

Kalchem International

Chemicals & Compounding Supplies

CERTIFICATE OF ANALYSIS

SAMPLE NAME	DOXYCYCLINE HYCLATE	SENDING SAMPLE UNIT	WORKSHOP ONE
Batch Number	1412117	Test Date	JUN..1.2015
Packing Size	25kg	Manufacture Date	JUN.2014
Quantity	500kg	Expiration Date	NOV.2018

<u>ITEM</u>	<u>SPECIFICATION</u>	<u>RESULTS</u>
Appearance	Yellow crystalline powder	<u>Corresponds</u>
Identification	A) % of HPLC test	
	B) Sulphuric acid yellow Color reaction	<u>Corresponds</u>
	C) Chloride's reaction	
pH	2.0 to 3.0	<u>2.4</u>
Specific Optical Rotation	-105° to 120° calculated on the Anhydrous, ethanol-free substance	<u>-110°</u>
Specific Absorbance	300-335at349 nm,calculated on The anhydrous,ethanol-free substance	<u>323</u>
Light-absorbing impurities	Not More Than 0.07 at 490 nm,calculated on The anhydrous,ethanol-free substance	<u>0.03</u>
Related Substances		
Metacycline	Not More Than 2.0%	
6-epidoxycycline	Not More Than 2.0%	<u>Conforms</u>
Any individual impurities	Not More Than 0.5%	
Disregard limit	Not More Than 0.1%	
Ethanol	4.3 to 6.0%	<u>4.6%</u>
Heavy Metals	Less Than 50ppm	<u><50ppm</u>
Water	1.4% to 2.8%	<u>2.1%</u>
Sulphated Ash	Not More Than 0.4%	<u><0.1%</u>
Assay	95.0- 102.0% of C ₂₂ H ₂₀ CLN ₂ O ₈ ,calculated on the anhydrous,ethanol-free substance	<u>98.1%</u>
Potency	880 ug/mg-940 ug/mg	910 ug/mg
Conclusion	The Above Product Conforms to BP2007/EP6	

Analyst:

Checker:

Supervision:

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