

# CHANGZHOU HANGYU PHARMACEUTICAL TECHNOLOGY CO., LTD.

## CERTIFICATE OF ANALYSIS

<b>Product Name: Aliskiren Hemifumarate</b>			
Batch No.:	20120220	Quantity:	5KGS
Manu. Date:	2012/02/20	Expiry Date:	2014/04/19
Date of Report:	2012/02/21	Package:	As Required

Item	Specification	Results
Appearance	A white to off-white solid	Complies
Melting Point	95°C to 105°C	95°C to 96°C
Specific Rotation	-19° to -23°	-20°
Identification	A. HPLC	Complies
	B. IR	Complies
Chloride	0.01% Max	Complies
Loss on drying	2.0% Max	1.7%
Residue on ignition	0.1% Max	0.05%
Heavy Metals	0.001% Max	Complies
Enantiomer	0.5% Max	Complies
Related Substances	Diastereoimer 0.15% Max	0.07%
	De-BOC AL-15 impurity 0.15% Max	0.06%
	De-DMP AL-16 impurity 0.15% Max	Not Detected
	AL-16 impurity 0.15% Max	Not Detected
	Any other individual impurity 0.1% Max	0.08%
	Total impurities 1.0% Max	0.21%
Residual Solvents	Ethanol 5000PPM Max	Not Detected
	Ethyl ether 5000PPM Max	Not Detected
	Acetonitrile 410PPM Max	Not Detected
	Tert-butylmethyl ether 5000PPM Max	Not Detected
	DMF 880PPM Max	Not Detected
Assay	98.0% to 102.0% (Calculated on the anhydrous basis)	99.7%

**Conclusion: Up to Standard for Export**