

Hallochem Group

Chongqing Waycome Pharmaceutical Co.,Ltd.

HALLOCHEM

CERTIFICATE OF ANALYSIS

Product Name:	Cytisine	
Botanical Name:	Leguminosae plant Sophora alopecuroides	
Plant Part:	Seed	
Batch Number:	20200121	
Quantity:	5kgs	
Manuf. Date:	2020-01-21	
Item	Specification	Result
Assay (HPLC)		
Cytisine (On anhydrous basis)	≥98%	99.1%
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	155.7°C
Optical Rotation:	-118° ~-125°	-120°
Bulk Density:	40-60g/100ml	Complies
Mesh Size:	80 mesh	Complies
Loss On Drying:	≤2.0%	1.0%
Chemical Control		
Residue on ignition:	≤0.1%	0.05%
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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ResiduesolventMethanol: $\leq 3000\text{ppm}$ Chloroform: $\leq 60\text{ppm}$ Acetone: $\leq 5000\text{ppm}$ **HALLOCHEM**

Complies

Complies

Complies

Microbiological ControlTotal Plate Count: $<1000\text{CFU/gm}$ Yeast&Mold: $<100\text{CFU/gm}$

Salmonella: Negative

E.Coli: Negative

Staphylococcus: Negative

Complies

Complies

Complies

Complies

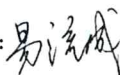
Complies

Storage: Closed keep in cool,dry and dark place ;keep from heat and strong light**Shelf life:** 36 Months

Quality Manager:



Rechecker:



Analyst:



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