

Product Specification – PHARMASAL® API

92763, 92764, 92765, 92768, 92770

	Complied	Reviewed	QM-endorsement	Released
Date	20.03.2023	20.03.2023	20.03.2023	20.03.2023
Signature	Steinberger	Herzog	Steinberger	Spreitz
Area of responsibility	QA	HL	QA	QP

Distribution list: PP, FP, Laboratory, Sales, Executive Board and Production Manager

IT document – Prints are not subject to the change service

PRODUCT-SPECIFICATION

Product Name:

Pharmasal
Chemically Pure Salt
Sodium Chloride, Natrii chloridum

Requirements

		Content	Unit	Methode
Assay	NaCl	≥ 99.5	%	EN973
Identification	Cl ⁻ / Na ⁺	positive		SOP #255
Appearance of Solution		clear, colourless		Ph.Eur/ SOP #207
Acidity or alkalinity		conforms		Ph.Eur/ SOP #216
Bromides	Br ⁻	≤ 100	ppm	SOP #255
Ferrocyanides	[Fe(CN) ₆] ₄ ⁴⁻	conforms		Ph.Eur
Iodides	I ⁻	≤ 10	ppm	SOP #255
		conforms Ph.Eur		
Nitrites (by Absorption A _{354nm})	NO ₂ ⁻	≤ 0,01	A	Ph.Eur/ SOP #214
Phosphates	PO ₄ ³⁻	≤ 25	ppm	SOP #255
Sulphates	SO ₄ ²⁻	≤ 200	ppm	SOP #255
Aluminium	Al	≤ 0,2	ppm	SOP #255
Arsenic	As	≤ 1	ppm	SOP #255
Barium	Ba	≤ 10	ppm	SOP #255
		conforms Ph.Eur		
Iron	Fe	≤ 2	ppm	SOP #255
Magnesium and Alkaline-Earth Metals calculated as Ca		≤ 100	ppm	SOP #255
Potassium	K	≤ 500	ppm	SOP #255
Heavy Metals calculated as Pb		≤ 3	ppm	SOP #255
Loss on Drying		≤ 0,5	%	Ph.Eur/ SOP #206
Insoluble Matters		≤ 50	ppm	SOP #207
Bacterial Endotoxins		≤ 5	IU/g	Ph.Eur
TAMC		≤ 10	CFU/g	Ph.Eur
TYMC		≤ 10	CFU/g	Ph.Eur

Residual solvents (Ph. Eur./ICH)

Impossible due to production process

Storage Conditions:

Store in a clean and dry place, nmt. 70% rel. humidity

Description:

Pharmasal® API is suitable for use in the manufacture of parenteral preparations.
Pharmasal® API is suitable for use in the manufacture of peritoneal dialysis solutions, haemodialysis solutions or haemofiltration solutions.

Primary Packaging:
LDPE foil

Articles available

Material Number:	92763	10 kg PE-bag	96 bags per pallet on Euro timber pallets with refundable deposit
	92764	25 kg PE-bag	40 bags per pallet on Euro timber pallets with refundable deposit
	92765	25 kg PE-bag	40 bags per pallet on Euro plastic pallets with refundable deposit
	92768	25 kg PE-bag	40 bags per pallet on ISPM-15 treated single use timber pallets
	92770	50 kg PE-bag	21 bags per pallet on Euro timber pallets with refundable deposit

Certification:

All our deliveries of Chemical Pure Salt correspond to this specification or with the current Ph.Eur., USP, BP and JP respectively.

The determination of each batch is carried out according to the methods described in Ph.Eur. or with validated methods.

The quality is confirmed by an individual certificate of analysis, issued for every batch.

CEP-certificate (Certificate of Suitability), R0-CEP 2004-315 (respective the following versions) confirms that our product meets the criteria described in the monograph "Sodium chloride" of the current European Pharmacopoeia.

The tests for bacterial endotoxins as well as the determination of the total aerobic microbial count (TAMC) and the total combined yeasts/moulds count (TYMC) are carried out by an officially certified laboratory.

Pharmasal is suitable for use in the manufacture of parenteral dosage forms, peritoneal dialysis solution, haemodialysis solution and haemofiltration solution.

Special note:

The product contains no anticaking additives, so caking occurs.

Retest date:

3 years after manufacturing date.