HALLOCHEM

Hallochem Group
Chongqing Waycome Pharmaceutical Co.,Ltd.

CERTIFICATE OF ANALYSIS-revised2

Product Name:	Cytisine
Botanical Name:	Leguminosae plant Sophora alopecuroides
Plant Part:	Seed
Batch Number:	20141220
Batch Quantity:	5kgs
Date:	2014-12-20

Item	Specification	Result
Assay (HPLC)		
Cytisine (On anhydrous basis)	≥98%	99.2%
Identification		
A:IR	IR spectrum corresponds to the reference spectrum	Complies
B: UV	Absorbance maxima between 200nm and 340nm is 232nm and 305nm	Complies
C:HPLC	The retention time of the major peak in the chromatogram of the Assay preparation corresponds to that in the chromatogram of the Standard preparation, as obtained in the Assay.	Complies
Physical Control		
Appearance:	Crystalline Powder	Complies
Color:	Off-White	Complies
Odor:	Characteristic	Complies
Melt point:	154℃~157℃	155℃
Optical Rotation:	-118° ~-125°	-120°
Bulk Density:	40-60g/100ml	Complies
Mesh Size:	80 mesh	Complies
Loss On Drying:	≤1%	0.8%
Chemical Control		
Residue on ignition:	≤0.1%	0.08%
Total Heavy Metals:	≤10PPM	Complies
Arsenic:	≤2PPM	Complies
Pb:	≤2PPM	Complies
Related Substances		
N-Methylcytisine	≤0.5%	Complies
N-Formylcytisine	≤0.5%	Complies
Individual unspecified impurity	≤0.3%	Complies
Total of other impurities	≤1.5%	Complies

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Residuesolvent		
Methanol:	≤3000ppm	Complies
Chloroform:	≤60ppm	Complies
Acetone:	≤5000ppm	Complies
Microbiological Control		
Total Plate Count:	<1000CFU/gm	Complies
Yeast&Mold:	<100CFU/gm	Complies
Salmonella:	Negative	Complies
E.Coli:	Negative	Complies
Staphylococcus:	Negative	Complies
Storage:	Closed keep in cool,dry and dark place ;keep from heat and strong light	
Shelf life:	36 Months	

Quality Manager: **Rechecker:** **Analyst:**

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