



山东新华制药股份有限公司

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Commodity: Hydrocortisone Base Micro EP8.0

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.		14033
Batch Quantity		10 KG
Appearance	White or almost white crystalline powder	White crystalline powder
Identification:		
A: Infrared absorption	Complies	Complies
B: HPLC	Complies	Complies
Specific Rotation (on the dried basis) (+°)	162-168	163.1
Related Substances: Impurity A (%)	≤0.2	0.06
Impurity B (%)	≤0.2	0.07
Impurity C (%)	≤0.5	Disregard
Impurity D (%)	≤0.5	0.4
Impurity E (%)	≤0.5	Disregard
Impurity F (%)	≤0.3	0.06
Impurity G (%)	≤0.4	0.1
Impurity H (%)	≤0.15	Disregard
Impurity I (%)	≤0.5	0.1
Impurity N (%)	≤0.15	Disregard
Any Individual Impurity (%)	≤0.10	0.066
Total Impurities (%)	≤2.0	0.99
Loss on drying (%)	≤1.0	0.22
Assay (on the dried basis) (%)	97.0~103.0	99.5
Residual Solvents:		
1,2-Dichloroethane (%)	≤5	Not detected
Methanol (ppm)	≤1000	638
Chloroform (ppm)	≤60	Not detected
Microbial Limits:		
Total aerobic microbial count (cfu/g)	≤800	<10
Fungi (cfu/g)	≤80	<10
E.Coli (cfu/g)	Not found	Not found
Particle Size		
< 5um (%)	≥90	95
Manuf. Date		NOV. 2014
Expiry Date		NOV. 2018

Conclusion: The product is tested in accordance with Ph. Eur 8.0. The above items meet the requirements.