Federal Agency for Medicines and Health Products

CERTIFICATE NUMBER: ***BE/GMP/2017/014***

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER [1, 2]

Part 1

Issued following an inspection in accordance with :
Art. 111(5) of Directive 2001/83/EC as amended

The competent authority of Belgium confirms the following:
The manufacturer: ***Janssen Pharmaceutica NV***
Site address: ***Janssen Pharmaceuticalaan 3, Geel, 2440, Belgium***

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:
Article 12 bis, § 4 of the Law of 25th March 1964 related to the Medicinal Products and Article 80 of the royal decree of 14 December 2006 related to medicinal products for human and veterinary use

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2017-04-06*** , it is considered that it complies with :

- The principles of GMP for active substances [3] 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. This certificate is valid only when presented with all pages and both Parts 1 and 2. The authenticity of this certificate may be verified in EudraGMDP. If it does not appear, please contact the issuing authority.

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[1] *The certificate referred to in paragraph 111(5) of Directive 2001/83/EC and 80(5) of Directive 2001/82/EC, shall also be required for imports coming from third countries into a Member State.*

[2] *Guidance on the interpretation of this template can be found in the Help menu of EudraGMDP database.*

[3] *These requirements fulfil the GMP recommendations of WHO.*

Part 2

Manufacture of active substance. Names of substances subject to inspection :
KETOCONAZOLE(en) / KETOCONAZOLE(nl)
ENILCONAZOLE(en) / ENILCONAZOLE(nl)
ITRACONAZOLE(en) / ITRACONAZOLE(nl)
FENTANYL(en) / FENTANYL(nl)
FENTANYL CITRATE(en) / FENTANYL CITRATE(nl)
DOMPERIDONE(en) / DOMPERIDONE(nl)
ALFENTANYL HYDROCHLORIDE(en) / ALFENTANYL HYDROCHLORIDE(nl)
KETANSERIN(en) / KETANSERIN(nl)
KETANSERIN TARTRATE(en) / KETANSERIN TARTRATE(nl)
ETRAVIRINE(en) / ETRAVIRINE(nl)
LEVOCABASTINE HYDROCHLORIDE(en) / LEVOCABASTINE HYDROCHLORIDE(nl)
RISPERIDONE(en) / RISPERIDONE(nl)
GALANTAMINE HYDROBROMIDE(en) / GALANTAMINE HYDROBROMIDE(nl)
PIPAMPERONE HYDROCHLORIDE(en) / PIPAMPERONE HYDROCHLORIDE(nl)
MICONAZOLE NITRATE(en) / MICONAZOLE NITRAAT(nl)
NEBIVOLOL HYDROCHLORIDE(en) / NEBIVOLOL HYDROCHLORIDE(nl)
HALOPERIDOL DECANOATE(en) / HALOPERIDOL DECANOATE(nl)
HALOPERIDOL(en) / HALOPERIDOL(nl)
PRUCALOPRIDE SUCCINATE(en) / PRUCALOPRIDE SUCCINATE(nl)
FLUSPIRILENE(en) / FLUSPIRILENE(nl)
BUPRENORPHINE(en) / BUPRENORPHINE(nl) / BUPRENORPHINE(nl) / BUPRENORPHINE(nl) / BUPRENORPHINE(nl) / BUPRENORPHINE(nl) / BUPRENORPHINE(nl) / BUPRENORPHINE(nl) / BUPRENORPHINE(nl) / BUPRENORPHINE(nl) / BUPRENORPHINE(nl) / BUPRENORPHINE(nl) / BUPRENORPHINE(nl) / BUPRENORPHINE(nl) / BUPRENORPHINE(nl) / BUPRENORPHINE(nl)
TAPENTADOL(en) / TAPENTADOL(nl)
RILPIVIRINE(en) / RILPIVIRINE(nl) / RILPIVIRINE(nl) / RILPIVIRINE(nl) / RILPIVIRINE(nl) / RILPIVIRINE(nl) / RILPIVIRINE(nl) / RILPIVIRINE(nl) / RILPIVIRINE(nl) / RILPIVIRINE(nl) / RILPIVIRINE(nl) / RILPIVIRINE(nl) / RILPIVIRINE(nl) / RILPIVIRINE(nl) / RILPIVIRINE(nl) / RILPIVIRINE(nl)
BROMPERIDOL DECANOATE(en) / BROMPERIDOL DECANOATE(nl)
MICONAZOLE(en) / MICONAZOLE(nl)
LOPERAMIDE HYDROCHLORIDE(en) / LOPERAMIDE HYDROCHLORIDE(nl)
PALIPERIDONE(en) / PALIPERIDONE(nl)
PALIPERIDONE PALMITATE(en) / PALIPERIDONE PALMITATE(nl) / PALIPERIDONE PALMITATE(nl) / PALIPERIDONE PALMITATE(nl) / PALIPERIDONE PALMITATE(nl) / PALIPERIDONE PALMITATE(nl) / PALIPERIDONE PALMITATE(nl) / PALIPERIDONE PALMITATE(nl) / PALIPERIDONE PALMITATE(nl) / PALIPERIDONE PALMITATE(nl) / PALIPERIDONE PALMITATE(nl) / PALIPERIDONE PALMITATE(nl) / PALIPERIDONE PALMITATE(nl) / PALIPERIDONE PALMITATE(nl) / PALIPERIDONE PALMITATE(nl) / PALIPERIDONE PALMITATE(nl)
DOMPERIDONE MALEATE(en) / DOMPERIDONE MALEATE(nl)
DAPOXETINE HYDROCHLORIDE(en) / DAPOXETINE HYDROCHLORIDE(nl)
CANAGLIFLOZIN(en) / CANAGLIFLOZIN(nl) / CANAGLIFLOZIN(nl) / CANAGLIFLOZIN(nl) / CANAGLIFLOZIN(nl) / CANAGLIFLOZIN(nl) / CANAGLIFLOZIN(nl) / CANAGLIFLOZIN(nl) / CANAGLIFLOZIN(nl) / CANAGLIFLOZIN(nl) / CANAGLIFLOZIN(nl) / CANAGLIFLOZIN(nl) / CAN

AGLIFLOZIN(nl) / CANAGLIFLOZIN(nl) / CANAGLIFLOZIN(nl) / CANAGLIFLOZIN(nl)
SIMEPREVIR(en) / SIMEPREVIR(nl)
RILPIVIRINE HYDROCHLORIDE(en) / RILPIVIRINE HYDROCHLORIDE(nl) / RILPIVIRINE HYDROCHLORIDE(nl) / RILPIVIRINE HYDROCHLORIDE(nl) / RILPIVIRINE HYDROCHLORIDE(nl) / RILPIVIRINE HYDROCHLORIDE(nl) / RILPIVIRINE HYDROCHLORIDE(nl) / RILPIVIRINE HYDROCHLORIDE(nl) / RILPIVIRINE HYDROCHLORIDE(nl) / RILPIVIRINE HYDROCHLORIDE(nl) / RILPIVIRINE HYDROCHLORIDE(nl) / RILPIVIRINE HYDROCHLORIDE(nl) / RILPIVIRINE HYDROCHLORIDE(nl)
AZAPERONE(en) / AZAPERONE(nl)
PIRITRAMIDE(en) / PIRITRAMIDE(nl)
PIMOZIDE(en) / PIMOZIDE(nl)
FLUNARIZINE DIHYDROCHLORIDE(en) / FLUNARIZINE DIHYDROCHLORIDE(nl)
ETOMIDATE(en) / ETOMIDATE(nl)
SUFENTANIL CITRATE(en) / SUFENTANIL CITRATE(nl)
CLOSANTEL SODIUM(en) / CLOSANTEL SODIUM(nl)
BUPRENORPHINE HYDROCHLORIDE(en) / BUPRENORPHINE HYDROCHLORIDE(nl)
PARCONAZOLE HYDROCHLORIDE(en) / PARCONAZOLE HYDROCHLORIDE(nl)
LOPERAMIDE OXIDE(en) / LOPERAMIDE OXIDE(nl)
DICLAZURIL(en) / DICLAZURIL(nl)
ABIRATERONE ACETATE(en) / ABIRATERONE ACETATE(nl)
BEDAQUILINE(en) / BEDAQUILINE(nl) / BEDAQUILLINE(nl) / BEDAQUILLINE(nl) / BEDAQUILLINE(nl) / BEDAQUILLINE(nl) / BEDAQUILLINE(nl) / BEDAQUILLINE(nl) / BEDAQUILLINE(nl) / BEDAQUILLINE(nl) / BEDAQUILLINE(nl) / BEDAQUILLINE(nl) / BEDAQUILLINE(nl) / BEDAQUILLINE(nl)
TELAPREVIR(en) / TELAPREVIR(nl) / TELAPREVIR(nl) / TELAPREVIR(nl) / TELAPREVIR(nl) / TELAPREVIR(nl) / TELAPREVIR(nl) / TELAPREVIR(nl) / TELAPREVIR(nl) / TELAPREVIR(nl) / TELAPREVIR(nl) / TELAPREVIR(nl) / TELAPREVIR(nl) / TELAPREVIR(nl) / TELAPREVIR(nl)
CINNARIZINE(en) / CINNARIZINE(nl)
DARUNAVIR(en) / DARUNAVIR(nl)

3. MANUFACTURING OPERATIONS - ACTIVE SUBSTANCES

Active Substance : KETOCONAZOLE

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 : dissolve crude API, filtering and crystalize as base or as salt
3.5	**General Finishing Steps**
	3.5.1 Physical processing steps : milling, sieving, homogenizing 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)

Active Substance : ENILCONAZOLE

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 : dissolve crude API, filtering and crystalize as base or as salt
3.5	**General Finishing Steps**
	3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)

Active Substance : ITRACONAZOLE

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 : dissolve crude API, filtering and crystalize as base or as salt
3.5	**General Finishing Steps**
	3.5.1 Physical processing steps : delumping, sieving, homogenizing 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)

Active Substance : FENTANYL

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
3.5	**General Finishing Steps**
	3.5.1 Physical processing steps : milling, sieving, homogenizing 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)

Active Substance : FENTANYL CITRATE

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 : dissolve crude API, filtering and crystalize as base or as salt
3.5	**General Finishing Steps**
	3.5.1 Physical processing steps : delumping, sieving, homogenizing 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)

Active Substance : DOMPERIDONE

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 : dissolve crude API, filtering and crystalize as base or as salt
3.5	**General Finishing Steps**
	3.5.1 Physical processing steps : milling, sieving, homogenizing 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)

Active Substance : ALFENTANYL 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 : dissolve crude API, filtering and crystalize as base or as salt
3.5	**General Finishing Steps**
	3.5.1 Physical processing steps : delumping, sieving, homogenizing 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)

Active Substance : KETANSERIN

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 : dissolve crude API, filtering and crystalize as base or as salt
3.5	**General Finishing Steps**
	3.5.1 Physical processing steps : milling, sieving, homogenizing 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)

Active Substance : KETANSERIN 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 : dissolve crude API, filtering and crystalize as base or as salt
3.5	**General Finishing Steps**
	3.5.1 Physical processing steps : milling, sieving, homogenizing 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)

Active Substance : ETRAVIRINE

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 : dissolve crude API, filtering and crystalize as base or as salt
3.5	**General Finishing Steps**
	3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)

Active Substance : LEVOCABASTINE 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 : dissolve crude API, filtering and crystalize as base or as salt
3.5	**General Finishing Steps**
	3.5.1 Physical processing steps : delumping, sieving, homogenizing 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)

Active Substance : RISPERIDONE

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 : dissolve crude API, filtering and crystalize as base or as salt
3.5	**General Finishing Steps**
	3.5.1 Physical processing steps : milling, sieving, homogenizing 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)

Active Substance : GALANTAMINE HYDROBROMIDE

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
3.5	**General Finishing Steps**
	3.5.1 Physical processing steps : delumping, milling, sieving, homogenizing 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)

Active Substance : PIPAMPERONE 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 : dissolve crude API, filtering and crystalize as base or as salt
3.5	**General Finishing Steps**
	3.5.1 Physical processing steps : milling, sieving, homogenizing 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)

Active Substance : MICONAZOLE NITRATE

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 : dissolve crude API, filtering and crystalize as base or as salt
3.5	**General Finishing Steps**
	3.5.1 Physical processing steps : milling, sieving, homogenizing 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)

Active Substance : NEBIVOLOL 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 : dissolve crude API, filtering and crystalize as base or as salt
3.5	**General Finishing Steps**
	3.5.1 Physical processing steps : milling, sieving, homogenizing 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)

Active Substance : HALOPERIDOL DECANOATE

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 : dissolve crude API, filtering and crystalize as base or as salt
3.5	**General Finishing Steps**
	3.5.1 Physical processing steps : delumping, homogenizing 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)

Active Substance : HALOPERIDOL

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 : dissolve crude API, filtering and crystalize as base or as salt
3.5	**General Finishing Steps**
	3.5.1 Physical processing steps : delumping, sieving, homogenizing 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)

Active Substance : PRUCALOPRIDE SUCCINATE

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 : dissolve crude API, filtering and crystalize as base or as salt
3.5	**General Finishing Steps**
	3.5.1 Physical processing steps : delumping, 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)

Active Substance : FLUSPIRILENE

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 : dissolve crude API, filtering and crystalize as base or as salt
3.5	**General Finishing Steps**
	3.5.1 Physical processing steps : delumping, sieving, homogenizing 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)

Active Substance : BUPRENORPHINE

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 : dissolve crude API, filtering and crystalize as base or as salt
3.5	**General Finishing Steps**
	3.5.1 Physical processing steps : delumping, homogenizing 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)

Active Substance : TAPENTADOL

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.1 Manufacture of active substance intermediates
3.5	**General Finishing Steps**
	3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)

Active Substance : RILPIVIRINE

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
3.5	**General Finishing Steps**
	3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material

	which is in direct contact with the substance) 3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)

Active Substance : BROMPERIDOL DECANOATE

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 : dissolve crude API, filtering and crystalize as base or as salt
3.5	**General Finishing Steps**
	3.5.1 Physical processing steps : delumping, sieving, homogenizing 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)

Active Substance : MICONAZOLE

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 : dissolve crude API, filtering and crystalize as base or as salt
3.5	**General Finishing Steps**
	3.5.1 Physical processing steps : milling, sieving, homogenizing 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)

Active Substance : LOPERAMIDE 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 : dissolve crude API, filtering and crystalize as base or as salt
3.5	**General Finishing Steps**
	3.5.1 Physical processing steps : milling, sieving, homogenizing

	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)

Active Substance : PALIPERIDONE

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.1 Manufacture of active substance intermediates
3.5	**General Finishing Steps**
	3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)

Active Substance : PALIPERIDONE PALMITATE

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.1 Manufacture of active substance intermediates
3.5	**General Finishing Steps**
	3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)

Active Substance : DOMPERIDONE MALEATE

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 : dissolve crude API, filtering and crystalize as base or as salt
3.5	**General Finishing Steps**
	3.5.1 Physical processing steps : delumping, sieving, homogenizing 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)

Active Substance : DAPOXETINE 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 : dissolve crude API, filtering and crystalize as base or as salt
3.5	**General Finishing Steps**
	3.5.1 Physical processing steps : milling, sieving, homogenizing 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)

Active Substance : CANAGLIFLOZIN

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 : dissolve crude API, filtering and crystalize as base or as salt
3.5	**General Finishing Steps**
	3.5.1 Physical processing steps : delumping, milling, sieving, homogenizing 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)

Active Substance : SIMEPREVIR

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 : dissolve crude API, filtering and crystalize as base or as salt
3.5	**General Finishing Steps**
	3.5.1 Physical processing steps : sieving, homogenizing 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)

Active Substance : RILPIVIRINE 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 : dissolve crude API, filtering and crystalize as base or as salt
3.5	**General Finishing Steps**
	3.5.1 Physical processing steps : milling, sieving, homogenizing 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)

Active Substance : AZAPERONE

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 : dissolve crude API, filtering and crystalize as base or as salt
3.5	**General Finishing Steps**
	3.5.1 Physical processing steps : sieving, homogenizing 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)

Active Substance : PIRITRAMIDE

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 : dissolve crude API, filtering and crystalize as base or as salt
3.5	**General Finishing Steps**
	3.5.1 Physical processing steps : delumping, sieving, homogenizing 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)

Active Substance : PIMOZIDE

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 : dissolve crude API, filtering and crystalize as base or as salt
3.5	**General Finishing Steps**
	3.5.1 Physical processing steps : milling, sieving, homogenizing 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)

Active Substance : FLUNARIZINE DIHYDROCHLORIDE

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 : dissolve crude API, filtering and crystalize as base or as salt
3.5	**General Finishing Steps**
	3.5.1 Physical processing steps : milling, sieving, homogenizing 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)

Active Substance : ETOMIDATE

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 : dissolve crude API, filtering and crystalize as base or as salt
3.5	**General Finishing Steps**
	3.5.1 Physical processing steps : delumping, sieving, homogenizing 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)

Active Substance : SUFENTANIL CITRATE

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 : dissolve crude API, filtering and crystalize as base or as salt
3.5	**General Finishing Steps**
	3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)

Active Substance : CLOSANTEL SODIUM

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 : dissolve crude API, filtering and crystalize as base or as salt
3.5	**General Finishing Steps**
	3.5.1 Physical processing steps : milling, sieving, homogenizing 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)

Active Substance : BUPRENORPHINE 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 : dissolve crude API, filtering and crystalize as base or as salt
3.5	**General Finishing Steps**
	3.5.1 Physical processing steps : milling, sieving, homogenizing 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)

Active Substance : PARCONAZOLE 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 : dissolve crude API, filtering and crystalize as base or as salt
3.5	**General Finishing Steps**
	3.5.1 Physical processing steps : milling, sieving, homogenizing 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)

Active Substance : LOPERAMIDE OXIDE

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 : dissolve crude API, filtering and crystalize as base or as salt
3.5	**General Finishing Steps**
	3.5.1 Physical processing steps : delumping, milling, sieving, homogenizing 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)

Active Substance : DICLAZURIL

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 : dissolve crude API, filtering and crystalize as base or as salt
3.5	**General Finishing Steps**
	3.5.1 Physical processing steps : milling, sieving, homogenizing 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)

Active Substance : ABIRATERONE ACETATE

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 : dissolve crude API, filtering and crystalize as base or as salt
3.5	**General Finishing Steps**
	3.5.1 Physical processing steps : 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)

Active Substance : BEDAQUILINE

3.5	**General Finishing Steps**
	3.5.1 Physical processing steps : milling, sieving, homogenizing 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)

Active Substance : TELAPREVIR

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 : dissolve crude API, filtering and crystalize as base or as salt
3.5	**General Finishing Steps**
	3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)

Active Substance : CINNARIZINE

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 : dissolve crude API, filtering and crystalize as base or as salt
3.5	**General Finishing Steps**
	3.5.1 Physical processing steps :

	milling, sieving, homogenizing 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)

Active Substance : DARUNAVIR

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.1 Manufacture of active substance intermediates
3.5	**General Finishing Steps**
	3.5.1 Physical processing steps : delumping, milling, sieving, homogenizing 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)

2017-07-13

Name and signature of the authorised person of the Competent Authority of Belgium

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