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24/02/2023

Hallochem Group

HALLOCHEM

Chongqing Waycome Pharmaceutical Co.,Ltd.

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)	≥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:	≤2.0%	0.50%

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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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:

宋永军

Rechecker:

易洪成

Analyst: 刘兵



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