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Certificate of Analysis

Product and Batch Information			
Product Name:	Thermopsis lanceolata Extract Powder	Country of Origin:	P.R. China
Botanic name:	<i>Thermopsis lanceolata</i>	Active ingredients	Cytisine
Batch No.:	CS-TLE-140516	Manufacture Date:	May 16, 2014.
Analysis Date:	May 18, 2014.	Expiry Date:	May 15, 2016.

Item	Specification	Result	Test Method
Active Ingredients			
Assay(% On Dried Base)	Cytisine $\geq 98.0\%$	99.76%	HPLC
Physical Control			
Appearance	Light yellow or white crystalline powder	Comforms	Visual
Odor	Characteristic	Comforms	Organoleptic
Taste	Characteristic	Comforms	Organoleptic
Loss on Drying	0.5% Max	0.35%	USP
Ash	0.2% Max	0.01%	USP
Identification	Positive	Conforms	IR, UV, HPLC & Colour reaction
Melting point	154°C~157°C	154.8-156.6°C	USP
Optical rotation	-120° to -125°	-122.5°	USP
Clarity of the solution	Not more intensely opalescent than reference suspension II	Conforms	USP
Color of the solution	Not more intensely coloured than reference solution Y1	Conforms	USP
Solubility	Freely soluble in water, methanol, ethanol, soluble in acetonitrile and chloroform	Conforms	USP
Part of Plant Used	Dried Seed	Conforms	/
Solvents Used	Purified Water & Ethanol	Conforms	/
Chemical Control			
Heavy metals	10ppm Max	Conforms	Atomic Absorption
Arsenic	2ppm Max	Conforms	Atomic Absorption
Lead	2ppm Max	Conforms	Atomic Absorption
Related substance	-N-methylcytisine $\leq 0.5\%$	Negative	USP
	-N-formylcytisine $\leq 0.5\%$	Negative	USP
	-Total impurities $\leq 1.0\%$	0.07%	USP
Chlorides	$\leq 0.020\%$	0.01%	USP
Residue on solvents	$\leq 0.50\%$	0.01%	USP
Residue of Pesticide	Negative	Conforms	USP
Microbiological Control			
Total Plate Count	10,000cfu/g Max	Conforms	USP
Yeast & Mold	300cfu/g Max	Conforms	USP
E.Coli	Negative	Conforms	USP
Salmonella sp.	Negative	Conforms	USP
Packing and Storage			
Packing	Pack in 1kg/Aluminum foil bag.		
Storage	Store in a well-closed container away from moisture and direct sunlight.		
Shelf Life	24 months if sealed and stored properly.		

Manufactured by Yangling Haotian Bio-technology

Commercialized by Wuxi Cima Science Co., Ltd.