



大连汉德姆精细化学品有限公司

DALIAN HANDOM CHEMICALS CO.,LTD.

Certificate of Analysis

Product Name: Minocycline Hydrochloride

Batch No.: HDC20230627

Manufacturing Date: Jun 27th, 2023

Packing: Bags inner, Cartons outside

CAS No.: 13614-98-7

Batch Quantity: 180.25kg

Retest Date: Jun 26th, 2025

Report Date: Jun 30th, 2023

Test Items	Specifications	Test Results	
Appearance	Yellow crystalline powder	Conforms	
Identification-IR	Corresponds to the reference	Conforms	
Identification-Chlorides	Be Positive	Conforms	
Appearance of Solution	Clear, $A_{450nm} \leq 0.23$	Clear, $A_{450nm} = 0.147$	
pH Value	3.5 ~ 4.5	4.0	
Light-absorbing impurities	$A_{560nm} \leq 0.06$	$A_{560nm} = 0.014$	
Water	5.0% ~ 8.0%	6.9%	
Sulfated Ash	Not more than 0.5%	0.01%	
Assay(Calculated on the anhydrous basis)	94.5% ~ 102.0%	99.7%	
Related Substances	Impurity A	Not more than 1.2%	0.34%
	Impurity B	Not more than 0.8%	0.14%
	Impurity C	Not more than 0.6%	0.18%
	Impurity D	Not more than 0.15%	<0.05%
	Impurity E	Not more than 0.6%	0.07%
	Impurity F	Not more than 0.5%	0.14%
	Impurity G	Not more than 0.5%	<0.05%
	Impurity H	Not more than 0.3%	0.18%
	Total impurities	Not more than 3.5%	1.1%
	Any other impurity	Not more than 0.10%	<0.05%



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	Impurity I	Not more than 0.15%	<0.05%
	RRT≈0.16	Not more than 0.20%	0.09%
Residual Solvents			
Ethanol		Not more than 5000ppm	2036ppm
Bacterial endotoxins		Less than 1.25 IU/mg	<1.25 IU/mg
Total aerobic microbial count		Not more than 1000 CFU/g	<500 CFU/g
Total yeasts and moulds count		Not more than 100 CFU/g	<50 CFU/g

Conclusion: The testing results of this batch are complied with the EP Standard.

Remarks: Frequency detection for microbial limits; test the first 10 batches, and then test one batch of every ten batches. In case of unqualified batches, test 10 consecutive batches, after all being conformed, test one batch of every ten batches. Excluding client's requirements.