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OMNICHEM

CERTIFICATE OF ANALYSIS

Product:	**TICAGRELOR**		
Manufacturing Site:	**Ajinomoto OmniChem Balen**	Customer:	**AstraZeneca**
Lot number:	**605770165B**	Order n° customer:	
Manufacturing date:	**26 January 2017**	Order n° AOC:	
Retest date:	**26 January 2020**	Date of issue:	**08 March 2017**

TEST	SPECIFICATION	RESULT
Appearance	White or off-white to pale pink powder	Off White Powder
Identification by IR	Conformity to the Reference Standard	Conformity to the Reference Standard
Assay by HPLC	98% – 102% w/w calculated on a solvent free basis	99.9
Residual Solvent by GC		
➢ Ethyl Acetate	NMT 0.5% w/w	<0.05
➢ Iso-octane	NMT 0.2% w/w	<0.02
Purity by HPLC		
➢ UL127	NMT 0.30% w/w	0.15
➢ UL133	NMT 0.25% w/w	nd
➢ UL134	NMT 0.2% w/w	<0.05
➢ AZ13232789	NMT 0.1% w/w	<0.05
➢ Any individual unspecified impurity	NMT 0.10% w/w	<0.05
➢ total organic impurities	NMT 1.0% w/w	0.15
Potential genotoxic impurity C3 (HPLC)	NMT 8 ppm	<8
Sulphated ash	NMT 0.6% w/w	<0.05
Particle size[i]		
➢ D90	NMT 30 µm	12
XRPD	Conforms to the Reference diffractogram (Form II)	Conform to the Reference diffractogram (Form II)

NMT=Not more than

K. Van den Broeck
QUALITY CONTROL

Reference : *Gel Version ID : CV.000-440-008.2.0*

[i] D (v, 0.9) identifies the 90% fraction of particles in the distribution (as determined by volume) which have a particle diameter at or below the value reported. For example, D (v, 0.9) = 15µm means that 90% of the particles have a particle diameter of ≤ 15µm.

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CERTIFICATE OF ANALYSIS

TICAGRELOR

Batch Number:	AAEC
Date of Manufacture:	Jan-2017
Re-test date:	Dec-2019
Specification:	CV.000-400-008.2.0

TEST/PROCEDURE	ACCEPTANCE CRITERIA	RESULT
Description	White or off-white to pale pink powder	Complies
Identification	Conformity to reference standard	Complies
Assay	98 % to 102 % w/w calculated on a solvent free basis	100 % w/w
Residual solvents		
Ethyl acetate	Not more than 0.5 % w/w	0.1 % w/w
iso-Octane	Not more than 0.2 % w/w	< 0.1 % w/w
Organic impurities		
UL127	Not more than 0.30 % w/w	0.10 % w/w
UL133	Not more than 0.25 % w/w	< 0.05 % w/w
UL134	Not more than 0.2 % w/w	< 0.1 % w/w
AZ13232789	Not more than 0.1 % w/w	< 0.1 % w/w
Any individual unspecificed impurity	Not more than 0.10 % w/w	< 0.05 % w/w
Total organic impurities	Not more than 1.0% w/w	0.1 % w/w
Potential genotoxic impurity (C3)	Not more than 8 ppm	< 8 ppm
Sulphated ash	Not more than 0.6 % w/w	0.2 % w/w
Particle size	D(v, 0.9) Not more than 30 µm	19 µm
Polymorphic form	Conformity to reference standard (Form II)	Complies

Document ID: Doc ID-003532483
Version Number: 1.0
Status: Approved
Document Status Date: 08/Mar/2017

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CERTIFICATE OF ANALYSIS

TICAGRELOR

Batch Number:	AAEC
Date of Manufacture:	Jan-2017
Re-test date:	Dec-2019
Specification:	CV.000-400-008.2.0

Comments: This certificate has been issued for regulatory purposes only and is not connected with any delivery of goods. NOT FOR COMMERCIAL USE.

I hereby certify that the above information is authentic and accurate. This batch of product has been manufactured including packaging and quality control at the above mentioned site(s), in full compliance with the GMP requirements. The batch processing and analysis records were reviewed and found to in compliance with GMP.

Released by:	Jessika Johansson	With Delegation from Qualified Person
Released on:	28-February-2017	
Issued by:	Peter Solsjö	Delegated Qualified Person
		2017-03-08
Reviewed by:	Christoffer Widholm	Delegated Qualified Person
		2017-03-08

Document ID: Doc ID-003532483
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CERTIFICATE OF ANALYSIS — 21 09 2017 - CPQP / Tros / 01

TICAGRELOR — Batch: LHCYAA9003
(CYPA 128) — co.No.: 040000190647

Product conforms to: — Regulatory Specification for Drug Substance CV.000-440-008.2.0

Tests	Results	Specification
Description (Visual inspection)	white powder	white or off white to pale pink powder
Identification (IR spectroscopy)	conforming	conforms to reference standard
Assay (HPLC, calculated on solvent free basis)	99,6 %	98 -102 %
Residual solvents (GC)		
Ethyl acetate	0,05 %	NMT 0,5 %
iso-octane	< 0,02 %	NMT 0,2 %
Organic impurities (HPLC)		
UL127	0,09 %	NMT 0,30 %
UL133	not detected	NMT 0,25 %
UL134	not detected	NMT 0,2 %
AZ13232789	< 0,05 %	NMT 0,1 %
Any individual unspecified impurity	not detected	NMT 0,10 % each
Total organic impurities	0,09 %	NMT 1,0 %
Potential genotoxic impurity (C3) (HPLC)	< 8 ppm	NMT 8 ppm
Sulphated ash (USP/Ph.Eur.)	0,3 %	NMT 0,6 %
Particle size (Laser diffraction)		
D(v, 0.9)	10 µm	NMT 30 µm
Polymorphic form (XRPD)	conforming	conformity to reference standard (Form II)
Manufacturing date	02 2017	
Retest date	02 2019	

Dr. E. Steinwender
Head of Product Release
Qualified Person