Certificate No: IT-API/193/H/2022

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 2022/04/29, 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
website: www.agenziafarmaco.it
SIS : 529

VI
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 **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)

Restrictions or clarifying remarks:

On a risk-based approach, the validity of the GMP certificate for this manufacturing site is not more than 42 months from the latest general GMP inspection conducted on 2022/04/29, except for AIFA's re-evaluation of the risk profile.

Rome, 2022/09/26

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

Dott. Michele Marangi
AIFA - GMP Inspections and Manufacturing Authorizations of APIs Office

Electronically signed according to the Italian legislation

Stamp duty paid according to the current Italian legislation.

AIFA - Italian Medicines Agency
GMP Inspections and Manufacturing Authorizations of APIs Office
Via del Tritone, n° 181 - 00187 ROMA (ITALY)
Tel.+39065978401
website: www.agenziafarmaco.it
SIS : 529