    - Filtration, Evaporation under vacuum, Blending/mixing
  - 3.5.2 Primary Packaging
  - 3.5.3 Secondary Packaging
- 3.6 Quality Control Testing
  - 3.6.1 Physical / Chemical testing

#### CARDAMOM TINCTURE, COMPOUND

- 3.2 Processing Activities of Active Substance from Natural Sources
  - 3.2.7 Other
    - Mixture prepared from bought in materials to BP monograph
- 3.5 General Finishing Steps
  - 3.5.1 Physical Processing Steps
    - Filtration, Mixing/blending
  - 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)

#### GENTIAN EXTRACT

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

3.2.6 Purification of extracted substance

3.5

General Finishing Steps

3.5.1 Physical Processing Steps

Filtration, Evaporation under vacuum, Blending/mixing

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)

VALERIAN 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

Filtration, Mixing/blending

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)

RHUBARB EXTRACT

3.2

Processing Activities of Active Substance from Natural Sources

3.2.1 Plant Source Extraction

3.2.6 Purification of extracted substance

3.5

General Finishing Steps

3.5.1 Physical Processing Steps

Filtration, Evaporation under vacuum, Blending/mixing

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)

#### SQUILL OXYMEL

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

Filtration, Evaporation under vacuum, Blending/mixing

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)

#### SQUILL 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

Filtration, Evaporation under vacuum, Blending/mixing

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)

#### LETTUCE AQUEOUS POWDERED EXTRACT

3.5 General Finishing Steps

3.5.3 Secondary Packaging

3.6 Quality Control Testing

3.6.1 Physical / Chemical testing

3.6.2 Microbiological testing (excluding sterility testing)

LIQUORICE LIQUID EXTRACT

3.5 General Finishing Steps

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

3.2.6 Purification of extracted substance

3.5 General Finishing Steps

3.5.1 Physical Processing Steps

Filtration, Evaporation under vacuum, Blending/mixing

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)

SLIPPERY ELM BARK 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

Filtration, Evaporation under vacuum, Blending/mixing

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)

#### POTASSIUM CHLORIDE

3.5 General Finishing Steps

3.5.2 Primary Packaging

3.5.3 Secondary Packaging

3.6 Quality Control Testing

3.6.1 Physical / Chemical testing

#### LIQUID PARAFFIN

3.5 General Finishing Steps

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)

#### CAPSICUM OLEORESIN 2.0%, REFINED AND STANDARDISED

3.2 Processing Activities of Active Substance from Natural Sources

3.2.1 Plant Source Extraction

3.2.6 Purification of extracted substance

3.5 General Finishing Steps

3.5.1 Physical Processing Steps

Filtration, Separation, Evaporation under vacuum, Blending/mixing

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)

#### SENEGA ROOT CONCENTRATED INFUSION

3.2 Processing Activities of Active Substance from Natural Sources

3.2.1 Plant Source Extraction

3.2.6 Purification of extracted substance

3.5 General Finishing Steps

3.5.1 Physical Processing Steps

Filtration, Evaporation under vacuum, Blending/mixing

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

3.2.6 Purification of extracted substance

3.5 General Finishing Steps

3.5.1 Physical Processing Steps

Filtration, Evaporation under vacuum, Blending/mixing

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)

PERU BALSAM

3.5 General Finishing Steps

3.5.1 Physical Processing Steps

Filtration

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)

#### CAPSICUM 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

Filtration, Blending/mixing

3.5.2 Primary Packaging

3.5.3 Secondary Packaging

3.6 Quality Control Testing

3.6.1 Physical / Chemical testing

#### GINGER EXTRACT

3.2 Processing Activities of Active Substance from Natural Sources

3.2.1 Plant Source Extraction

3.2.6 Purification of extracted substance

3.5 General Finishing Steps

3.5.1 Physical Processing Steps

Filtration, Evaporation under vacuum, Blending/mixing

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

3.2.7 Other

Mixture prepared from bought in materials to BP monograph

3.5 General Finishing Steps

3.5.1 Physical Processing Steps

Filtration, Mixing/blending

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)

#### MAGNESIUM SULFATE HEPTAHYDRATE

3.5 General Finishing Steps

3.5.2 Primary Packaging

3.5.3 Secondary Packaging

3.6 Quality Control Testing

3.6.1 Physical / Chemical testing

#### VALERIAN EXTRACT

3.5 General Finishing Steps

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)

#### SENEGA TINCTURE

3.2 Processing Activities of Active Substance from Natural Sources

3.2.1 Plant Source Extraction

3.2.6 Purification of extracted substance

3.5 General Finishing Steps

3.5.1 Physical Processing Steps

Filtration, Evaporation under vacuum, Blending/mixing

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)

#### IPECACUANHA EXTRACT

3.2 Processing Activities of Active Substance from Natural Sources

3.2.1 Plant Source Extraction

3.2.6 Purification of extracted substance

3.5 General Finishing Steps

3.5.1 Physical Processing Steps

Filtration, Evaporation under vacuum, Blending/mixing

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

3.2 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

Filtration

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)

#### ZINC OXIDE

3.5 General Finishing Steps

3.5.2 Primary Packaging

3.5.3 Secondary Packaging



**Restrictions or Remarks**

This certificate is issued based on a remote inspection of GMP compliance during COVID-19 travel restrictions. A risk-based site inspection programme remains in force.

26/10/2020	Name and signature of the authorised person of the Competent Authority of United Kingdom
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