



Jinan Hongfangde Pharmatech Co., Ltd.
Tel/Fax:0531-88870908
Email: sdhfdchem@163.com
Website: www.hfdpharma.com

CERTIFICATE OF ANALYSIS

Product name	Hydroxyethyl Starch200/0.5		
Batch No.	19032601	Mfg. Date	2019.03.26
Report Date	2019.03.29	Exp. Date	2021.03.25
Package	25kg/drum	Quantity	685kg

Inspection Items	Accepted Standard	Results
Appearance	White or off white powder	Off white powder
Optical rotation	+ 185.0°~ + 195.0°	+ 188°
clarity and color of solution	λ 400nm absorbance <0.05,turbidity not deeper than NO1 standard	Complies
Identification	(1)To complies positive reaction	Complies
	(2) complies with standard	Complies
pH	4.5~6.5	5.1
Intrinsic viscosity $[\eta]$	15.0~19.0	18.3
Heavy metals	$\leq 10\text{ppm}$	Complies
Loss on drying	$\leq 5.0\%$	2.9%
Sodium chloride(NaCl)	$\leq 0.6\%$	0.12%
MS	0.43~0.55	0.49
Glycol	$\leq 0.062\%$	Complies
Ethylene oxide	$\leq 0.001\%$	Complies
Chlorethyl alcohol	$\leq 0.0005\%$	Complies
weight-average molecular weight	190000~290000	266700
weight-average molecular weight (10%department)	≤ 780000	601900
weight-average molecular weight (90%department)	≥ 13000	62250
Undue toxicity	Should complies	Complies
Bacterial endotoxin	$\leq 10\text{EU/g}$	Complies
Microbial limit	Should complies	Complies
Assay	$\geq 98.5\%$ (on dry base ,deducts the sodium chloride)	100.1%
Conclusion : Complies with enterprise standard		

Analyst :shilijuan

Checker:wuaho

Supervisor :lichao