

Unipharm Pharmaceutical Industry Co., Ltd 山东优阜药业科技有限公司

Certificate of Analysis

Product	HYDROXYETHYL STARCH 130/0.4		
Batch No.	2F200301	Approval Date	04/10/2020
Mfg. Date	03/2020	Exp. Date	02/2023
Tests	Results	Specifications	
Character	Complies	Should comply	
Identification	Complies	Chemistry reaction, should be positive reaction	
	Complies	By IR absorption, to match with the working standard	
рН	5.6	4.5-7.0	
Appearance of solution	Complies	Should comply	
Absorbance	0.022	Max.0.025 at 400nm	
Loss on drying	2.8%	≤15.0%	
Heavy metals	<10ppm	≤10ppm	
Sodium chloride	0.03%	≤0.1%	
Ethylene glycol	0.0024%	Not more than 0.004%	
Ethylene oxide	0%	Not more than 0.0001%	
2-Chloroethanol	0%	Not more than 0.0005%	
Mw	124 300	110 500~149 500	
Mw10%min	21573	≥15 000	
Mw10%max	373545	≤380 000	
Molar Substitution	0.41	0.368~0.432	
C2/C6 ratio	8.5	7.2~10.8	
Microbial contamination	Complies	TAMC not more than 100CFU/g	
Bacterial endotoxins	Complies	≤2.5IU/g	
Conclusion: Conforms to H	EP 8.0 standard.		

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