Agenzia Italiana del Farmaco

AIFA

Certificate No: IT-API/16/H/2017

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER

Part 1

Issued following an inspection in accordance with Art. 111(5) of Directive 2001/83/EC

The competent authority of Italy confirms the following:
The manufacturer EPO ISTITUTO FARMOCHIMICO FITOTERAPICO S.R.L.
Site address VIA NORMA PARENTI, 5 - 20090 PIEVE EMANUELE (MI)

Is an active substance manufacturer that has been inspected in accordance with Art. 111(1) of Directive 2001/83/EC transposed in the following national legislation: **D.L. n. 219 of 24th April 2006 art. 53**

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on 2016/02/26, it is considered that it complies with the Good Manufacturing Practice requirements referred to in the principles of GMP for active substances referred to in Article 47 of Directive 2001/83/EC.

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.
The authenticity of this certificate may be verified in EudraGMDP. If it does not appear, please contact the issuing authority.

AIFA - Italian Medicines Agency
GMP Inspections and Manufacturing Authorizations of APIs Office
Via del Tritone, n° 181 - 00187 ROMA (ITALY)
Tel.+390659784409 Fax +390659784617
website: www.agenziafarmaco.it
SIS : 2072

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Part 2

Name and address of the site:

EPO ISTITUTO FARMOCHIMICO FITOTERAPICO S.R.L. - VIA NORMA PARENTI, 5, 20090 PIEVE EMANUELE (MI)

Name of the active Substances manufactured or imported:
BELLADONNA LIQUID EXTRACT STANDARDISED BELLADONNA SOFT EXTRACT STANDARDISED BELLADONNA DRY EXTRACT STANDARDISED IPECACUANHA LIQUID EXTRACT STANDARDISED

3. Manufacturing Operations - Active Substances

3 - Manufacturing Operations - Active Substances
BELLADONNA LIQUID EXTRACT STANDARDISED

3.2	Extraction of Active Substance from Natural Sources
	3.2.1. Extraction of substance from plant source
3.5	General Finishing Steps
	3.5.1. Physical processing steps solvent evaporation, standardisation 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)

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3 - Manufacturing Operations - Active Substances BELLADONNA SOFT EXTRACT STANDARDISED	
3.2	Extraction of Active Substance from Natural Sources
	3.2.1. Extraction of substance from plant source
3.5	General Finishing Steps
	3.5.1. Physical processing steps solvent evaporation, standardisation 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 - Manufacturing Operations - Active Substances BELLADONNA DRY EXTRACT STANDARDISED	
3.2	Extraction of Active Substance from Natural Sources
	3.2.1. Extraction of substance from plant source
3.5	General Finishing Steps
	3.5.1. Physical processing steps solvent evaporation 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 - Manufacturing Operations - Active Substances IPECACUANHA LIQUID EXTRACT STANDARDISED	
3.2	Extraction of Active Substance from Natural Sources

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	3.2.1. Extraction of substance from plant source
3.5	General Finishing Steps
	3.5.1. Physical processing steps solvent evaporation, standardisation 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)

Restrictions or clarifying remarks:

According to Italian legislation, all the active substances of biological origin listed in this document have undergone an authorization procedure. BELLADONNA DRY EXTRACT STANDARDISED: drying and primary packaging steps are outsorced. The Inspectorate adopted a risk-based approach for planning of inspections, therefore the validity of the GMP certificate for this manufacturing site is not more than 42 months from the last general GMP inspection, which was conducted on 2016/02/26. It will still be AIFA's right to re-evaluate the validity of the GMP certificate based on risk profile changes.

Rome, 2017/02/06

Name and signature of the authorised person of the Competent Authority of Republic of Italy

Dott.ssa Isabella Marta
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