

HANGZHOU DINGYAN CHEM CO.,LTD

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## CERTIFICATE OF ANALYSIS

NO: DYC101704211

Product Name	Nalfurafine
CAS Number	152658-17-8
Molecular Structure	HCI HCI
Molecular Formula	C28H33CIN2O5
Batch Number	20161212
Mfg.&Exp Date	2016-12-12,2019-12-31
Test Date	2016-12-12

Items	Standard	Result
Appearance	White or light yellow powder	Off-white powder
Solubility	Should be soluble in water and methanol, slightly soluble in ethanol, almost insoluble in ethyl acetate ether	complies
Identification	<ol> <li>In the chromatogram recorded under the content determination, the retention time of the main peak of the test solution should be consistent with the retention time of the main peak of the reference solution</li> <li>Should be at 207nm and 280nm wavelength at the maximum absorption</li> <li>The infrared absorption spectrum of this product should be consistent with the map of the reference substance</li> <li>Should show the identification of chloride reaction</li> </ol>	complies
РН	4.5-6.5	5.5
Sulfate	≤0.1%	<0.1%
Water	≤6.0%	4.2%
Heavy metal	≤20.0%	<20.0%
Related substance	Simple impurity ≤0.3% Total impurities ≤ 1.0%	0.08% 0.33%

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remaining solvent	Ethyl acetate ≤0.5%	0.08%
	Toluene ≤0.089%	ND
Residue on ignition	≤0.1%	0.06%
Assay,	Has C <sub>28</sub> H <sub>32</sub> N <sub>2</sub> O <sub>5</sub> .HCL, 98.0%-102.0%	100.0%
Anhydrous calculation		100.0%
Conclusion	Qualited	

QUALITE VOCONTROCO, Ltd.

Quality Control Melinda

CHECK:姚仙娟

INSPECTOR: 刘清风

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