愛爾蘭-1

This is a certified true copy of the original
Signed:
Ref: CM/2360 1001-641 14-028
Date: 21/7/14

HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

CERTIFICATE NUMBER:

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:
Site address:

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 ***2014-03-14***, 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.
(3) These requirements fulfil the GMP recommendations of WHO.

[1] The authorisation referred to in paragraph 40(1) of Directive 2001/83/EC and 44(1) of Directive 2001/82/EC, as amended, 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] the Competent Authority is responsible for appropriate linking of the authorisation with the manufacturer's application (Art. 42(3) of Directive 2001/83/EC and Art. 46(3) of Directive 2001/82/EC as amended)

ture of active substance. Names of substances subject to inspection:

3. MANUFACTURING OPERATIONS - ACTIVE SUBSTANCES *(Include extra rows where necessary)*	
Active substance(s):	
3.1	**Extraction 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 (Purification step only)*
3.5	**General finishing steps**
	3.5.1 Physical processing steps: *Drying* 3.5.2 Primary packaging 3.5.3 Secondary packaging
3.6	**Quality control testing**
	3.6.1 Physical / chemical testing
Active substance(s): ***ATAZANAVIR SULPHATE (en)***	
3.1	**Extraction 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, Delumping* 3.5.2 Primary packaging 3.5.3 Secondary packaging
3.6	**Quality control testing**
	3.6.1 Physical / chemical testing