

Medicines and Healthcare products Regulatory Agency

CERTIFICATE NUMBER : UK API 1175 Insp GMP 1175/2404-0019

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 : A NELSON AND COMPANY LIMITED

Site address : A NELSON AND COMPANY LIMITED, UNIT 1, UNIT 5-9 ENDEAVOUR WAY, LONDON, SW19 8UH, 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 21/10/2019 , 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 :

- [1000009827] ATROPA BELLADONNA
- [3000010211] ACIDUM ARSENICOSUM
- [2000015834] ACONITUM NAPELLUS
- [3000009578] SULFUR
- [4000009468] CHAMOMILLA RECUTITA
- [2000012889] RHUS TOXICODENDRON

- [2000016235] THUJA OCCIDENTALIS
- [3000010349] STRYCHNOS IGNATII
- [2000015911] ARNICA MONTANA
- [3000009881] NATRUM CHLORATUM
- [3000014402] SEPIA OFFICINALIS
- [1000000327] PULSATILLA
- [2000011624] EUPHRASIA OFFICINALIS
- [2000011750] GELSEMIUM SEMPERVIRENS
- [3000007953] STRYCHNOS NUX-VOMICA

3. MANUFACTURING OPERATIONS - ACTIVE SUBSTANCES

ATROPA BELLADONNA

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

As per HAB/GHP monograph.

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)

ACIDUM ARSENICOSUM

3.5 General Finishing Steps

3.5.1 Physical Processing Steps

As per HAB/GHP monograph.

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)

ACONITUM NAPELLUS

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

As per HAB/GHP monograph.

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)

SULFUR

3.5 General Finishing Steps

3.5.1 Physical Processing Steps

As per HAB/GHP monograph.

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)

CHAMOMILLA RECUTITA

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

As per HAB/GHP monograph.

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)

RHUS TOXICODENDRON

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
As per HAB/GHP monograph.
 - 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)

THUJA OCCIDENTALIS

- 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
As per HAB/GHP monograph.
 - 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)

STRYCHNOS IGNATII

- 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
As per HAB/GHP monograph.
 - 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)

ARNICA MONTANA

- 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
As per HAB/GHP monograph.
 - 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)

NATRUM CHLORATUM

- 3.5 General Finishing Steps
 - 3.5.1 Physical Processing Steps
As per HAB/GHP monograph.
 - 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)

SEPIA OFFICINALIS

- 3.2 Processing Activities of Active Substance from Natural Sources
 - 3.2.2 Animal Source Extraction

- 3.5 General Finishing Steps
 - 3.5.1 Physical Processing Steps
As per HAB/GHP monograph.
 - 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)

PULSATILLA

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
As per HAB/GHP monograph.

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)

EUPHRASIA OFFICINALIS

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
As per HAB/GHP monograph.

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)

GELSEMIUM SEMPERVIRENS

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
As per HAB/GHP monograph.

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)

STRYCHNOS NUX-VOMICA

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

As per HAB/GHP monograph.

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)

06/12/2019	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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