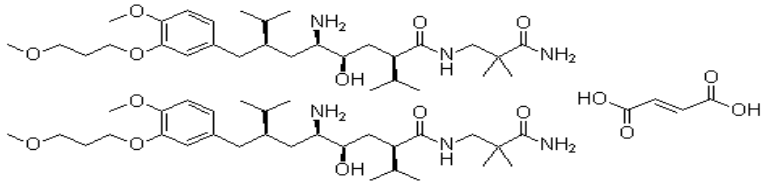


CERTIFICATE OF ANALYSIS

NO: DYC021407112

Product name	Aliskiren hemifumarate
CAS Number	173334-58-2
Molecule Structure	
Molecule Formula	C64H110N6O16
Batch number	20140614
Manuf.Date&Exp.Date	2014-06-14,2016-06-14
Testing date	2014-06-15

Items	Standard	Result
Appearance	A white to off white solid	Complies
Identification	A.HPLC:RRT _{test solution} is similar to RRT _{reference solution} B.IR: similar to reference substance	Complies
Specific rotation	-8° ~ -12°	-10.7°
Chlorides	Not more than 100ppm	Complies
Loss on drying	Not more than 2.0%	0.8%
Sulfated ash	Not more than 0.1%	0.02%
Heavy metals	Not more than 10ppm	Complies
Related substances	ALD3 Not more than 0.15% ALD2 Not more than 0.15% TK1-10 Not more than 0.15% TK1-9 Not more than 0.15% Any other individual impurity ≤0.10% Total impurities ≤1.0%	Not detected 0.07% Not detected Not detected Not detected 0.07%
Enantiomer	Not more than 0.15%	Not detected
Acetates	Not more than 3000ppm	Not detected
Residual solvents	Methanol 3000ppm max Ethanol 5000ppm max Ethyl ether 5000ppm max Isopropanol 5000ppm max Acetonitrile 410ppm max Dichloromethane 600ppm max	Not detected Not detected Not detected Not detected 87ppm Not detected



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	Tert-butyl methyl ether	5000ppm max	Not detected
	Hexane	290ppm max	Not detected
	Isopropyl ether	5000ppm max	Not detected
	Ethyl acetate	5000ppm max	Not detected
	Tetrahydrofuran	720ppm max	Not detected
	1,4-Dioxane	380ppm max	Not detected
	Toluene	890ppm max	Not detected
Assay	98.0~102.0%(on the dried basis)		99.7%
Conclusion	The results above meet all requirements under Aliskiren Hemifumarate in in-house standard		

Hangzhou Dingyan Chem Co., Ltd.
QUALITY CONTROL: *Xuefen Chen* CHECK: 姚仙娟 INSPECTOR: 刘清风
Quality Control Signature(s)