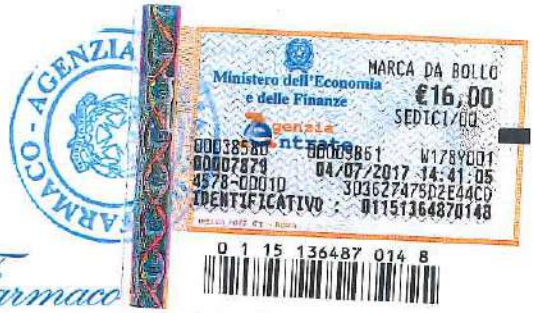
Agenzia Italiana del Farmaco

AIFA



Certificate No: IT-API/112/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 BIOFER S.P.A.
Site address Via Canina, 2 - 41036 MEDOLLA (MO)

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 2017/06/09, 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 : 812

CG
GMP

Agenzia Italiana del Farmaco

AIFA

Part 2

Name and address of the site:

BIOFER S.P.A. - Via Canina, 2, 41036 MEDOLLA (MO)

Name of the active Substances manufactured or imported:
FOLIC ACID
CALCIUM FOLINATE
CALCIUM FOLINATE CRUDE
CALCIUM LEVOFOLINATE PENTAHYDRATE
FERRIC HYDROXIDE POLYMALTOSE COMPLEX
SODIUM FERRIC GLUCONATE COMPLEX IN SUCROSE
DALTEPARIN SODIUM
PROTEOLYTIC ENZYME
HEPARIN CALCIUM
HEPARIN SODIUM
HEPARIN SODIUM CRUDE
HEPARINOID CRUDE
IRON DEXTRAN
IRON MALTOBIONATE
IRON PROTEIN ACETYL ASPARTYLATE
IRON SUCROSE
GABEXATE MESILATE
FERRIC SODIUM GLUCONATE
HYDROCORTISONE
HYDROCORTISONE HYDROGEN SUCCINATE
HYDROCORTISONE SODIUM PHOSPHATE
HYDROCORTISONE SODIUM SUCCINATE BUFFERED STERILE
METHYLPREDNISOLONE
METHYLPREDNISOLONE HYDROGEN SUCCINATE
METHYLPREDNISOLONE SODIUM SUCCINATE STERILE
METHYLPREDNISOLONE SODIUM SUCCINATE BUFFERED STERILE
PREDNISOLONE
PREDNISOLONE SODIUM PHOSPHATE
SULODEXIDE
THIOPENTAL
THIOPENTAL SODIUM AND SODIUM CARBONATE STERILE

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 : 812

CG
GMP

3. Manufacturing Operations - Active Substances

3 - Manufacturing Operations - Active Substances

CALCIUM FOLINATE

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.1. Manufacture of active substance intermediates **3.1.2.** Manufacture of crude active substance **3.1.3.** Salt formation / Purification steps: salt formation,crystallisation
3.5	**General Finishing Steps**
	3.5.1. Physical processing steps drying, granulation **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) **3.6.4.** Biological testing

3 - Manufacturing Operations - Active Substances

CALCIUM LEVOFOLINATE PENTAHYDRATE

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 : 812

CG
GMP

Agenzia Italiana del Farmaco

AIFA

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.3. Salt formation / Purification steps: crystallisation
3.5	**General Finishing Steps**
	3.5.1. Physical processing steps drying, granulation **3.5.2.** Primary Packaging (enclosing / sealing the active substance within packaging material which is in direct contact with the substance) **3.5.3.** Secondary Packaging (placing the sealed primary package within outer packaging material or container. This also includes any labelling of 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) **3.6.4.** Biological testing

3 - Manufacturing Operations - Active Substances

FERRIC HYDROXIDE POLYMALTOSE COMPLEX

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.1. Manufacture of active substance intermediates **3.1.2.** Manufacture of crude active substance **3.1.3.** Salt formation / Purification steps: ultrafiltration
3.5	**General Finishing Steps**
	3.5.1. Physical processing steps spray drying **3.5.2.** Primary Packaging (enclosing / sealing the active substance v packaging material which is in direct contact with the substance) **3.5.3.** Secondary Packaging (placing the sealed primary package wi

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 : 812

CG
GMP

	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) **3.6.4.** Biological testing

3 - Manufacturing Operations - Active Substances

SODIUM FERRIC GLUCONATE COMPLEX IN SUCROSE

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.1. Manufacture of active substance intermediates **3.1.2.** Manufacture of crude active substance **3.1.3.** Salt formation / Purification steps: ultrafiltration
3.5	**General Finishing Steps**
	3.5.1. Physical processing steps lyophilisation, granulation **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) **3.6.4.** Biological testing

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 : 812

CG
GMP

Agenzia Italiana del Farmaco

AIFA

3 - Manufacturing Operations - Active Substances

DALTEPARIN SODIUM

3.2	**Extraction of Active Substance from Natural Sources**
	3.2.5. Modification of extracted substance animal source **3.2.6.** Purification of extracted substance animal source
3.5	**General Finishing Steps**
	3.5.1. Physical processing steps lyophilisation, granulation **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) **3.6.4.** Biological testing

3 - Manufacturing Operations - Active Substances

PROTEOLYTIC ENZYME

3.2	**Extraction of Active Substance from Natural Sources**
	3.2.2. Extraction of substance from animal source **3.2.6.** Purification of extracted substance

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 : 812

CG
GMP

	animal source
3.5	**General Finishing Steps**
	3.5.1. Physical processing steps lyophilisation, granulation **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)

3 - Manufacturing Operations - Active Substances

HEPARIN CALCIUM

3.2	**Extraction of Active Substance from Natural Sources**
	3.2.6. Purification of extracted substance animal source **3.2.7.** Other salt formation
3.5	**General Finishing Steps**
	3.5.1. Physical processing steps lyophilisation, granulation **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)

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 : 812

Agenzia Italiana del Farmaco

AIFA

3.6	**Quality Control Testing**
	3.6.1. Physical / Chemical testing **3.6.2.** Microbiological testing (excluding sterility testing) **3.6.4.** Biological testing

3 - Manufacturing Operations - Active Substances

HEPARIN SODIUM

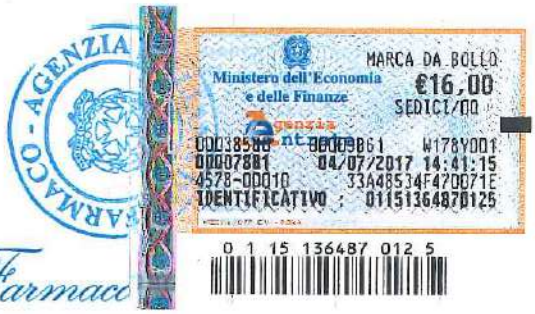
3.2	**Extraction of Active Substance from Natural Sources**
	3.2.6. Purification of extracted substance animal source
3.5	**General Finishing Steps**
	3.5.1. Physical processing steps lyophilisation, granulation **3.5.2.** Primary Packaging (enclosing / sealing the active substance within packaging material which is in direct contact with the substance) **3.5.3.** Secondary Packaging (placing the sealed primary package within outer packaging material or container. This also includes any labelling of 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) **3.6.4.** Biological testing

3 - Manufacturing Operations - Active Substances

IRON DEXTRAN

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 : 812

CG
GMP



3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.1. Manufacture of active substance intermediates **3.1.2.** Manufacture of crude active substance **3.1.3.** Salt formation / Purification steps: ultrafiltration
3.5	**General Finishing Steps**
	3.5.1. Physical processing steps spray drying **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) **3.6.4.** Biological testing

3 - Manufacturing Operations - Active Substances

IRON MALTOBIONATE

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.1. Manufacture of active substance intermediates **3.1.2.** Manufacture of crude active substance **3.1.3.** Salt formation / Purification steps: ultrafiltration
3.5	**General Finishing Steps**
	3.5.1. Physical processing steps lyophilisation, granulation

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 : 812

CG
GMP

	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) **3.6.4.** Biological testing

3 - Manufacturing Operations - Active Substances

IRON PROTEIN ACETYL ASPARTYLATE

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.1. Manufacture of active substance intermediates **3.1.2.** Manufacture of crude active substance **3.1.3.** Salt formation / Purification steps: filtration
3.5	**General Finishing Steps**
	3.5.1. Physical processing steps drying, granulation **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 th 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)

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 : 812

CG
GMP

3 - Manufacturing Operations - Active Substances

IRON SUCROSE

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.1. Manufacture of active substance intermediates **3.1.2.** Manufacture of crude active substance **3.1.3.** Salt formation / Purification steps: ultrafiltration
3.5	**General Finishing Steps**
	3.5.1. Physical processing steps lyophilisation, granulation **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) **3.6.4.** Biological testing

3 - Manufacturing Operations - Active Substances

GABEXATE MESILATE

3.1	**Manufacture of Active Substance by Chemical Synthesis**

	3.1.1. Manufacture of active substance intermediates **3.1.2.** Manufacture of crude active substance **3.1.3.** Salt formation / Purification steps: salt formation,crystallisation
3.5	**General Finishing Steps**
	3.5.1. Physical processing steps lyophilisation, granulation **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) **3.6.4.** Biological testing

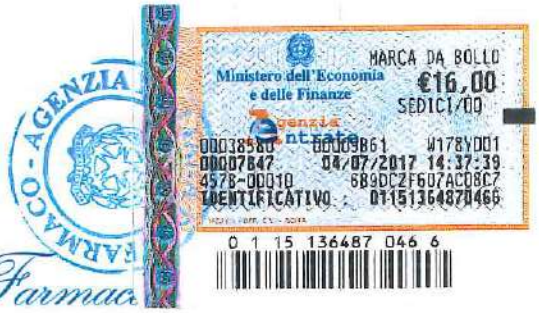
3 - Manufacturing Operations - Active Substances

FERRIC SODIUM GLUCONATE

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.1. Manufacture of active substance intermediates **3.1.2.** Manufacture of crude active substance **3.1.3.** Salt formation / Purification steps: ultrafiltration
3.5	**General Finishing Steps**
	3.5.1. Physical processing steps spray drying **3.5.2.** Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)

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 : 812

CG
GMP



	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)

3 - Manufacturing Operations - Active Substances

HYDROCORTISONE HYDROGEN SUCCINATE

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.2. Manufacture of crude active substance Special Requirements Other: Hormones or substances with hormonal activity **3.1.3.** Salt formation / Purification steps: precipitation
3.5	**General Finishing Steps**
	3.5.1. Physical processing steps drying, granulation **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)

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 : 812

Agenzia Italiana del Farmaco

AIFA

3 - Manufacturing Operations - Active Substances

HYDROCORTISONE SODIUM PHOSPHATE

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.2. Manufacture of crude active substance Special Requirements Other: Hormones or substances with hormonal activity **3.1.3.** Salt formation / Purification steps: salt formation,distillation,filtration
3.6	**Quality Control Testing**
	3.6.1. Physical / Chemical testing **3.6.2.** Microbiological testing (excluding sterility testing) **3.6.4.** Biological testing

3 - Manufacturing Operations - Active Substances

HYDROCORTISONE SODIUM SUCCINATE BUFFERED STERILE

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.2. Manufacture of crude active substance Special Requirements Other: Hormones or substances with hormonal activity **3.1.3.** Salt formation / Purification steps: precipitation
3.6	**Quality Control Testing**
	3.6.1. Physical / Chemical testing **3.6.2.** Microbiological testing (excluding sterility testing) **3.6.4.** Biological testing

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 : 812

CG
GMP

Agenzia Italiana del Farmaco

AIFA

3 - Manufacturing Operations - Active Substances

METHYLPREDNISOLONE HYDROGEN SUCCINATE

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.2. Manufacture of crude active substance Special Requirements Other: Hormones or substances with hormonal activity **3.1.3.** Salt formation / Purification steps: precipitation
3.5	**General Finishing Steps**
	3.5.1. Physical processing steps drying,granulation **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)

3 - Manufacturing Operations - Active Substances

METHYLPREDNISOLONE SODIUM SUCCINATE STERILE

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.2. Manufacture of crude active substance

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 : 812

CG
GMP

	Special Requirements Other: Hormones or substances with hormonal activity **3.1.3.** Salt formation / Purification steps: precipitation
3.6	**Quality Control Testing**
	3.6.1. Physical / Chemical testing **3.6.2.** Microbiological testing (excluding sterility testing) **3.6.4.** Biological testing

3 - Manufacturing Operations - Active Substances

METHYLPREDNISOLONE SODIUM SUCCINATE BUFFERED STERILE

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.2. Manufacture of crude active substance Special Requirements Other: Hormones or substances with hormonal activity **3.1.3.** Salt formation / Purification steps: precipitation
3.6	**Quality Control Testing**
	3.6.1. Physical / Chemical testing **3.6.2.** Microbiological testing (excluding sterility testing) **3.6.4.** Biological testing

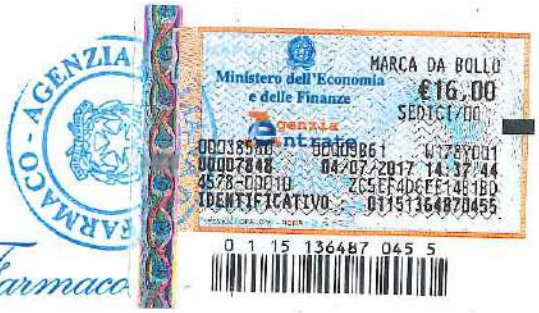
3 - Manufacturing Operations - Active Substances

PREDNISOLONE SODIUM PHOSPHATE

3.1	**Manufacture of Active Substance by Chemical Synthesis**

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 : 812

CG
GMP



	3.1.2. Manufacture of crude active substance Special Requirements Other: Hormones or substances with hormonal activity **3.1.3.** Salt formation / Purification steps: salt formation,distillation,filtration
3.6	**Quality Control Testing**
	3.6.1. Physical / Chemical testing **3.6.2.** Microbiological testing (excluding sterility testing) **3.6.4.** Biological testing

3 - Manufacturing Operations - Active Substances

SULODEXIDE

3.2	**Extraction of Active Substance from Natural Sources**
	3.2.6. Purification of extracted substance animal source
3.5	**General Finishing Steps**
	3.5.1. Physical processing steps spray drying **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) **3.6.4.** Biological testing

Agenzia Italiana del Farmaco

AIFA

3 - Manufacturing Operations - Active Substances

THIOPENTAL SODIUM AND SODIUM CARBONATE STERILE

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.3. Salt formation / Purification steps: salt formation
3.4	**Manufacture of sterile active substance**
	3.4.1. Aseptically prepared
3.5	**General Finishing Steps**
	3.5.1. Physical processing steps lyophilisation, granulation **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) **3.6.4.** Biological testing

Name and address of the site:

Magazzino - Via Ermanno Barbieri, 3/5 - 41036 - MEDOLLA (MO)

Name of the active Substances manufactured or imported:

ACTIVE SUBSTANCES (NON-STERILE AND OF NON- BIOLOGICAL ORIGIN)
ACTIVE SUBSTANCES (STERILE AND/OR BIOLOGICAL ORIGIN)

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 : 812

CG
GMP

Agenzia Italiana del Farmaco

AIFA

3. Manufacturing Operations - Active Substances

3 - Manufacturing Operations - Active Substances

ACTIVE SUBSTANCES (NON-STERILE AND OF NON- BIOLOGICAL ORIGIN)

3.5	General Finishing Steps
	3.5.4. Other storage

3 - Manufacturing Operations - Active Substances

ACTIVESUBSTANCES (STERILE AND/OR BIOLOGICAL ORIGIN)

3.5	General Finishing Steps
	3.5.4. Other storage

4. Other Activities - Active Substance:

Importation of:
FOLIC ACID (Confidential); CALCIUM FOLINATE CRUDE (Confidential); HEPARIN SODIUM CRUDE (Confidential); HEPARINOID CRUDE (Confidential); HYDROCORTISONE (Confidential); METHYLPREDNISOLONE (Confidential); PREDNISOLONE (Confidential); THIOPENTAL (Confidential)

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 : 812

Agenzia Italiana del Farmaco

AIFA

Restrictions or clarifying remarks:

According to Italian legislation, all the sterile and/or biological origin active substances listed in this document have undergone an authorisation procedure. Imported APIs marked as confidential undergo further processing within the importing site. Hydrocortisone sodium succinate sterile buffered, Methylprednisolone sodium succinate sterile, Methylprednisolone sodium succinate sterile buffered: sterilised via sterile filtration (outsourced). 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 30 months from the last general GMP inspection, which was conducted on 2017/06/09. It will still be AIFA's right to re-evaluate the validity of the GMP certificate based on risk profile changes.

Rome, 2017/08/30

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

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 : 812

AUTENTICA DI COPIA DI DOCUMENTO

CERTIFICO io sottoscritto dottor PAOLO VINCENZI Notaio iscritto nel Collegio Notarile del Distretto di Modena con residenza in Carpi che, la presente copia fotostatica riprodotta su venti facciate di dieci mezzi fogli, è conforme al suo originale, che mi è stato esibito dal signor Melloni Andrea nato a Ferrara il 27 maggio 1985, con residenza e domicilio fiscale in Copparo (FE), Via Svevo n. 28, per conto della società "BIOFER S.p.a." con sede legale in Medolla (MO), Via Canina n. 2, numero di iscrizione del Registro delle Imprese di Modena e codice fiscale 03618030484, ed alla quale previa collazione è stato da me restituito.

Si rilascia per uso amministrativo.

Medolla, otto ottobre duemiladiciotto.

APOSTILLE

(Convention de la Haye du 5 octobre 1961)

1. Stato: Repubblica Italiana

Il presente atto pubblico

2. è stato firmato da Vincenzo PAOLO

3. operante in qualità di notaio

4. è munito del sigillo/timbro dello STATO

.....

5. in Modena

6. da

.....

col numero 2432/18

Sigillo/bollo

.....

IL PROCURATORE

(Dott.ssa Lucia Musti)

Apposto il 12 OTT 2018

IL PROCURATORE

(Dott.ssa Lucia Musti)

PROCURA DELLA REPUBBLICA PRESSO IL TRIBUNALE MODENA