

**ANALYSIS CERTIFICATE**

**CODE:** 141130      **BATCH:** 0001250003

**PRODUCT:**

**ISSUE DATE:** 09/11/2017

**RETEST DATE:** 11/2023

<b>SPECIFICATIONS</b>	<b>GUARANTEE VALUE</b>	<b>ACTUAL VALUE</b>
Assay (Acidim.)	27,0-30,0 %*	28,1%*
Identity according to Pharmacopoeias:	passes test	Passes test
Density 20/20	0,892-0,901*	0,898*
Maximum limit of impurities		
Appearance of solution	passes test	Passes test
Insoluble matter in H <sub>2</sub> O	passes test	Passes test
Non-volatile matter	0,002 %	0,002 %
Reducing substances to KMnO <sub>4</sub>	passes test	Passes test
Residue on ignition	0,01 %	0,001 %
Chloride (Cl)	0,0001%	<0,0001%
Sulphur compounds (as SO <sub>4</sub> )	0,0005 %	<0,0005 %
Phosphate (PO <sub>4</sub> )	0,0005 %	<0,0005 %
Carbonate (as CO <sub>3</sub> )	0,005%	<0,005%
Residual solvents (Ph.Eur/USP)	passes test	Passes test
Pyridine and homologues (as C <sub>6</sub> H <sub>5</sub> N)	0,0002%	<0,0002%
Heavy metals (as Pb)	0,0001%	<0,0001%
Ca	0,001 %	<0,001 %
Fe	0,000025 %	<0,000025 %
Mg	0,001 %	<0,001 %
Elemental impurities (ICH Q3D):		
Class 1		
Cd	0,5 ppm	<0,5 ppm
Pb	0,5 ppm	<0,5 ppm
As	0,4 ppm	<0,4 ppm
Hg	1,5 ppm	<1,5 ppm
Class 2A		
Co	5 ppm	<5 ppm
V	10 ppm	<10 ppm
Ni	20 ppm	<20 ppm
Class 2B		
Tl	0,8 ppm	<0,8 ppm
Au	10 ppm	<10 ppm
Pd	10 ppm	<10 ppm
Ir	10 ppm	<10 ppm
Os	10 ppm	<10 ppm
Rh	10 ppm	<10 ppm
Ru	10 ppm	<10 ppm
Se	15 ppm	<15 ppm
Ag	15 ppm	<15 ppm
Pt	10 ppm	<10 ppm
Class 3		
Li	55 ppm	<55 ppm
Sb	120 ppm	<120 ppm
Ba	140 ppm	<140 ppm
Mo	25 ppm	<25 ppm
Cu	250 ppm	<250 ppm
Sn	600 ppm	<600 ppm
Cr	25 ppm	<25 ppm

\* At the moment of the batch analysis.

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Quality Assurance Director  
Director de Garantía Calidad  
**P. Verge**

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