

# 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

LOT: 0160312

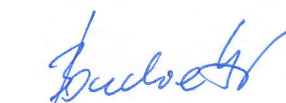
Tests	Specifications	Results
<b>Description</b>		
Visual inspection	White to creamy white powder	Complies
<b>Identification</b>		
IR spectrometry (2.2.24)	Complies with reference	Complies
Specific optical rotation (2.2.7)	-22.5 ° to -26.5° (dried basis)	-23.6°
<b>Purity</b>		
Appearance of solution (2.2.1, 2.2.2 II)	Clear and NMT BY <sub>6</sub> or B <sub>6</sub>	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 impurities	NMT 1.0%	0.6%
<b>Assay</b>		
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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