



F. & A. PHARMA-Handels-GmbH

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Report No. :COA-KL-EP10-11

NO.588,FENGZE ROAD,TIANTAI,ZHEJIANG
317200,CHINA

ZHEJIANG TIANTAI PHARMACEUTICAL CO., LTD.

ZHEJIANG TIANTAI PHARMACEUTICAL CO., LTD.

CERTIFICATE OF ANALYSIS

Name of product Clindamycin Hydrochloride Material No. 04101B
Batch No. K-210417B Quantity 221.14Kg
Package 25Kg/Drum Mfg Date 2021-04-09
Report Date 2021-07-28 Retest Date 2024-04-09

Items		Specification	Results
Characters	Appearance	White or almost white crystalline powder	White crystalline powder
	Solubility	Very soluble in water, slightly soluble in ethanol (96%).	Conform
pH by pH meter		3.0~5.0	4.4
Identification		A. IR spectrum conforms to RS	Conform
		D. Chlorides reaction	Conform
Water by KF		3.0~6.0%	4.1%
Specific optical rotation		+135°~ +150°	+143°
Sulphated ash		≤0.5%	0.05%
Related substances by HPLC		Impurity A (Lincomycin) ≤0.5%	0.28%
		Impurity B (Clindamycin B) ≤2.0%	0.55%
		Impurity C (7-epiclindamycin) ≤4.0%	0.75%
		RRT0.36 ≤0.5%	0.12%
		RRT0.71 ≤0.5%	0.18%
		RRT0.87 ≤0.5%	0.16%
		Any other impurity ≤0.10%(each)	N.D.
		Total Related substances ≤6.0%	2.0%
Assay by HPLC		92.0~102.0% (on anhydrous basis)	98.4%
Residual solvents by GC		Ethanol ≤5000ppm	N.D.
		Acetone ≤5000ppm	175ppm
		Chloroform ≤60ppm	N.D.
Conclusion		Complies EP10	

QC 王-马

QA 张丽梅

ZHEJIANG TIANTAI PHARMACEUTICAL CO., LTD.

CERTIFICATE OF ANALYSIS

Name of product Clindamycin Hydrochloride

Material No. 04101B

Batch No. K-210418B

Quantity 220.78Kg

Package 25Kg/Drum

Mfg Date 2021-04-09

Report Date 2021-07-28

Retest Date 2024-04-09

Items		Specification	Results
Characters	Appearance	White or almost white crystalline powder	White crystalline powder
	Solubility	Very soluble in water, slightly soluble in ethanol (96%).	Conform
pH by pH meter		3.0~5.0	4.4
Identification		A. IR spectrum conforms to RS	Conform
		D. Chlorides reaction	Conform
Water by KF		3.0~6.0%	4.1%
Specific optical rotation		+135°~ +150°	+143°
Sulphated ash		≤0.5%	0.04%
Related substances by HPLC		Impurity A (Lincomycin) ≤0.5%	0.34%
		Impurity B (Clindamycin B) ≤2.0%	0.57%
		Impurity C (7-epiclindamycin) ≤4.0%	0.78%
		RRT0.36 ≤0.5%	0.14%
		RRT0.71 ≤0.5%	0.17%
		RRT0.87 ≤0.5%	0.17%
		Any other impurity ≤0.10%(each)	N.D.
		Total Related substances ≤6.0%	2.2%
Assay by HPLC		92.0~102.0% (on anhydrous basis)	98.3%
Residual solvents by GC		Ethanol ≤5000ppm	N.D.
		Acetone ≤5000ppm	202ppm
		Chloroform ≤60ppm	N.D.
Conclusion		Complies EP10	

QC 张亚

QA 张丽梅

ZHEJIANG TIANTAI PHARMACEUTICAL CO., LTD.

ZHEJIANG TIANTAI PHARMACEUTICAL CO., LTD.

CERTIFICATE OF ANALYSIS

Name of product Clindamycin Hydrochloride Material No. 04101B
 Batch No. K-210419B Quantity 221.08Kg
 Package 25Kg/Drum Mfg Date 2021-04-10
 Report Date 2021-07-28 Retest Date 2024-04-10

Items		Specification	Results
Characters	Appearance	White or almost white crystalline powder	White crystalline powder
	Solubility	Very soluble in water, slightly soluble in ethanol (96%).	Conform
pH by pH meter		3.0~5.0	4.4
Identification		A. IR spectrum conforms to RS	Conform
		D. Chlorides reaction	Conform
Water by KF		3.0~6.0%	3.9%
Specific optical rotation		+135°~ +150°	+143°
Sulphated ash		≤0.5%	0.04%
Related substances by HPLC		Impurity A (Lincomycin) ≤0.5%	0.28%
		Impurity B (Clindamycin B) ≤2.0%	0.54%
		Impurity C (7-epiclindamycin) ≤4.0%	0.77%
		RRT0.36 ≤0.5%	0.10%
		RRT0.71 ≤0.5%	0.17%
		RRT0.87 ≤0.5%	0.15%
		Any other impurity ≤0.10%(each)	N.D.
		Total Related substances ≤6.0%	2.0%
Assay by HPLC		92.0~102.0% (on anhydrous basis)	97.8%
Residual solvents by GC		Ethanol ≤5000ppm	N.D.
		Acetone ≤5000ppm	144ppm
		Chloroform ≤60ppm	N.D.
Conclusion		Complies EP10	

QC 

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