

杭州东瑞医药科技有限公司
HANGZHOU DAWN RAY PHARMACEUTICAL CO.,LTD.

CERTIFICATE OF ANALYSIS

Betulinic acid(Brich bark powder extract)

Batch No.: DR20130107	Piece: 10.0kg
Plant Part: Bark	Plant Latin Name: Betula platyphylla
Country of Origin: China	Extraction Solvent: Ethanol,water
Manufacture Date: 2013.01.07	Expiry Date: 2015.01.06

TESTS:

Items	Specification	Results	Methods
Appearance	White or off white fine powder		
Bulk density(g/ml)	0.25~0.45	Conforms	ASTM D1895B
Particle size	98% pass through 60mesh	Conforms	AOAC973.03
Loss on drying	≤ 2.0%	1.12%	USP33
Ash content	≤ 2.0%	0.37%	USP33
Betulinic acid	≥ 98%	98.34%	HPLC(Dried basis)
Heavy metals	≤ 10ppm	Conforms	USP33
Lead	≤ 1.5ppm	Conforms	ICP-MS
Arsenic	≤ 1.0ppm	Conforms	ICP-MS
Mercury	≤ 0.2ppm	Conforms	ICP-MS
Residue solvents	Ethanol: ≤1000ppm	Conforms	GC
Microbiological specification	Total aerobic(CFU/g): ≤1000	Conforms	USP33
	Mold and yeast(CFU/g): ≤100	Conforms	USP33
	Coliform: Negative	Negative	USP33
	Salmonella:Negative	Negative	USP33
Remarks	1) Non-irradiated,Non-GMO,Non-allergen; 2) Storage: Store in tightly closed plastic bag and keep in a cool dry place.Do not freeze.Keep always from strong direct light. 3) Safety precaution:Wearing of protective goggles or safety glasses is recommended.If accidentally instilled into the eyes,immediately rinse thoroughly with water and get medical care. Wash skin with soap and water upon contact.		

Conclusion: The results conform with the standard.

Checked by: _____

Approved by: _____

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