

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:	CTS20221203
Quantity:	5kgs
Manuf. Date:	2022-12-25

Item	Specification	Result
Assay (HPLC)		
Cytisine (On anhydrous basis)	$\geq 98\%$	99.4%

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	155.6°C
Optical Rotation:	-118° ~-125°	-120°
Bulk Density:	40-60g/100ml	Complies
Mesh Size:	80 mesh	Complies
Loss On Drying:	$\leq 2.0\%$	0.50%

Chemical Control

Residue on ignition:	$\leq 0.1\%$	0.05%
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:	$\leq 3000\text{ppm}$	Complies
Chloroform:	$\leq 60\text{ppm}$	Complies
Acetone:	$\leq 5000\text{ppm}$	Complies

Microbiological Control

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