



K alchem International, Inc
Compounding Chemicals You Can Trust

PRODUCT:	TADALAFIL, USP	EXPIRATION DATE:	05/2022
FINISHED LOT NO:	19H29-U02-002441	MFG DATE:	06/2019
CAS#	171596-29-5	SPECIFICATIONS:	USP

Certificate of Analysis

TEST CRITERIA	SPECIFICATIONS	RESULTS
DESCRIPTION	White powder or almost white powder.	White Powder
SOLUBILITY	Freely soluble in dimethylsulphoxide, slightly soluble in methylene chloride and practically insoluble in water.	Freely soluble in dimethylsulphoxide, slightly soluble in methylene chloride and practically insoluble in water.
IDENTIFICATION A) I.R.	IR spectrum of sample should be concordant with that of the working standard.	IR spectrum of sample is concordant with that of standard spectrum.
IDENTIFICATION B) HPLC	The retention time of the major peak of the sample solution corresponds to that of identification solution, as obtained in the test for Enantiomeric and diastereomeric purity.	The retention time of the major peak of the sample solution corresponds to that of identification solution, as obtained in the test for Enantiomeric and diastereomeric purity.
ASSAY (Dried Basis)	97.0%-102.0%	100.3%
SPECIFIC ROTATION	+54° to +62°	+58°

LOSS ON DRYING (At 105°C for 3 hrs under vacuum)	NMT 0.5%	0.21% w/w
RESIDUE ON IGNITION	NMT 0.10%	0.04% w/w
ORGANIC IMPURITIES BY HPLC		
METHOD – 1		
a) Amido impurity	NMT 0.1%	BDL
b) Any individual impurity	NMT 0.10%	BDL
c) Total impurities	NMT 0.3%	BDL
METHOD-11		
d) Uncyclised impurity	NMT 37.5 ppm	Not Detected
e) Chloroacetyl impurity	NMT 37.5ppm	Not Detected
Enantiomeric and Diastereomeric purity by HPLC		
a) 6R,12aS diastereomer	NMT 0.1%	0.02%
b) 6S,12aS Enantiomer	NMT 0.1%	Not Detected
c) 6S,12aR diastereomer	NMT 0.1%	Not Detected
ASSAY by HPLC (On dried basis)	Not less than 97.5% and not more than 102.5%	99.6% w/w
Residual solvents by GC		
Methanol	NMT 3000 ppm	Not Detected
Isopropyl alcohol	NMT 5000 ppm	Below Quantification Limit
Dichloromethane	NMT 600 ppm	56 ppm
Triethylamine	NMT 320 ppm	Not Detected
Dimethyl sulfoxide content	NMT 5000 ppm	Below Quantification Limit

DATE OF RELEASE: _____ **ANALYSIS #** _____

APPROVED BY/ DATE: _____

Kalyn R Tabor, Quality Control