



HANGZHOU DINGYAN CHEM CO., LTD
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CERTIFICATE OF ANALYSIS

NO: DYC051607044

Product name	Tiamulin hydrogen fumarate
CAS Number	55297-96-6
Molecule Formula	C32H51N08S
Batch number	20151205
Manuf. Date&Exp. Date:	2015-12-05;2017-12-04
Testing date	2015-12-05

Items	Standard	Result
Appearance	White or almost white crystalline powder	Qualified
Identification	HPLC: Retention time from test solution corresponds to standard solution IR: IR spectrum of sample corresponds to reference standard	Conforms Conforms
Appearance of solution	Clear and colorless, absorbance at 400nm and 650nm are not greater than 0.150 and 0.030	Clear colorless 400nm: 0.013 650nm: 0.006
Melting Point	143—149℃	144.8—146.0℃
Specific optical rotation	+24° --- +28°	+26.6°
PH	3.1—4.1	3.5
Loss on drying	≤0.5%	0.31%
Residue on ignition	≤0.1%	0.08%
Heavy metals	≤0.001%	Conform
Residue solvents	≤0.5%	0.18%
Chromatographic Purity	Single identified impurity≤1.0% Single unidentified impurity≤0.5% Total impurities≤2.0%	Conforms
Content of Fumarate	83.7—87.3mg	85.7mg
Assay dry basis	98.0%—102.0%	100.1%
Conclusion	It conforms with USP36 standard.	

QUALITY CONTROL: *Hangzhou Dingyan Chem Co., Ltd.*
Quality Control *Lucy Tang*
Signature(s)

CHECK: 姚仙娟

INSPECTOR: 刘清风