



Agenzia Italiana del Farmaco

AIFA



Certificate No: IT-API/65/H/2014

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 OLON S.P.A.

Site address Via Scaldasole, 33 - 27020 DORNO (PV)

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 02/28/2014, 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, after which time the issuing authority should be consulted.

The authenticity of this certificate may be verified with the issuing authority.

AIFA Italian Medicines Agency
Manufacturing Authorization Office
Via del Tritone, n° 181 - 00187 ROMA (ITALY)
Tel. +390659784489 Fax +390659784312
website: www.agenziafarmaco.it
SIS : 1212

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Part 2

Name and address of the site:

OLON S.P.A. - Via Scaldasole, 33, 27020 DORNO (PV)

Name of the active Substances manufactured or imported:

ACICLOVIR
ALTHIAZIDE
BEZAFIBRATE
FENOFIBRATE
IBUPROFEN
IBUPROFEN LYSINE
IBUPROFEN SODIUM
SOBREROL

3 - Manufacturing Operations - Active Substances

ACICLOVIR

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: Crystallisation
3.5	General Finishing Steps
	3.5.1. Physical processing steps drying,milling/micronisation,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)



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3.6	Quality Control Testing
	3.6.1. Physical / Chemical testing

3 - Manufacturing Operations - Active Substances

ALTHIAZIDE

3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.2. Manufacture of crude active substance 3.1.3. Salt formation / Purification steps: purification
3.5	General Finishing Steps
	3.5.1. Physical processing steps drying,milling/micronisation,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 - Manufacturing Operations - Active Substances

BEZAFIBRATE

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: crystallisation
3.5	General Finishing Steps
	3.5.1. Physical processing steps drying,milling/micronisation,sieving

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	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 - Manufacturing Operations - Active Substances **FENOFIBRATE**

3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.2. Manufacture of crude active substance 3.1.3. Salt formation / Purification steps: purification
3.5	General Finishing Steps
	3.5.1. Physical processing steps drying,milling/micronisation 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 - Manufacturing Operations - Active Substances **IBUPROFEN LYSINE**

3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.3. Salt formation / Purification steps:

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	purification, salt formation
3.5	General Finishing Steps
	3.5.1. Physical processing steps drying, milling/micronisation 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 - Manufacturing Operations - Active Substances

IBRUPROFEN SODIUM

3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.3. Salt formation / Purification steps: salt formation, purification
3.5	General Finishing Steps
	3.5.1. Physical processing steps drying, milling/micronisation 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



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3 - Manufacturing Operations - Active Substances **SOBREROL**

3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.2. Manufacture of crude active substance 3.1.3. Salt formation / Purification steps: crystallisation
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

4. Other Activities - Active Substance:

Importation of:

IBUPROFEN (Confidential)

Restrictions or clarifying remarks:

Imported APIs marked as confidential undergo further processing within the importing site.

Rome, 09/19/2014

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

Dott. Renato Massimi
AIFA – Manufacturing Authorization Office

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