BACHEM

Certificate of Analysis

Product	**CARBIDOPA**
Article number	**4037809**
Lot number	**L-1610-101-193/5000159**
Date of Manufacture	January, 2011
Date of Retest	January, 2016
Date of Release	March 10, 2011
Analysis number	73980
Release number	12472
Specifications	Conform to current USP and Eur. Ph. specifications
Quantity	25 kg **to** METAPHARMACEUTICALS
Storage Conditions	Room temperature

LOTE: 0)603)2

Tests	Specifications	Results
Description		
Visual inspection	White to creamy white powder	Complies
Identification		
IR spectrometry (2.2.24)	Complies with reference	Complies
Specific optical rotation (2.2.7)	-22.5 ° to -26.5° (dried basis)	-23.6°
Purity		
Appearance of solution (2.2.1, 2.2.2 II)	Clear and NMT BY_6 or B_6	Complies
Specific optical rotation (2.2.7)	-22.5 ° to -26.5° (dried basis)	-23.6°
Heavy metals (2.4.8)	NMT 10 ppm	NMT 10 ppm
Loss on drying (2.2.32)	6.9 to 7.9%	7.7%
Sulfated ash (2.4.14)	NMT 0.1%	0.04%
Hydrazine (2.2.27)	NMT 20 ppm	NMT 20 ppm
Residual solvents (2.4.24)		
Ethanol	NMT 5000 ppm	34 ppm
Toluene	NMT 890 ppm	< 1 ppm
Related substances by HPLC (2.2.29)		
Specified impurities		
Methyldopa	NMT 0.5%	0.35%
3-o-Methylcarbidopa	NMT 0.5%	Not detected
Carbidopamethylester	NMT 0.15%	0.09%
Carbidopaethylester	NMT 0.15%	Not detected
Unknown impurity	NMT 0.10%	Not detected
Unspecified impurities		
Unknown impurity	NMT 0.10%	0.09%
Total impurites	NMT 1.0%	0.6%
Assay		
Potentiometric titration (2.2.20)	98.5 to 101.0% (dried basis)	100.2%
HPLC <621>	98.0 to 102.0%	99.2%

I hereby certify that the above information is authentic and accurate. This batch of product has been manufactured, including packaging and quality control at Bachem SA in Vionnaz / Switzerland in full compliance with the GMP requirements of the local Regulatory Authority and according to the ICH Q7 Guideline for APIs. The batch processing, packaging and analysis records were reviewed and found to be in compliance with GMP.

Date: March 21, 2012
Bachem SA

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