HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Health Products Regulatory Authority

CERTIFICATE NUMBER: *21677/ASR12195*

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 Ireland confirms the following:
The manufacturer: ***Eli Lilly Kinsale Limited***
Site address: ***Dunderrow, Kinsale, Co. Cork, P17 NY71, Ireland***

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:
Medicinal Products (Control of Manufacture) Regulations 2007 to 2013.

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2018-12-07*** , 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.

---

[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.*

An tÚdarás Rialála Táirgí Sláinte, Teach Kevin O'Malley, Ionad Phort an Iarla, Ardán Phort an Iarla, Baile Átha Cliath 2, Éire
Health Products Regulatory Authority, Kevin O'Malley House, Earlsfort Centre, Earlsfort Terrace, Dublin 2, D02XP77, Ireland
T: +353 1 676 4971 • F: +353 1 676 7836 • info@hpra.ie • www.hpra.ie

Part 2

Manufacture of active substance. Names of substances subject to inspection :
RALOXIFENE HYDROCHLORIDE(en)
ATOMOXETINE HYDROCHLORIDE(en)
OLANZAPINE(en)
BARICITINIB(en)
ABEMACICLIB(en)
PEMETREXED DISODIUM HEPTAHYDRATE(en)
OLANZAPINE MICRONISED(en)
OLANZAPINE PAMOATE MONOHYDRATE(en)

3. MANUFACTURING OPERATIONS - ACTIVE SUBSTANCES	
Active Substance : RALOXIFENE 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 and De-agglomeration 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
Active Substance : ATOMOXETINE 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 and De-agglomeration 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)

An tÚdarás Rialála Táirgí Sláinte, Teach Kevin O'Malley, Ionad Phort an Iarla, Ardán Phort an Iarla, Baile Átha Cliath 2, Éire
Health Products Regulatory Authority, Kevin O'Malley House, Earlsfort Centre, Earlsfort Terrace, Dublin 2, D02XP77, Ireland
T: +353 1 676 4971 • F: +353 1 676 7836 • info@hpra.ie • www.hpra.ie

3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing
Active Substance : OLANZAPINE	
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, De-agglomeration 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
Active Substance : BARICITINIB	
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 and De-agglomeration 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing 3.6.2 Microbiological testing excluding sterility testing
Active Substance : ABEMACICLIB	
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 :

An tÚdarás Rialála Táirgí Sláinte, Teach Kevin O'Malley, Ionad Phort an Iarla, Ardán Phort an Iarla, Baile Átha Cliath 2, Éire
Health Products Regulatory Authority, Kevin O'Malley House, Earlsfort Centre, Earlsfort Terrace, Dublin 2, D02XP77, Ireland
T: +353 1 676 4971 • F: +353 1 676 7836 • info@hpra.ie • www.hpra.ie

	Crystallisation
3.5	**General Finishing Steps**
	3.5.1 Physical processing steps : Drying, Milling/Micronisation, Sieving 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing

Active Substance : PEMETREXED DISODIUM HEPTAHYDRATE

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 : Diacid salt formation
3.5	**General Finishing Steps**
	3.5.1 Physical processing steps : Drying, De-agglomeration 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing 3.6.2 Microbiological testing excluding sterility testing

Active Substance : OLANZAPINE MICRONISED

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 : 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)

An tÚdarás Rialála Táirgí Sláinte, Teach Kevin O'Malley, Ionad Phort an Iarla, Ardán Phort an Iarla, Baile Átha Cliath 2, Éire
Health Products Regulatory Authority, Kevin O'Malley House, Earlsfort Centre, Earlsfort Terrace, Dublin 2, D02XP77, Ireland
T: +353 1 676 4971 • F: +353 1 676 7836 • info@hpra.ie • www.hpra.ie

3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing
Active Substance : OLANZAPINE PAMOATE MONOHYDRATE	
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 3.6.2 Microbiological testing excluding sterility testing

2019-03-07

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

CERTIFIED HPRA

Mr. Oisin Daly
Health Products Regulatory Authority
Tel: *+353 31 6764971*
Fax:

An tÚdarás Rialála Táirgí Sláinte, Teach Kevin O'Malley, Ionad Phort an Iarla, Ardán Phort an Iarla, Baile Átha Cliath 2, Éire
Health Products Regulatory Authority, Kevin O'Malley House, Earlsfort Centre, Earlsfort Terrace, Dublin 2, D02XP77, Ireland
T: +353 1 676 4971 • F: +353 1 676 7836 • info@hpra.ie • www.hpra.ie