



Certificate No: IT-API/50/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 OLON S.P.A.

Site address VIA MILANO, 186 - 20024 GARBAGNATE MILANESE (MI)

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 2017/06/23, 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.

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Page 1



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Part 2

Name and address of the site:

**OLON S.P.A. - VIA MILANO, 186, 20024 GARBAGNATE MILANESE
(MI)**

Name of the active Substances manufactured or imported:

ACECLIDINE HYDROCHLORIDE
ACITRETIN
ADAPALENE
ALITRETINOIN
AMFEPRAMONE HYDROCHLORIDE
BENZPHETAMINE HYDROCHLORIDE
BUMETANIDE
BUPROPION HYDROCHLORIDE
CLIDINIUM BROMIDE
CHLORCYCLIZINE HYDROCHLORIDE
DEQUALINIUM CHLORIDE
DICYCLOVERINE HYDROCHLORIDE
ETRETINATE
FAMCICLOVIR
PHENDIMETRAZINE TARTRATE
FENRETINIDE
PHENTERMINE HYDROCHLORIDE
FLUOXETINE HYDROCHLORIDE
ISOTRETINOIN
MEMANTINE HYDROCHLORIDE
MINOXIDIL
OTILONIUM BROMIDE
PIPENZOLATE BROMIDE
PRIDINOL MESILATE
PROCYCLIDINE HYDROCHLORIDE
SELEGILINE HYDROCHLORIDE
SIBUTRAMINE HYDROCHLORIDE ANHYDROUS
TAZAROTENE
TRETINOIN



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TRIHENYDROL HYDROCHLORIDE
VALACICLOVIR HYDROCHLORIDE

3 - Manufacturing Operations - Active Substances ACECLIDINE HYDROCHLORIDE

3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.1. Manufacture of active substance intermediates 3.1.3. Salt formation / Purification steps: salt formation
3.5	General Finishing Steps
	3.5.1. Physical processing steps drying,milling 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 ACITRETIN

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,sieving,micronisation

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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 ADAPALENE

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 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	
ALITRETINOIN	
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, sieving, 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	
AMFEPRAMONE HYDROCHLORIDE	
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 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

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	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

BENZPHETAMINE HYDROCHLORIDE

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 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

BUMETANIDE

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:

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	precipitation
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

BUPROPION HYDROCHLORIDE

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 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 - Manufacturing Operations - Active Substances CLIDINIUM BROMIDE	
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 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 CHLORCYCLIZINE HYDROCHLORIDE	
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 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

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	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 DEQUALINIUM CHLORIDE

3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.1. Manufacture of active substance intermediates 3.1.3. Salt formation / Purification steps: crystallisation, salt formation
3.5	General Finishing Steps
	3.5.1. Physical processing steps drying, milling, sieving, 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 DICYCLOVERINE HYDROCHLORIDE

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

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	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 - Manufacturing Operations - Active Substances ETRETINATE

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, 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



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3 - Manufacturing Operations - Active Substances FAMCICLOVIR	
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 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 PHENDIMETRAZINE TARTRATE	
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
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	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 FENRETINIDE (Confidential)

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,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 PHENTERMINE HYDROCHLORIDE

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

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3.5	General Finishing Steps
	3.5.1. Physical processing steps drying,sieving,milling 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

FLUOXETINE HYDROCHLORIDE

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 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 ISOTRETINOIN

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,sieving,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 MEMANTINE HYDROCHLORIDE

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 3.5.2. Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)

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	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

MINOXIDIL

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 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

OTILONIUM BROMIDE

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

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	3.1.3. Salt formation / Purification steps: crystallisation
3.5	General Finishing Steps
	3.5.1. Physical processing steps drying, milling 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

PIPENZOLATE BROMIDE

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 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 PRIDINOL 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: crystallisation
3.5	General Finishing Steps
	3.5.1. Physical processing steps drying, milling 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 PROCYCLIDINE HYDROCHLORIDE

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 3.5.2. Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)

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	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 **SELEGILINE HYDROCHLORIDE**

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 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 **SIBUTRAMINE HYDROCHLORIDE ANHYDROUS**

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

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	crystallisation
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

TAZAROTENE

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, sieving, 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

TRETINOIN

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,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

TRIHENXYPHENIDYL HYDROCHLORIDE

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

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	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 VALACICLOVIR HYDROCHLORIDE

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 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

Restrictions or clarifying remarks:

Manufactured APIs marked as confidential are for clinical use only. 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 36 months from the last general GMP inspection, which was conducted on 2017/06/23. It will still be AIFA's right to re-evaluate the validity of the GMP certificate based on risk profile changes.



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Rome, 2018/04/03

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



Marisa Delbò

Dott.ssa Marisa Delbò
AIFA - GMP Inspections and Manufacturing
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