



山东新华制药股份有限公司

Shandong Xinhua Pharmaceutical Co., Ltd

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Commodity: Hydrocortisone Base Micro EP 8.0

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.		14010
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	162.4
Related Substances: Impurity A (%)	≤0.2	0.08
Impurity B (%)	≤0.2	0.07
Impurity C (%)	≤0.5	Disregard
Impurity D (%)	≤0.5	0.3
Impurity E (%)	≤0.5	Disregard
Impurity F (%)	≤0.3	Disregard
Impurity G (%)	≤0.4	0.2
Impurity H (%)	≤0.15	Disregard
Impurity I (%)	≤0.5	0.1
Impurity N (%)	≤0.15	Not detected
Any Individual Impurity (%)	≤0.10	0.077
Total Impurities (%)	≤2.0	1.0
Loss on drying (%)	≤1.0	0.17
Assay (on the dried basis) (%)	97.0~103.0	100.2
Residual Solvents:		
1,2-Dichloroethane (%)	≤5	Not detected
Methanol (ppm)	≤1000	348
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		2014-05-04
Expiry Date		2018-05
Packing Date		2014-05-21

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

THIS PRODUCT DOES NOT CONTAINS RAW MATERIAL FROM ANIMAL ORIGIN