AGENZIA ITALIANA DEL FARMACO

Certificate No: IT-API/15/H/2018

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 FARMACEUTICI DAMOR S.P.A.
Site address Via E. Scaglione, 27 - 80145 NAPOLI (NA)

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 2017/07/20, 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.+39065978401 Fax +390659784617
website: www.agenziafarmaco.it
SIS : 529

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GMP

Part 2

Name and address of the site:

FARMACEUTICI DAMOR S.P.A. - Via E. Scaglione, 27, 80145 NAPOLI (NA)

Name of the active Substances manufactured or imported:
TRITICUM VULGARE WHOLE HERB(Triticum vulgare)AQUEOUS EXTRACT

3. Manufacturing Operations - Active Substances

3 - Manufacturing Operations - Active Substances

TRITICUM VULGARE WHOLE HERB(Triticum vulgare)AQUEOUS EXTRACT

3.2	**Extraction of Active Substance from Natural Sources**
	3.2.1. Extraction of substance from plant source **3.2.6.** Purification of extracted substance plant source
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 **3.6.2.** Microbiological testing (excluding sterility testing)

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Restrictions or clarifying remarks:

According to Italian legislation, all the active substances of biological origin listed in this document have undergone an authorization procedure.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 48 months from the last general GMP inspection, which was conducted on 2017/07/20. It will still be AIFA's right to re-evaluate the validity of the GMP certificate based on risk profile changes.

Rome, 2018/02/15

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

Dott.ssa Marisa Delbò
AIFA - GMP Inspections and Manufacturing Authorizations of APIs Office

This is a certified copy of the certificate issued on 2017/07/20 consisting of 3 sheets; the validity of the reprinted GMP certificate is the same as the original certificate and is indicated in paragraph Restriction or clarifying remarks.

For ratification

Aifa-GMP Inspection and Manufacturing Authorizations of APIs Office
Dott.ssa Marisa Delbò

Rome, 2018/06/12

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