

Changzhou Extraordinary Pharmatech co.,LTD

常州非凡医药科技有限公司

No4 HouYang chemical industrial park.Changzhou P.R.China Tel/Fax:86-519-82111935/86-519-82611250 www.feifanchem.com

CERTIFICATE OF ANALYSIS

Name	of	Product:
Pyrrolidine,2-[2-[(1R)-1-(4-chlorophenyl)-1-phenylethoxy]ethyl]-1-methyl-,		
(2R)-,(2E)-2-butenedioate (1:1)		
Batch No.: 20171122	CAS:14976-57-9	
Quantity: 8kg	Manufacture date: 2017.11.22	
Test date: 2017.11.22	Retest date: 2019.11.21	

Test Items	Quality Standard	Test Result
Appearance	White or almost white crystalline powder	Conforms
Assay	R98.0%~102.0%	99.5%
Test (clarity and colour of methanol solution)	clear and colorless, if turbid, should conform the rule, if has colour, should conform the rule	Conforms
Loss on drying	≤ 0.5%	0.03%
Heavy Metal (as Pb)	≤0.002%	Conforms
Specific rotation	+15°~+18°	+16.3°
Solubility	Slightly soluble in methanol, very slightly soluble in water or trichloromethane	Conforms
Related substance	Single impurity ≤0.5%	Conforms
	Total impurity ≤1.0%	Conforms
Identify	The location of the test aticle's principal spot is same as the 2Treference2T 2Tsubstance2T	Conforms
	TThe infra-red reference spectra of test article confirms with the 0T2Treference2T spectrum	Conforms



Changzhou Extraordinary Pharmatech co.,LTD

常州非凡医药科技有限公司

No4 HouYang chemical industrial park.Changzhou P.R.China Tel/Fax:86-519-82111935/86-519-82611250 www.feifanchem.com

Acidity	3.2~4.2	3.54
Storage conditions	Cool and dry, no more than 26℃	

Conclusion: This product conforms to the USP36.

Analyst: 工業

Checker:

VA

Supervisor: