



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: Soya Lecithin(Injection Grade)

Batch No.: HDC20230303

Manufacturing Date: Mar 3rd, 2023

Retest Date: Mar 2nd, 2024

Quantity: 100kg

Packing: 1kg/Aluminum Foil Bag

Method of calibration: China pharmacopoeia, 2020 Edition, Part IV

Test Items	Specifications	Test Results
Characters	Yellow to brown semisolid or lumps	Yellow semi-solid
Solubility	The product is soluble in ethyl ether and ethanol, but insoluble in acetone	Consistent with standard requirements
Acid Value	Not more than 12 mgKOH/g	2.3 mgKOH/g
Iodine Value	90 gI/100g ~ 110 gI/100g	109.0 gI/100g
POV	Not more than 3.0	0
Identification Test	(1) White precipitate should be produced	Consistent with standard requirements
	(2) Brick red precipitate should be produced	Consistent with standard requirements
	(3) In the chromatograms recorded by phosphatidylcholine and phosphatidylethanolamine under the content determination item, the retention time of the main peak of the test solution should be consistent with that of the main peak of the control solution	Consistent with standard requirements
350nm Luster	Not more than 0.5	0.1
Substances insoluble in acetone	Not less than 90.0%	92.1%
Substances insoluble in hexane	Not more than 0.3%	0.09%
Moisture	Not more than 1.5%	1.2%
Protein Content	Consistent with standard requirements	Consistent with standard requirements
Heavy Metals	Not more than 0.0005%	<0.0005%
Arsenic salts	Not more than 0.0002%	<0.0002%
Lead(Pb)	Not more than 0.0002%	<0.0002%
Residual ethanol	Not more than 0.2%	0.041%
Residual acetone	Not more than 0.2%	0.0007%
Residual diethyl ether	Not more than 0.2%	0
Residual petroleum ether	Not more than 0.05%	0
Residual n-hexane	Not more than 0.02%	0
Residual solvent	Not more than 0.5%	0.0417%



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LPE	Not more than 0.5%	0
LPC	Not more than 3.5%	0.9%
LPC+LPE	Not more than 4.0%	0.9%
PI	Not more than 5.0%	0
Total related substance	Not more than 8.0%	0.9%
Total number of aerobe, moulds and yeasts	Not more than 100 CFU/g	Consistent with standard requirements
Escherichia coli	Negative/g	Not detected
Salmonella	Negative/10g	Not detected
Bacterial endotoxins	Less than 2.0 EU/g	Consistent with standard requirements
P	Not less than 3.3%	3.58%
N	1.5% ~ 2.0%	1.7%
PC	Not less than 88.0%	94.1%
PE	Not more than 20.0%	0
PC+PE	Not less than 88.0%	94.1%

Conclusion: The testing results of this batch are complied with the Standard of ChP 2020 Part IV.

Storage Conditions: Preserved in unopened original containers in a cool dry place before using; kept away from direct sunlight, heat and moisture.