

Lote 0030415

Hallochem Group

HALLOCHEM

Chongqing Waycome Pharmaceutical Co.,Ltd.

CERTIFICATE OF ANALYSIS-Revised

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)	$\geq 98\%$	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°C~157°C	155°C
Optical Rotation:	-118° ~-125°	-120°
Bulk Density:	40-60g/100ml	Complies
Mesh Size:	80 mesh	Complies
Loss On Drying:	$\leq 1\%$	0.8%

Chemical Control

Residue on ignition:	$\leq 0.1\%$	0.08%
Total Heavy Metals:	$\leq 10\text{PPM}$	Complies
Arsenic:	$\leq 2\text{PPM}$	Complies
Pb:	$\leq 2\text{PPM}$	Complies

Related Substances

N-Methylcytisine	$\leq 0.5\%$	Complies
N-Formylcytisine	$\leq 0.5\%$	Complies
Individual unspecified impurity	$\leq 0.3\%$	Complies
Total of other impurities	$\leq 1.5\%$	Complies



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Residuesolvent

Methanol: $\leq 3000\text{ppm}$
Chloroform: $\leq 60\text{ppm}$
Acetone: $\leq 5000\text{ppm}$

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Complies

Complies

Complies

Microbiological Control

Total Plate Count: $<1000\text{CFU/gm}$
Yeast&Mold: $<100\text{CFU/gm}$
Salmonella: Negative
E.Coli: Negative
Staphylococcus: Negative

Complies

Complies

Complies

Complies

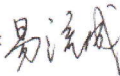
Complies

Storage: Closed keep in cool,dry and dark place ;keep from heat and strong light
Shelf life: 24 Months

Quality Manager:



Rechecker:



Analyst:



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