

CERTIFICATE OF ANALYSIS

PRODUCT: Clemastine fumarate	DATE OF MANUFACTURE: Jun. 10, 2014
PACKING: 1KG, 5KG/BARREL	DATE OF TEST: Jun. 11, 2014
STANDARD: USP36	EXPIRY DATE: Jun. 09, 2018
BATCH NO.: 20140610	

	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 ₂₁ H ₂₆ ClNO·C ₄ H ₄ O ₄ 98.0% ~ 102.0%	99.5%
Conclusion		It conforms with USP36	

TESTED BY: Xu lulu
 CHECKED BY: Zhang Dechen