

山东新华制药股份有限公司

Lot: 0011212

Shandong Xinhua Pharmaceutical Company Limited

14 Dongyi Road, Zhangdian District, Zibo, Shandong, P.R.China

Tel: 86-533-2185102; Fax: 86-533-2282825

Certificate of Analysis

Commodity: Hydrocortisone Base Micro EP7.0

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.		12034
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	164.2
Related Substances:		
Impurity A (%)	≤0.2	0.1
Impurity B (%)	≤0.2	Disregard
Impurity C (%)	≤0.5	Disregard
Impurity D (%)	≤0.5	0.4
Impurity E (%)	≤0.5	Disregard
Impurity F (%)	≤0.3	Disregard
Impurity G (%)	≤0.4	Disregard
Impurity H (%)	≤0.15	Disregard
Impurity I (%)	≤0.5	0.2
Impurity N (%)	≤0.15	Not detected
Other unknown impurity (%)	≤0.10	0.065
Total Impurities (%)	≤2.0	0.91
Loss on drying (%)	≤1.0	0.12
Assay (on the dried basis) (%)	97.0~103.0	99.7
Residual Solvents:		
1,2-Dichloroethane (ppm)	≤5	Not detected
Methanol (ppm)	≤1000	100
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	92
Manuf. Date		JUN.2012
Expiry Date		JUN.2016

Conclusion: The product is tested in accordance with EP7.0. The above items meet the requirements.

SHANDONG XINHUA PHARMACEUTICAL CO., LTD.

[Signature]
Chen