

Xi'an DELI Biochemical Industry Co.,Ltd.

Inspection Report(模板)

Report number:2019004

Name	Hydroxypropyl Betadex		
Manufacturer	Xi'an DELI Biochemical Industry Co., Ltd.	Batch weight	1800Kg
Lot number	20190120	Date of production	2019.01.20
Pack	Medical plastic bags	Expiry date	2022.01.19
Standard	USP40-NF35	Date received	2019.01.24
Testing purpose	Routine test	Report date	2019.02.01
ASSAY	SPECIFICATION	RESULTS	
IDENTIFICATION			
A	Same absorption bands	pass	
B	It meets the requirements of the test for Clarity of solution	pass	
ASSAY			
MOLAR SUBSTITUTION			
Acceptance criteria	0.40-1.50	0.83	
IMPURITIES			
HEAVY METALS	NMT 20ppm	<10ppm	
LIMIT OF BETADEX PROPYLENE GLYCOL OTHER RELATED SUBSTANCES			
Betadex	NMT 1.5%	0.0053%	
Propylene glycol	NMT 2.5%	0.029%	
Any other single impurity	NMT 0.25%	Not detected	
Total impurities excluding betadex and propylene glycol	NMT1.0%	Not detected	
LIMIT OF PROPYLENE OXIDE			
Acceptance criteria	NMT 0.0001%	pass	
SPECIFIC TESTS			
MICROBIAL ENUMERATION TESTS and TESTS FOR SPECIFIED MICROORGANISMS			
The total aerobic microbial count	NMT 1000cfu/g	<100cfu/g	
The total combined molds and yeasts count	NMT 100cfu/g	<100cfu/g	
LOSS ON DRYING			
Acceptance criteria	NMT 10.0%	2.28%	
CLARITY OF SOLUTION			
Acceptance criteria	See USP40-NF35	pass	
BACTERIAL ENDOTOXINS TEST			
Acceptance criteria	See USP40-NF35	<10 IU/g	
CONDUCTIVITY			
Acceptance criteria	NMT200 μ S.cm ⁻¹	20 μ S.cm ⁻¹	
ADDITIONAL REQUIREMENTS			
PACKAGING AND STORAGE	See USP40-NF35	pass	
LABELING	See USP40-NF35	pass	

Conclusion: The sample is in compliance with the USP40-NF35

Opinion: Agree leave factory.

quality checker:

final appraiser: