

杭州东瑞医药科技有限公司
HANGZHOU DAWN RAY PHARMACEUTICAL CO.,LTD.

CERTIFICATE OF ANALYSIS

Chlortetracycline Hydrochloride(Non-sterile bulk)

Batch No.: DR20130507	Quantity: 849.67kg
Date Of Report: 2013.05.16	Specification: EP7.0
Manufacture Date: 2013.05.07	Expiry Date: 2016.05.07

TESTS:

Items	Specification	Results
Appearance	A yellow powder,slightly soluble in water and in alcohol.It dissolves in solutions of slkali hydroxides and carbonates.	Conforms
Identification A	The principal spot in the chromatogram obtained with the test solution is similar in position,colour and size to the principal spot in the chromatogram obtained with reference solution.	Conforms
Identification B	To about 2mg add 5ml of sulphuric acid R.A deep blue colour develops which becomes bluish-green.Add the solution to 2.5ml of water.The colour becomes brownish.	Conforms
Identification C	Gives reaction of chlorides	Conforms
PH	2.3 ~3.3(10mg/ml)	2.4
Specific optical rotation	-235.0°~-250.0°(2.5mg/ml)	-243.0°
Absorbance	≤0.40(5mg/ml,460nm)	0.16
TC HCL(Anhydrous substance)	≤8.0%	4.7%
Heavy metals	≤50ppm	<50ppm
Water	≤2.0%	0.4%
Sulfated ash	≤0.5%	0.1%
CTC HCL(Anhydrous substance)	≥89.5%	92.8%

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TC.HCL+CTC.HCL(Anhydrous substance)	94.5%~102.0%	97.5%
Related substance		
Impurity A	≤4.0%	1.5%
4-EPI-Isochlortetracycline	≤0.8%	0.3%
Demeclocycline	≤0.7%	0.1%
Total of 4-EPI-Isochlortetracycline and demeclocycline	≤1.0%	0.4%
2-Acetyl-2-decarboxamido-chlortetracycline	≤0.3%	<0.1%
Any other detectable impurity	≤0.1%	<0.1%
Formaldehyde	≤5ppm	1ppm
Sulfate	≤0.02%	<0.02%
Iron	≤50ppm	<50ppm
Magnesium	≤50ppm	6ppm
Zinc	≤10ppm	3ppm
Proteins	≤0.1%	<0.1%
Crude fibre	≤0.1%	<0.1%
Ethanol	≤5000ppm	3979ppm
Methanol	≤3000ppm	Not detected
Conclusion: The results conform to EP7.0.		



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