

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:	CTS20241201
Batch Quantity:	35kgs
Manuf. Date:	2024-12-22

Item	Specification	Result
Assay (HPLC)		
Cytisine (On anhydrous basis)	≥98%	98.7%

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	155.8°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%	0.08%
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

Add:No. 138 YuWu Road, XinMin Town, DianJiang 408302, chongqing,china

METAPHARMACEUTICAL

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Alcandro
05/05/2026

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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	

Storage: Closed keep in cool (0-4℃) , dry and dark place ;keep from heat and strong light

Quality Manager:

吴家豪

Rechecker:

易汝成

Analyst: 刘琪



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