



**HUADONG MEDICINE CO. LTD.**  
700, SHIXIANG ROAD, HANGZHOU, 310011, CHINA

Lot: C070911

CERTIFICATE OF ANALYSIS

**ACARBOSE**

Batch No.:	110605AKEP	Manu. Date:	JUNE 27, 2011
Packing:	5kgs/ drum	Anal. Date:	JULY 7, 2011
Quantity:	5.00kgs	Expi. Date:	JUNE 26, 2013

TEST		SPECIFICATION	RESULT
Appearance		White or yellowish, amorphous powder	White amorphous powder
Identification A (IR)		Should be conform	Conform
Identification B (HPLC)		Should be conform	Conform
Assay(on anhydrous basis)		95.0-102.0%	96.4%
Water		≤4.0%	1.9%
Absorbance		≤0.15	0.03%
Specific optical rotation		+168 to +183°	+178°
Sulfated ash		≤0.2%	0.1%
pH		5.5-7.5	5.9
Heavy metals		Not more than 20ppm	Conform
Related substance	Impurity A	Max 0.6%	0.3%
	Impurity B	Max 0.5%	Not detected
	Impurity C	Max 1.5%	0.4%
	Impurity D	Max 1.0%	0.2%
	Impurity E	Max 0.2%	Not detected
	Impurity F	Max 0.3%	Not detected
	Impurity G	Max 0.3%	Not detected
	Impurity H	Max 0.2%	Not detected
Any other impurities		Each impurity Max 0.2%	Not detected
Total impurities		Max 3.0%	0.9%
Bacteria		≤1000cfu/g	10cfu/g
Mould & Yeast		≤100cfu/g	<10cfu/g
Escherichia coli		None	No detected
Conclusion :		Complied with EP 6.0	

本证明书所列商品经我公司检验结果如下, 特此证明

This is to certify that we, the undersigned, have inspected/tested the quality of the above mentioned goods and found the result as follows:

**BE UP TO THE EP6.0 STANDARD**

华东医药股份有限公司

HUADONG MEDICINE CO. LTD.

Storage: Store in an airtight container, protect from light.

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