

09/05/2023

Hallochem Group

HALLOCHEM

Chongqing Waycome Pharmaceutical Co.,Ltd.

CERTIFICATE OF ANALYSIS

Product name	Hyaluronidase	Batch No.	HYD20230302
Manuf. Date	2023-03-12	Expiry Date	2025-03-11
Quantity	28.4g	Test Standard	EP10
Total activity	100 MIU	Test date	2023-03-23

TEST	SPECIFICATIONS	RESULTS
Description	White or yellowish-white , amorphous powder	Complies
Clarity of solution	Clear	Complies
Solubility	Soluble in water , practically insoluble in acetone and ethanol	Complies
Identification	According to the requirements	Complies
PH	4.5-7.5	6.4
Loss on drying	$\leq 5.0\%$	4.12%
Tyrosine	540nm: $\leq 0.1\mu\text{g}/\text{IU}$	Complies
Bacterial endotoxins	$\leq 0.2\text{EU}/\text{IU}$	Complies
Absorbance	280nm: ≤ 0.60 (300IU/ml) 260nm: ≤ 0.42 (300IU/ml)	280nm:0.068 260nm:0.042
Potency	≥ 3000 IU/mg	3521.6 IU/mg
Microbial Limit	TAMC : $\leq 10^2$ CFU/g API TYMC : $\leq 10^2$ CFU/g API Escherobacteriaceae , Pseudomonas aeruginose and Staphylococcus aureus should be absent .	Complies Complies Complies

Storage: Preserve in tight containers,protected from light and store at 2-8°C

Conclusion: The product complies with the requirements of EP10 standard

Add:No. 138 YuWu Road, XinMin Town, DianJiang 408302, chongqing,china

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