



DALIAN HANDOM CHEMICALS CO.,LTD.

Add.: RM702, Unit 1, Building 21, Liuhe Road, Ganjingzi Dist, Dalian, Liaoning, China
E-mail: info@handomchemicals.com Web.: www.handomchemicals.com

Certificate of Analysis

Product Name: Egg Yolk Lecithin

Batch No.: HDC20230823

Manufacturing Date: Aug 23rd, 2023

Retest Date: Aug 22nd, 2025

Quantity: 86.30kg

Report Date: Aug 31st, 2023

Method of calibration: Egg yolk lecithin (for injection) in Part IV of the 2020 edition of the Chinese Pharmacopoeia

Test Items		Specifications	Test Results
Characters		This product is milky white or light yellow powder or waxy solid with a slight peculiar odor.	Conforms
Solubility		This product is soluble in ethanol, ether, chloroform or petroleum ether (boiling range: 40°C~60°C), and is almost insoluble in acetone and water.	Conforms
Acid Value		Not more than 20.0 mgKOH/g	2.58 mgKOH/g
Saponification Value		195 ~ 212 mgKOH/g	198 mgKOH/g
Iodine Value		60 ~ 73 gI/100g	63 gI/100g
Peroxide Value		Not more than 3.0	2.4
Identification Test		(1) Should be positive	Conforms
		(2) Should be positive	Conforms
		(3) In the chromatograms recorded under the determination of phosphatidylcholine and phosphatidylethanolamine, the retention time of the main peak of the test solution should be consistent with the retention time of the main peak of the reference solution.	Conforms
Free fatty acids		Not more than 1%	Conforms
Triglyceride		Not more than 3%	Conforms
Cholesterol		Not more than 2%	Conforms
Palmitic acid		Not more than 0.2%	Conforms
Related Substances	Phosphatidylinositol	Not more than 5.0%	0.18%
	Lysophosphatidylethanolamines	Not more than 1%	0.08%
	Sphingomyelin	Not more than 3.0%	1.8%
	Lysophosphatidylcholine	Not more than 3.5%	2.2%
	Lysophosphatidylethanolamines+Lysophosphatidylcholine	Not more than 4.0%	2.3%



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	Contains the total amount of the above-mentioned substances	Not more than 8.0%	4.3%
Residual Solvents	Ethanol	Not more than 0.2%	0.001%
	Acetone	Not more than 0.2%	0.0005%
	Diethyl Ether	Not more than 0.2%	Not detected
	Petroleum Ether	Not more than 0.05%	Not detected
	n-Hexane	Not more than 0.02%	Not detected
	Total Residual Solvents	Not more than 0.5%	0.002%
Moisture		Not more than 3%	0.96%
Protein Content		The solution should not be bluish purple or reddish purple	Conforms
Heavy Metals		Not more than 0.0005%	Conforms
Arsenic salt		Not more than 0.0002%	Conforms
Bacterial endotoxins		Less than 2.0 EU/g	Conforms
Total aerobic microbial count		Not more than 100 CFU/g	< 10 CFU/g
Total combined yeasts and mould count		Not more than 100 CFU/g	< 10 CFU/g
Escherichia coli		Negative/g	Not detected
Salmonella		Negative/10g	Not detected
Phosphorus (P)		3.5% ~ 4.1%	3.7%
Nitrogen (N)		1.75% ~ 1.95%	1.82%
Phosphatidylcholine (PC)		Not less than 68%	85.1%
Phosphatidylethanolamine (PE)		Not more than 20%	2.91%
PC+PE		Not less than 80%	88%

Conclusion: This product was tested according to the Egg Yolk Lecithin (for injection), Part IV, 2020 Edition of the Chinese Pharmacopoeia, and the results were in compliance with the regulations.