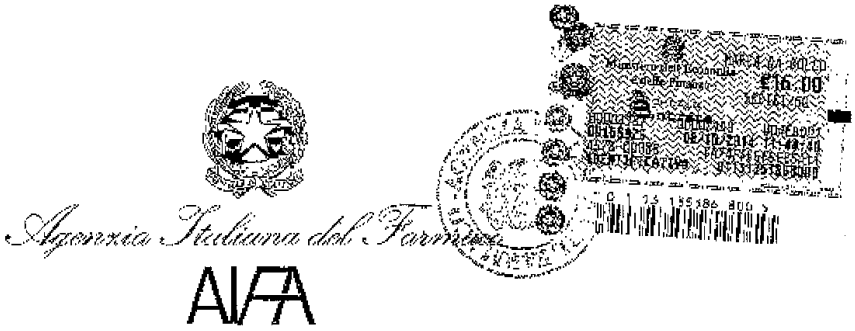


Certificate No: IT-API/77/H/2014

## 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 PROCOS S.P.A.
Site address Via Matteotti, 249 - 28062 CAMERI (NO)

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 10/31/2013, 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.

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Part 2

## Name and address of the site:

**PROCOS S.P.A. - Via Matteotti, 249, 28062 CAMERI (NO)**

Name of the active Substances manufactured or imported:

ALVERINE CITRATE
[redacted]
CLOFEDANOL HYDROCHLORIDE
CHLOROPYRAMINE HYDROCHLORIDE
DALFAMPRIDINE
[redacted]
DROFENINE HYDROCHLORIDE
FELBAMATE
PHENELZINE SULFATE
PHENYLTOLOXAMINE CITRATE
GUANFACINE HYDROCHLORIDE
ILOPERIDONE
ISOPROPAMIDE IODIDE
LABETALOL HYDROCHLORIDE
LEVOSULPIRIDE
LURASIDONE HYDROCHLORIDE
MEMANTINE HYDROCHLORIDE
METHOXYPHENAMINE HYDROCHLORIDE
NAFTIDROFURYL HYDROGEN OXALATE
NAFTOPIDIL
[redacted]
ORPHENADRINE CITRATE
ORPHENADRINE HYDROCHLORIDE
PYRIDOSTIGMINE BROMIDE
PROPAFENONE HYDROCHLORIDE
RANOLAZINE
SIVELESTAT SODIUM TETRAHYDRATE
TROSPIUM CHLORIDE
TUAMINOHEPTANE SULFATE

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| 3 - Manufacturing Operations - Active Substances<br>ALVERINE CITRATE | |
|---|---|
| 3.1 | Manufacture of Active Substance by Chemical Synthesis |
| | 3.1.1. Manufacture of active substance intermediates<br>3.1.2. Manufacture of crude active substance<br>3.1.3. Salt formation / Purification steps:<br>Crystallisation |
| 3.5 | General Finishing Steps |
| | 3.5.1. Physical processing steps<br>Drying, sieving, milling/micronisation<br>3.5.2. Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)<br>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<br>[redacted] | |
|---|---|
| 3.1 | Manufacture of Active Substance by Chemical Synthesis |
| | 3.1.1. [redacted]<br>3.1.2. [redacted]<br>3.1.3. [redacted] |
| 3.5 | General Finishing Steps |
| | 3.5.1. [redacted]<br>3.5.2. [redacted]<br>3.5.3. [redacted] |

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|---|---|
| | [redacted] |
| 3.6 | Quality Control Testing |
| | 3.6.1. [redacted] |

| 3 - Manufacturing Operations - Active Substances<br>CLOFEDANOL HYDROCHLORIDE | |
|---|---|
| 3.1 | Manufacture of Active Substance by Chemical Synthesis |
| | 3.1.1. Manufacture of active substance intermediates<br>3.1.2. Manufacture of crude active substance<br>3.1.3. Salt formation / Purification steps:<br>Crystallisation |
| 3.5 | General Finishing Steps |
| | 3.5.1. Physical processing steps<br>Drying, sieving, milling/micronisation<br>3.5.2. Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)<br>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<br>CHLOROPYRAMINE HYDROCHLORIDE | |
|---|---|
| 3.1 | Manufacture of Active Substance by Chemical Synthesis |
| | 3.1.1. Manufacture of active substance intermediates<br>3.1.2. Manufacture of crude active substance<br>3.1.3. Salt formation / Purification steps:<br>Crystallisation |
| 3.5 | General Finishing Steps |
| | 3.5.1. Physical processing steps<br>Drying, sieving, milling/micronisation |

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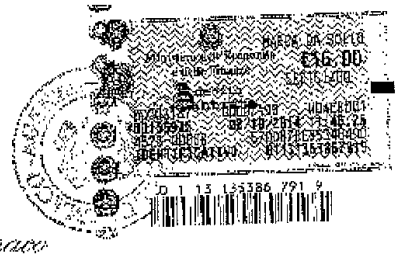

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| | **3.5.2.** Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)<br>**3.5.3.** Secondary Packaging (placing the sealed primary package within an outer packaging material 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**<br>**DALFAMPRIDINE** | |
|---|---|
| 3.1 | **Manufacture of Active Substance by Chemical Synthesis** |
| | **3.1.1.** Manufacture of active substance intermediates<br>**3.1.2.** Manufacture of crude active substance<br>**3.1.3.** Salt formation / Purification steps:<br>Crystallisation |
| 3.5 | **General Finishing Steps** |
| | **3.5.1.** Physical processing steps<br>Drying, sieving, milling/micronisation<br>**3.5.2.** Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)<br>**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 identificationor traceability (lot numbering) of the active substance) |
| 3.6 | **Quality Control Testing** |
| | **3.6.1.** Physical / Chemical testing |

| **3 - Manufacturing Operations - Active Substances**<br>[redacted] | |
|---|---|
| 3.1 | **Manufacture of Active Substance by Chemical Synthesis** |
| | **3.1.1.** [redacted]<br>**3.1.2.** [redacted]<br>**3.1.3.** [redacted] |

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| | [redacted] |
| 3.5 | General Finishing Steps |
| | 3.5.1. [redacted] |
| | 3.5.2. [redacted] |
| | 3.5.3. [redacted] |
| 3.6 | Quality Control Testing |
| | 3.6.1. [redacted] |

| 3 - Manufacturing Operations - Active Substances<br>DROFENINE HYDROCHLORIDE | |
|---|---|
| 3.1 | Manufacture of Active Substance by Chemical Synthesis |
| | 3.1.1. Manufacture of active substance intermediates<br>3.1.2. Manufacture of crude active substance<br>3.1.3. Salt formation / Purification steps:<br>Crystallisation |
| 3.5 | General Finishing Steps |
| | 3.5.1. Physical processing steps<br>Drying, sieving, milling/micronisation<br>3.5.2. Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)<br>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<br>FELBAMATE | |
|---|---|
| 3.1 | Manufacture of Active Substance by Chemical Synthesis |
| | 3.1.2. Manufacture of crude active substance<br>3.1.3. Salt formation / Purification steps:<br>Crystallisation |
| 3.5 | General Finishing Steps |
| | 3.5.1. Physical processing steps<br>Drying, sieving, milling/micronisation<br>3.5.2. Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)<br>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<br>PHENELZINE SULFATE | |
|---|---|
| 3.1 | Manufacture of Active Substance by Chemical Synthesis |
| | 3.1.1. Manufacture of active substance intermediates<br>3.1.2. Manufacture of crude active substance<br>3.1.3. Salt formation / Purification steps:<br>Crystallisation |
| 3.5 | General Finishing Steps |
| | 3.5.1. Physical processing steps<br>Drying, sieving, milling/micronisation<br>3.5.2. Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)<br>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<br>PHENYLTOLOXAMINE CITRATE | |
|---|---|
| 3.1 | Manufacture of Active Substance by Chemical Synthesis |
| | 3.1.1. Manufacture of active substance intermediates<br>3.1.2. Manufacture of crude active substance<br>3.1.3. Salt formation / Purification steps:<br>Crystallisation |
| 3.5 | General Finishing Steps |
| | 3.5.1. Physical processing steps<br>Drying, sieving, milling/micronisation<br>3.5.2. Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)<br>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<br>GUANFACINE HYDROCHLORIDE | |
|---|---|
| 3.1 | Manufacture of Active Substance by Chemical Synthesis |
| | 3.1.1. Manufacture of active substance intermediates<br>3.1.2. Manufacture of crude active substance<br>3.1.3. Salt formation / Purification steps:<br>Crystallisation |
| 3.5 | General Finishing Steps |
| | 3.5.1. Physical processing steps<br>Drying, sieving, milling/micronisation<br>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<br>ILOPERIDONE | |
|---|---|
| 3.1 | Manufacture of Active Substance by Chemical Synthesis |
| | 3.1.1. Manufacture of active substance intermediates<br>3.1.2. Manufacture of crude active substance<br>3.1.3. Salt formation / Purification steps:<br>Crystallisation |
| 3.5 | General Finishing Steps |
| | 3.5.1. Physical processing steps<br>Drying, sieving, milling/micronisation<br>3.5.2. Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)<br>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<br>ISOPROPAMIDE IODIDE | |
|---|---|
| 3.1 | Manufacture of Active Substance by Chemical Synthesis |
| | 3.1.1. Manufacture of active substance intermediates<br>3.1.2. Manufacture of crude active substance<br>3.1.3. Salt formation / Purification steps:<br>Crystallisation |

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| 3.5 | General Finishing Steps |
|---|---|
| | 3.5.1. Physical processing steps<br>Drying, sieving, milling/micronisation<br>3.5.2. Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)<br>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<br>LABETALOL HYDROCHLORIDE | |
|---|---|
| 3.1 | Manufacture of Active Substance by Chemical Synthesis |
| | 3.1.1. Manufacture of active substance intermediates<br>3.1.2. Manufacture of crude active substance<br>3.1.3. Salt formation / Purification steps:<br>Crystallisation |
| 3.5 | General Finishing Steps |
| | 3.5.1. Physical processing steps<br>Drying, sieving, milling/micronisation<br>3.5.2. Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)<br>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<br>LEVOSULPIRIDE | |
|---|---|
| 3.1 | Manufacture of Active Substance by Chemical Synthesis |
| | 3.1.2. Manufacture of crude active substance<br>3.1.3. Salt formation /Purification steps:<br>crystallisation |
| 3.5 | General Finishing Steps |
| | 3.5.1. Physical processing steps<br>Drying, sieving, milling/micronisation<br>3.5.2. Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)<br>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<br>LURASIDONE HYDROCHLORIDE | |
|---|---|
| 3.1 | Manufacture of Active Substance by Chemical Synthesis |
| | 3.1.1. Manufacture of active substance intermediates<br>3.1.2. Manufacture of crude active substance<br>3.1.3. Salt formation / Purification steps:<br>crystallisation |
| 3.5 | General Finishing Steps |
| | 3.5.1. Physical processing steps<br>drying, sieving, milling/micronisation<br>3.5.2. Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)<br>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<br>MEMANTINE HYDROCHLORIDE | |
|---|---|
| 3.1 | Manufacture of Active Substance by Chemical Synthesis |
| | 3.1.1. Manufacture of active substance intermediates<br>3.1.2. Manufacture of crude active substance<br>3.1.3. Salt formation / Purification steps:<br>Crystallisation |
| 3.5 | General Finishing Steps |
| | 3.5.1. Physical processing steps<br>Drying, sieving, milling/micronisation<br>3.5.2. Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)<br>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<br>METHOXYPHENAMINE HYDROCHLORIDE | |
|---|---|
| 3.1 | Manufacture of Active Substance by Chemical Synthesis |
| | 3.1.1. Manufacture of active substance intermediates<br>3.1.2. Manufacture of crude active substance<br>3.1.3. Salt formation / Purification steps:<br>Crystallisation |
| 3.5 | General Finishing Steps |
| | 3.5.1. Physical processing steps<br>Drying, sieving, milling/micronisation<br>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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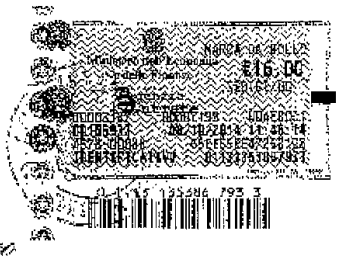

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| | 3.5.3. Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance) |
| 3.6 | Quality Control Testing |
| | 3.6.1. Physical / Chemical testing |

| 3 - Manufacturing Operations - Active Substances<br>NAFTIDROFURYL HYDROGEN OXALATE | |
|---|---|
| 3.1 | Manufacture of Active Substance by Chemical Synthesis |
| | 3.1.1. Manufacture of active substance intermediates<br>3.1.2. Manufacture of crude active substance<br>3.1.3. Salt formation / Purification steps:<br>Crystallisation |
| 3.5 | General Finishing Steps |
| | 3.5.1. Physical processing steps<br>Drying, sieving, milling/micronisation<br>3.5.2. Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)<br>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<br>NAFTOPIDIL | |
|---|---|
| 3.1 | Manufacture of Active Substance by Chemical Synthesis |
| | 3.1.1. Manufacture of active substance intermediates<br>3.1.2. Manufacture of crude active substance<br>3.1.3. Salt formation / Purification steps:<br>Crystallisation |

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| 3.5 | General Finishing Steps |
| | 3.5.1. Physical processing steps<br>Drying, sieving, milling/micronisation<br>3.5.2. Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)<br>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 [redacted] | |
|---|---|
| 3.1 | Manufacture of Active Substance by Chemical Synthesis |
| | 3.1.1. [redacted]<br>3.1.2. [redacted]<br>3.1.3. [redacted] |
| 3.5 | General Finishing Steps |
| | 3.5.1. [redacted]<br>3.5.2. [redacted]<br>3.5.3. [redacted] |
| 3.6 | Quality Control Testing |
| | 3.6.1. [redacted] |

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| 3 - Manufacturing Operations - Active Substances<br>ORPHENADRINE CITRATE | |
|---|---|
| 3.1 | Manufacture of Active Substance by Chemical Synthesis |
| | 3.1.1. Manufacture of active substance intermediates<br>3.1.2. Manufacture of crude active substance<br>3.1.3. Salt formation / Purification steps:<br>Crystallisation |
| 3.5 | General Finishing Steps |
| | 3.5.1. Physical processing steps<br>Drying, sieving, milling/micronisation<br>3.5.2. Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)<br>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<br>ORPHENADRINE HYDROCHLORIDE | |
|---|---|
| 3.1 | Manufacture of Active Substance by Chemical Synthesis |
| | 3.1.1. Manufacture of active substance intermediates<br>3.1.2. Manufacture of crude active substance<br>3.1.3. Salt formation / Purification steps:<br>Crystallisation |
| 3.5 | General Finishing Steps |
| | 3.5.1. Physical processing steps<br>Drying, sieving, milling/micronisation<br>3.5.2. Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)<br>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 |

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| | numbering) of the active substance) |
| 3.6 | Quality Control Testing |
| | 3.6.1. Physical / Chemical testing |

| 3 - Manufacturing Operations - Active Substances<br>PYRIDOSTIGMINE BROMIDE | |
|---|---|
| 3.1 | Manufacture of Active Substance by Chemical Synthesis |
| | 3.1.1. Manufacture of active substance intermediates<br>3.1.2. Manufacture of crude active substance<br>3.1.3. Salt formation / Purification steps:<br>Crystallisation |
| 3.5 | General Finishing Steps |
| | 3.5.1. Physical processing steps<br>Drying, sieving, milling/micronisation<br>3.5.2. Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)<br>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<br>PROPAFENONE HYDROCHLORIDE | |
|---|---|
| 3.1 | Manufacture of Active Substance by Chemical Synthesis |
| | 3.1.1. Manufacture of active substance intermediates<br>3.1.2. Manufacture of crude active substance<br>3.1.3. Salt formation / Purification steps:<br>Crystallisation |
| 3.5 | General Finishing Steps |
| | 3.5.1. Physical processing steps<br>Drying, sieving, milling/micronisation<br>3.5.2. Primary Packaging (enclosing / sealing the active substance within a |

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| | packaging material which is in direct contact with the substance)<br>**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 beused 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**<br>**RANOLAZINE** | |
|---|---|
| **3.1** | **Manufacture of Active Substance by Chemical Synthesis** |
| | **3.1.1.** Manufacture of active substance intermediates<br>**3.1.2.** Manufacture of crude active substance<br>**3.1.3.** Salt formation / Purification steps:<br>Crystallisation |
| **3.5** | **General Finishing Steps** |
| | **3.5.1.** Physical processing steps<br>Drying, sieving, milling/micronisation<br>**3.5.2.** Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)<br>**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**<br>**SIVELESTAT SODIUM TETRAHYDRATE** | |
|---|---|
| **3.1** | **Manufacture of Active Substance by Chemical Synthesis** |
| | **3.1.1.** Manufacture of active substance intermediates<br>**3.1.2.** Manufacture of crude active substance<br>**3.1.3.** Salt formation / Purification steps:<br>Crystallisation |

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|---|---|
| 3.5 | General Finishing Steps |
| | 3.5.1. Physical processing steps<br>Drying, sieving, milling/micronisation<br>3.5.2. Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)<br>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<br>TROSPIUM CHLORIDE | |
|---|---|
| 3.1 | Manufacture of Active Substance by Chemical Synthesis |
| | 3.1.1. Manufacture of active substance intermediates<br>3.1.2. Manufacture of crude active substance<br>3.1.3. Salt formation / Purification steps:<br>Crystallisation |
| 3.5 | General Finishing Steps |
| | 3.5.1. Physical processing steps<br>Drying, sieving, milling/micronisation<br>3.5.2. Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)<br>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<br>TUAMINOHEPTANE SULFATE | |
|---|---|
| 3.1 | Manufacture of Active Substance by Chemical Synthesis |
| | 3.1.1. Manufacture of active substance intermediates<br>3.1.2. Manufacture of crude active substance<br>3.1.3. Salt formation / Purification steps:<br>Crystallisation |
| 3.5 | General Finishing Steps |
| | 3.5.1. Physical processing steps<br>Drying, sieving, milling/micronisation<br>3.5.2. Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)<br>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.

Rome, 10/21/2014

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

Dott. Renato Massimi
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