



武汉福鑫化工有限公司

Wuhan Fortuna Chemical Co.,Ltd

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CERTIFICATE OF ANALYSIS

Product: Soybean lecithin (Injection)

Lot No.: 150327

Mfg. date: Mar., 27, 2015

Quantity: 1kg

Exp. date: Mar., 26, 2017

Items	Specifications	Results
Appearance	Similar white to yellow lump (Internal control)	Yellow lump
Solubility	Soluble in Ether and Ethanol, insoluble in Acetone	Conforms
Identification	(1) Should be a positive reaction	Positive
	(2) Should be a positive reaction	Positive
Acid value	Not more than 30	1.0
Iodine value	Not less than 75	99.4
Peroxide value	Not more than 5	0
Color of solution	Absorbance not more than 0.8 at 350nm	0.03
Acetone insoluble	Not less than 90%	96.38%
Hexane insoluble	Not more than 0.3%	0.07%
Water	Not more than 1.5%	0.21%
Heavy metals	Not more than 20ppm	Conforms
Arsenic	Not more than 2ppm	Conforms
Residual solvents	Ethanol: Not more than 0.5%	0.0031%
	Acetone: Not more than 0.5%	Not detected
	Dichloromethane: Not more than 0.06%	Not detected
Related substances	Lysophosphatidyl ethanolamine: Not more than 0.5%	Not detected
	Lysophosphatidylcholine: Not more than 3.5% (Internal control)	0.6%
Protein	Not detected (Internal control)	Conforms
pH	5.0~7.0 (Internal control)	5.9
Assay (on dry basis)	Phosphorus: Not less than 2.7%	3.8%
	Nitrogen: 1.5%~2.0%	1.7%
	Phosphatidylcholine: Not less than 98.0% (Internal control)	98.31%
	Phosphatidylethanolamine: Not more than 15.0% (Internal control)	Not detected
	Phosphatidylinositol: Not more than 5.0%	Not detected
Bacteriological account	C.F.U. not more than 100/g, Moulds not more than 100/g, E.coli, Salmonellae, Staphylococcus aur, Pseudomonas aerug. All negative /10g (Internal control)	Conforms
Endotoxin	Not more than 2 EU/g	Conforms
Conclusion	Complies with China pharmacopoeia 2010 and Inner controlling standard of Enterprise (Injection)	

QC: Luo Xiaofeng

Tester: AT02

Re-tester: AT01