Agenzia Italiana del Farmaco

AIFA

Certificate No: IT-API/103/H/2016

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 AGENZIA INDUSTRIE DIFESA - STABILIMENTO CHIMICO FARMACEUTICO MILITARE
Site address Via Reginaldo Giuliani, 201 - 50141 FIRENZE (FI)

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 2015/06/25, 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 : 2638

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Part 2

Name and address of the site:

AGENZIA INDUSTRIE DIFESA - STABILIMENTO CHIMICO FARMACEUTICO MILITARE - Via Reginaldo Giuliani, 201, 50141 FIRENZE (FI)

Name of the active Substances manufactured or imported:
CANNABIS INFLORESCENCE

3. Manufacturing Operations - Active Substances

3 - Manufacturing Operations - Active Substances

CANNABIS INFLORESCENCE

3.5	**General Finishing Steps**
	3.5.1. Physical processing steps drying,milling, sieving **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 **3.6.2.** Microbiological testing (excluding sterility testing)

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Restrictions or clarifying remarks:

The active substance undergoes gamma radiation irradiation by a third contractor for the purpose of bioburden reduction. The validity of the GMP certificate for this manufacturing site is 36 months from the last general GMP/ approval inspection, which was conducted on 2015/06/25.

Rome, 2016/12/12

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

Dott.ssa Isabella Marta
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