



辽宁奥克医药辅料股份有限公司

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CERTIFICATE OF ANALYSIS

Product: Macrogols (PEG) 400 Batch NO.: FL220406017
Package: 200kg/barrel Quantity: 150barrel*200kg
Analysis date: 2022.04.13 Report date: 2022.04.15
Manufacturing date: 2022.04.06 Valid date: 2024.04.05
Technical specification: Current EP/USP

Test items	Analytical methods	Standard	Result	Result found
Appearance (25°C)	Current EP	Clear,viscous,colourless or almost colourless, hygroscopic liquid	Conforms	Qualified
Identification	Current EP	A	Conforms	Qualified
	Current EP	B	Conforms	Qualified
	Current EP	C	Conforms	Qualified
Appearance of solution	Current EP	Meet requirements	Conforms	Qualified
Completeness and Color of Solution	Current USP	Meet requirements	Conforms	Qualified
Acidity or alkalinity	Current EP	Meet requirements	Conforms	Qualified
pH (5% in water)	Current USP	4.5~7.5	5.1	Qualified
Average Molecular Weight	Current USP	380~420	418	Qualified
Viscosity(20°C, mPa·s)	Current EP	105~130	123	Qualified
Viscosity(98.9°C, cst)	Current USP	6.8~8.0	7.4	Qualified
Hydroxyl value	Current EP	264~300	268	Qualified
Reducing substances	Current EP	Meet requirements	Conforms	Qualified
Ethylene Glycol and Diethylene Glycol (%)	Current USP	≤0.25	0.006	Qualified
Ethylene Glycol and Diethylene Glycol (%)	Current EP	≤0.4	0.006	Qualified
Formaldehyde (ppm)	Current EP	≤15	Conforms	Qualified
Ethylene oxide(ppm)	Current EP	≤1	0.04	Qualified
Dioxan(ppm)	Current EP	≤10	<2.59	Qualified
Free Ethylene Oxide(μg/g)	Current USP	≤10	0.04	Qualified
1,4-Dioxane(μg/g)	Current USP	≤10	<2.59	Qualified
Water (%)	Current EP	≤2.0	0.02	Qualified
Sulfated ash(%)	Current EP	≤0.2	<0.2	Qualified
Residue on Ignition (%)	Current USP	≤0.1	<0.1	Qualified
Heavy Metals (ppm)	Current USP	≤5	Conforms	Qualified
Grade	Pharmaceutical grade			
Conclusion	According to Current EP、Current USP standard,the results meet the requirements.			

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Recheck: 吴晓

Analyst: jmw