

## CERTIFICATE OF ANALYSIS

PRODUCT: Clemastine fumarate	DATE OF MANUFACTURE: Oct. 25, 2012
PACKING: 1KG, 5KG/BARREL	DATE OF TEST: Oct. 26, 2012
STANDARD: USP30	EXPIRY DATE: Oct. 24, 2016
BATCH NO.: 20121025	

	Items	Specifications	Results
1	Appearance	White or almost white crystalline powder	White crystalline powder
2	Solubility	Slightly soluble in methanol, very slightly soluble in water or trichloromethane	Conforms
3	Specific rotation	+15° ~ +18°	+16.3°
4	Identification	The location of the test article's principal spot is same as the reference substance	The location is same
		The infra-red reference spectra of test article confirms with the reference spectrum	Conforms
5	Test (clarity and colour of methanol solution)	clear and colorless, if turbid, should conform the rule, if has colour, should conform the rule	clear and colorless
6	Acidity	3.2~4.2	3.54
7	Loss on drying	0.5% Max	0.03%
8	Heavy Metal (as Pb)	0.002% Max	Conforms
9	Related substance	Single impurity ≤0.5% Total impurity ≤1.0%	Conforms
10	Assay(on dried)	Calculated on the anhydrous substance, should contain C <sub>21</sub> H <sub>26</sub> ClNO·C <sub>4</sub> H <sub>4</sub> O <sub>4</sub> 98.0%~102.0%	99.5%
Conclusion		It conforms with USP30	

TESTED BY: Xu lulu  
 CHECKED BY: Zhang Dechen