Swissmedic Swiss Agency for Therapeutic Products

CERTIFICATE NUMBER: ***GMPEHV-CH-1003779***

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER

Part 1

Issued under the provisions of the Mutual Recognition Agreement between the European Union and ***Switzerland***.

The competent authority of Switzerland confirms the following:
The manufacturer: ***Phytomed AG***
Site address: ***Tschamerie 25, Hasle B. Burgdorf, 3415, Switzerland***
OMS Organisation Id. / OMS Location Id.: ***ORG-100033684*** / ***LOC-100052882***

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2022-03-04*** , it is considered that it complies with

The Good Manufacturing Practice requirements referred to in the Agreement of Mutual Recognition between the European Union and ***Switzerland***

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. 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 EudraGMDP. If it does not appear, please contact the issuing authority.

Part 2

Human Medicinal Products Veterinary Medicinal Products

1 MANUFACTURING OPERATIONS	
1.2	**Non-sterile products**
	1.2.1 Non-sterile products (processing operations for the following dosage forms) 1.2.1.1 Capsules, hard shell 1.2.1.2 Capsules, soft shell 1.2.1.4 Impregnated matrices 1.2.1.5 Liquids for external use 1.2.1.6 Liquids for internal use 1.2.1.8 Other solid dosage forms 1.2.1.11 Semi-solids 1.2.1.13 Tablets
	1.2.2 Batch certification
1.3	**Biological medicinal products (list of product types)**
	1.3.1 Biological medicinal products (list of product types) 1.3.1.6 Human or animal extracted products
	1.3.2 Batch Certification (list of product types) 1.3.2.6 Human or animal extracted products
1.4	**Other products or manufacturing activity**
	1.4.1 Manufacture of 1.4.1.1 Herbal products 1.4.1.2 Homoeopathic products
1.5	**Packaging**
	1.5.1 Primary Packaging 1.5.1.1 Capsules, hard shell 1.5.1.2 Capsules, soft shell 1.5.1.4 Impregnated matrices 1.5.1.5 Liquids for external use 1.5.1.6 Liquids for internal use 1.5.1.8 Other solid dosage forms 1.5.1.11 Semi-solids 1.5.1.13 Tablets
	1.5.2 Secondary packaging
1.6	**Quality control testing**

	1.6.3 Chemical/Physical

Manufacture of active substance. Names of substances subject to inspection:
SWISSMEDIC LIST OF APIS, SEE 4 ACTIVE SUBSTANCES(en)

3. MANUFACTURING OPERATIONS - ACTIVE SUBSTANCES Active Substance:SWISSMEDIC LIST OF APIS, SEE 4 ACTIVE SUBSTANCES	
3.2	**Extraction of Active Substance from Natural Sources**
	3.2.1 Extraction of substance from plant source 3.2.2 Extraction of substance from animal source 3.2.4 Extraction of substance from mineral source 3.2.6 Purification of extracted substance
3.5	**General Finishing Steps**
	3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing

4. Other Activities - Active Substances:
Herbal active pharmaceutical ingredients, Spagyrica, Homeopathica, Phytotherapeutica, Gemmotherapeutica, Cannabis sativa extract, Cannabidiol, Cannabidiol oil solution

2022-12-12

Name and signature of the authorised person of the Competent Authority of Switzerland

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Confidential
Swissmedic, Schweizerisches Heilmittelinstitut, Institut suisse des produits thérapeutiques, Istituto svizzero per gli agenti terapeutici
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