

Kalchem International

Chemicals & Compounding Supplies

Certificate of Analysis

COMMODITY: HYDROCORTISONE USP 38

This is to certify that we, the undersigned, have inspected the quality of the above mentioned goods and found the result of the inspection as below:

Items	Specification	Results
Batch No.		16003
Appearance	White or almost white crystalline powder	White crystalline powder
Identification		
IR:	Conform	Conform
UV:	Conform	Conform
Specific Rotation (on the dried basis)(+ °)	150-156	153.1
Loss on drying (%)	≤0.5	0.33
Residue on ignition (%)	≤0.5	0.3
Chromatographic purity:		
Any individual impurity (%)	≤0.5	0.25
Total impurities (%)	≤2.0	1.3
Assay (on the dried basis) (%)	97.0-102.0	99.7
Melting range(°C)	About 215(213~222) (melt and decompose simultaneously)	216.5~218.0 (melt and decompose simultaneously)
Residual solvents:		
Methanol(ppm)	≤1000	353
Chloroform(ppm)	≤60	Not detected
1,2-dichlorethane(ppm)	≤5	Not detected
Microbial limits:		
Total aerobic microbial counts (cfu/g)	≤100	<10
Fungi (cfu/g)	≤10	<10
Pathogenic micro.: E.Coli, P.aeruginosa, Salmonella Species and S.aureus	Not detected	Not detected
Particle Size ≤5um (%)	≥90	94
Manuf. Date		2015-12-04
Expiry Date		2019-12

Conclusion: The product is tested in accordance with USP38. The above items meet the requirement.

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