

Kalchem International

Chemicals & Compounding Supplies

Certificate of Analysis

Record number: MY-SOP-ZG103.00/01

Name: <u>Amantadine Hydrochloride</u>	Analytical Report No.: <u>15-JJ-0415</u>
BatchNo: <u>JJ201505012-013</u>	Date Of Sampling: <u>2015/05/06</u>
Batch Quantity: <u>8Kg</u>	Date Of Reporting: <u>2015/05/07</u>
Specification: <u>/</u>	Please check the unit: <u>A Workshop</u>
According: <u>USP35</u>	Date Of Expiry: <u>2018/05/05</u>

Test Items	Specification	Result
Description	White crystalline powder	White crystalline powder
Identification	Infrared Absorption	Conformed
Clarity and color of solution	Clear and nearly colorless	Conformed
pH	3.0~5.5	4.0
Heavy metals	≤0.001 %	<0.001 %
Organic volatile (acetone)	≤0.5%	Conformed
Chromatographic purity	Any individual impurity≤0.3%	0.10 %
	total impurities ≤1.0%	0.15 %
Assay (moisture)	98.5%~101.5%	99.8%

Conclusion: Conforming to the standard of USP35

QC MANAGER: 

CHECKED BY: 

TESTED BY: 

Kalchem International, Inc
 224 South Main Street - Lindsay, OK 73052
 Toll Free 888-298-9905 | FAX: 405-756-2373