

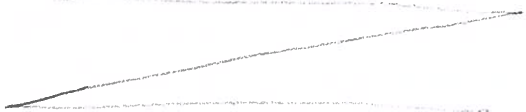
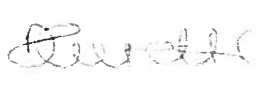
CERTIFICATE OF ANALYSISIssued by QA Aime Silvia *A*Date 10/11/2020

CoA 86000434 V2.0

Product VIGABATRIN**Product Code:** 86000434**Lot No.:** 200019**Analysis No.:** QC-000003873**Lot size:** Kg. 1.080,000**Packaging:** 50 Kg in drums**Shipped Q.ty:** Kg. 550,000**Order Ref.:** SO00000782**Specification:** GAPS006/10E**MFG. Date:** 21 april 2020**Retest Date:** 20 april 2025**Release date:** 1 july 2020**Non sterile "API" - To be used as a non-sterile product to enter the manufacturing of non-parenteral drug product**
PRODUCTION DATA

SINGLE LAYER LOT		OP. 200019	kg. 1.080,00
TEST ITEMS	LIMITS	RESULTS	
Description	White or almost white powder	C	
Identification	Positive	P	
Solubility	Freely soluble in water, slightly soluble in methanol, practically insoluble in methylene chloride	C	
Transmittance	Record (%)	100,0	
Melting range	171 - 177°C, within a 3°C range with decomposition	172.1-174.0	
Specific rotation	-0,5° to +0,5°	0,0	
Water Content (KF)	NMT 0,5%	0,1	
Sulphated ash	NMT 0,1%	< 0,1	
Heavy metals	NMT 10 ppm	<10	
Colour Index	Clear and not more intensely colored than Y6 or BY6	Y7	
Tapped density	0,60 to 0,85 g/ml	0,71	
Foreign material	NMT 10 ppm	1	
Particle size (US serie sieves): on n°30 (600 µ)	NMT 1%	< 1	
Particle size (US serie sieves): thru n°270 (53 µ)	NMT 50%	31	
Residual solvents: Ethanol	NMT 0,5%	0,2	
Residual solvents: Isopropanol	NMT 0,1%	< 0,1	
Residual solvents: Total	NMT 0,6%	0,2	
Related substances: Impurity A (5-VP)	NMT 0,15%	ND	
Related substances: Impurity B (2-EG)	NMT 0,15%	ND	
Related substances: unspecified impurities each EP	NMT 0,05%	ND	
Related substances: Total EP	NMT 0,5%	0,1	
Related substances: Impurity D (GABA)	NMT 0,2%	0,1	
Potentiometric assay (on dried substance)	98,5 to 101,5%	100,5	
Flowability test	Record	32	

The API meets all of the applicable specifications and the batch has been manufactured under conditions complying with all relevant GMP, or the equivalent requirements in the country of manufacture, the master batch record, and all other applicable regulatory documents

Observations	QUALITY ASSURANCE	A = Absent C = Compliant P = Positive ND = Not Detectable # = Not Performed
	 Curetti Daniela Date <u>10.11.2020</u>	