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

CERTIFICATE OF ANALYSIS

Tranexamic acid

Batch No.: DR20140212	**Quantity :**529.6kg
Manufacture Date: 2014.02.12	**Expiry Date:** 2017.02.11

TESTS:

Items	Specification	Results
Characters	White or almost white,crystalline powder	White crystalline powder
	Freely soluble in water and in glacial acetic,practically insoluble in acetone and in ethanol （96%)	Conforms
Identification	Corresponds to USP tranexamic acid RS	Conforms
PH	7.0-8.0	7.3
Related substance		
Impurity A	≤0.1%	N,D
Impurity B	≤0.2%	0.06%
Impurity C	≤0.1%	0.004%
Impurity D	≤0.1%	0.007%
Any other single impurity	≤0.1%	N,D
Total impurities	≤0.2%	0.07%
Residual solvent		
Chlorobenzene	≤360ppm	N,D
Xylene	≤2170ppm	N,D
Ethanol	≤5000ppm	N,D
Heavy metals	≤10ppm	<10ppm
Loss on drying	≤0.5%	0.1%
Residue on ignition	≤0.1%	<0. 1%
Chloride and sulfate	≤0.014%	<0. 014%
Microbial limits		
TAMC	≤1000cfu/g	10cfu/g
TYMC	≤100cfu/g	<10cfu/g
Specified microorganisms	Absent	N,D
Assay	99.0-101.0% C8H15NO2(on dried base)	99.7%
Conclusion: The results conform with USP36.		

质检专用章 QUALITY STAMP

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