SUPPORTING DOCUMENTATION & SERVICES

PharmaFine® Premium may be able to support your assessment through:

- Material Qualification Dossier
- Cleanroom ISO Class 8 / EU GMP Grade D handling
- Bacterial Endotoxin Test
- Microbial Limit Test
- ICH Q3C residual solvents information
- ICH Q3D elemental impurities information

OUR COMMITMENT TO QUALITY

At DC Fine Chemicals, quality is at the heart of everything we do. Our products and processes adhere to a comprehensive range of international regulations:

- EXCiPACT certification for the PharmaFine® product line
- GMP facility audit performed by an independent third-party company
- GDP certification since 2018
- ISO 9001 certification since 2011
- ISO 14001 certification since 2021
- RGSEAA / RSIPAC registration since 2019
- Halal and Kosher certifications since 2020

This approach conforms to the principles of EU Guidelines 2015/C 95/02, supporting the formalised risk assessment used to determine the appropriate GMP expectations for excipients in medicinal products.

DC Fine Chemicals
A different kind of chemistry

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Need support with raw material assessment?

Contact our team:
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@dcfinechemicals

Latest PharmaFine® Premium product list:

The information provided by DC Fine Chemicals is intended to support technical, documentary and regulatory assessment. Final suitability, qualification, validation and approval for any specific application, including parenteral applications, must be determined exclusively by the customer.

PharmaFine

PharmaFine® Premium

RAW MATERIALS FOR PARENTERAL ASSESSMENT

DC Fine Chemicals
A different kind of chemistry

PHARMACEUTICAL RAW MATERIALS

WITH GREATER CONTROL FOR DEMANDING PROCESSES

PharmaFine® is DC Fine Chemicals' dedicated range of pharmaceutical raw materials and excipients, designed to support customers who have strict quality, audit or regulatory requirements and may require additional data, stronger documentation and a more structured basis for raw material assessment.

PharmaFine® Product Portfolio

	PharmaFine® Select	PharmaFine® Expert	PharmaFine® Premium
Compliance with pharmacopeias: EP, USP, BP, JP (upon request)	✓	✓	✓
Detailed documentation for risk assessment	✓	✓	✓
Additional microbiological testing: TAMC and TYMC (when applicable)		✓	✓
Specific microorganisms testing (upon request)		✓	✓
Bacterial endotoxin testing			✓
Adaptable endotoxin limits (upon request)			✓

PharmaFine® Premium

PARENTERAL ASSESSMENT

Within this range, DC Fine Chemicals offers selected raw materials to support customers who are assessing materials for demanding pharmaceutical processes, including projects related to parenteral applications.

PharmaFine® Premium provides an enhanced level of support through bacterial endotoxin testing and additional documentation when applicable.

product list

	DCFC Code	Description	CAS
A	115624	Acetic acid (glacial) 100%, Ph. Eur., USP, low endotoxin	64-19-7
	100301	Adenosine, low endotoxin	58-61-7
	114653	Aluminium stearate, NF, low endotoxin	7047-84-9
	114654	Aluminium stearate, Ph. Eur., low endotoxin	7047-84-9
B	117230	Benzethonium chloride, low endotoxin, USP	121-54-0
	114033	Benzyl alcohol, JP, NF, Ph. Eur., low endotoxin	100-51-6
	101893	Boric acid, NF, Ph. Eur., low endotoxin	10043-35-3
C	103902	Citric acid anhydrous, Ph. Eur., USP, FCC, JP, low endotoxin	77-92-9
	103912	Citric acid monohydrate, Ph. Eur., USP, low endotoxin	5949-29-1
D	108185	D(–)-Mannitol, Ph. Eur., USP, low endotoxin	69-65-8
	114192	D(+)-Biotin, Ph. Eur., USP, low endotoxin	58-85-5
	116463	D(+)-Glucose anhydrous, Ph. Eur., USP, low endotoxin	50-99-7
	106482	D(+)-Glucose monohydrate, Ph. Eur., USP, low endotoxin	14431-43-7
	113851	D-(+)-Raffinose pentahydrate, low endotoxin	17629-30-0
	110575	di-Potassium hydrogen phosphate anhydrous, Ph. Eur., USP, low endotoxin	7758-11-4
	111735	di-Sodium hydrogen phosphate anhydrous, Ph. Eur., USP, low endotoxin	7558-79-4
	111741	di-Sodium hydrogen phosphate dihydrate, Ph. Eur., USP, low endotoxin	10028-24-7
	115633	di-Sodium tetraborate decahydrate, Ph. Eur., NF, low endotoxin	1303-96-4
	126160	D-Lactose monohydrate, Ph. Eur., USP, low endotoxin	64044-51-5
E	125050	Ethyl oleate, NF, Ph. Eur., low endotoxin	111-62-6
	115771	Ethylenediaminetetraacetic acid calcium disodium salt hydrate, Ph. Eur., USP, FCC, low endotoxin	23411-34-9
	105902	Ethylenediaminetetraacetic acid disodium salt dihydrate, Ph. Eur., USP, FCC, low endotoxin	6381-92-6
F	118212	Folic acid, Ph. Eur. USP, low endotoxin	59-30-3
G	106540	Glycerol, Ph. Eur., USP, low endotoxin	56-81-5
H	106773	HEPES, for biopharmaceutical production, low endotoxin	7365-45-9
	114460	Hydroxyethyl starch 200/0.5, Ph. Eur., low endotoxin	9005-27-0
L	120771	L-(-)-Fucose, low endotoxin	2438-80-4
	101272	L(+)-Ascorbic acid, Ph. Eur., USP, FCC, low endotoxin	50-81-7
	107791	Lactose monohydrate, Ph. Eur., USP, low endotoxin	10039-26-6
	100321	L-Alanine, Ph. Eur., low endotoxin	56-41-7
	101250	L-Arginine monohydrochloride, Ph. Eur., USP, JP, low endotoxin	1119-34-2
	101243	L-Arginine, Ph. Eur., USP, low endotoxin	74-79-3

	DCFC Code	Description	CAS
L	106532	L-Glutamine, USP, JP, low endotoxin	56-85-9
	106901	L-Histidine, Ph. Eur., USP, JP, low endotoxin	71-00-1
	117431	Liquefied phenol, USP, low endotoxin	108-95-2
M	115493	Magnesium chloride hexahydrate, Ph. Eur., USP, low endotoxin	7791-18-6
	108093	Magnesium sulfate heptahydrate, Ph. Eur., USP, JP, low endotoxin	10034-99-8
	108091	Magnesium sulfate heptahydrate, USP, low endotoxin	10034-99-8
	108590	Methyl 4-hydroxybenzoate, JP, NF, Ph. Eur., low endotoxin	99-76-3
N	105291	N,N-Dimethylacetamide, Ph. Eur, BP, low endotoxin	127-19-5
	119440	Nicotinamide, Ph. Eur., USP, low endotoxin	98-92-0
P	110512	Potassium chloride, Ph. Eur., USP, low endotoxin	7447-40-7
	110872	1,2-Propanediol, Ph. Eur., USP, low endotoxin	57-55-6
	110921	Propyl 4-hydroxybenzoate, NF, Ph. Eur., low endotoxin	94-13-3
R	120592	Riboflavin, Ph. Eur., USP, low endotoxin	83-88-5
S	111472	Sodium acetate anhydrous, USP, low endotoxin	127-09-3
	111484	Sodium acetate trihydrate, Ph. Eur., USP, low endotoxin	6131-90-4
	125960	Sodium caprylate, Ph. Eur., USP, ChP, low endotoxin	1984-06-1
	111651	Sodium dihydrogen phosphate anhydrous, USP, low endotoxin	7558-80-7
	111661	Sodium dihydrogen phosphate dihydrate, Ph. Eur., USP, low endotoxin	13472-35-0
	120013	Sodium dihydrogen phosphate monohydrate, USP, low endotoxin	10049-21-5
	116163	Sodium disulfite, NF, Ph. Eur., JP, low endotoxin	7681-57-4
	111776	Sodium hydroxide pellets, NF, Ph. Eur., for biopharmaceutical production, low endotoxin	1310-73-2
	111791	Sodium iodide, Ph. Eur., USP, low endotoxin	7681-82-5
	115611	Sodium perborate tetrahydrate, Ph. Eur., low endotoxin	10486-00-7
	111963	Sodium sulfite anhydrous, Ph. Eur, NF, low endotoxin	7757-83-7
	112181	Succinic acid, NF, low endotoxin	110-15-6
	112192	Sucrose, JP, NF, Ph. Eur., low endotoxin	57-50-1
T	122760	Taurine, USP, low endotoxin	107-35-7
	112601	Thimerosal, Ph. Eur., USP, low endotoxin	54-64-8
	122890	Trehalose dihydrate, Ph. Eur., low endotoxin	6138-23-4
	113311	Tris(hydroxymethyl) aminomethane, Ph. Eur., USP, low endotoxin	77-86-1
	111613	tri-Sodium citrate dihydrate, Ph. Eur., USP, low endotoxin	6132-04-3
	120022	tri-Sodium phosphate dodecahydrate, USP, low endotoxin	10101-89-0