



K alchem International, Inc
Compounding Chemicals You Can Trust

PRODUCT:	TERBINAFINE HCL, EP	EXPIRATION DATE:	09/02/21
FINISHED LOT NO:	18E24-U12-045603	MFG DATE:	02/10/18
CAS#	78628-80-5	SPECIFICATIONS:	EP
MANUFACTURER:	QILU ANTIBIOTICS PHARMACEUTICAL CO.	COUNTRY:	CHINA

Certificate of Analysis

TEST CRITERIA	SPECIFICATIONS	RESULTS
APPEARANCE	White powder or almost white powder.	Conforms
SOLUBILITY	Very slightly soluble or slightly soluble in water, freely soluble in anhydrous ethanol.	Conforms
IDENTIFICATION A) I.R.	Conforms	Conforms
IDENTIFICATION B	Conforms	Conforms
ASSAY (Dried Basis)	99.0%-101.0%	100.7%

RELATED COMPOUND B	≤0.15%	0.15%
RELATED COMPOUND E	≤0.05%	0.05%
RELATED COMPOUNDS (any)	≤0.10%	0.02%
RELATED COMPOUNDS (total)	≤0.3%	0.0%
LOSS ON DRYING	≤ 0.5%	0.1%
Residual solvents	Conforms	Conforms
ELEMENTAL IMPURITIES	Conforms	Conforms
SULFATED ASH	≤0.1%	0.1%

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

APPROVED BY/ DATE: _____

Kalyn R Tabor, Quality Control