DELIVERING PATIENT SAFETY WITH THE RIGHT PARTNER

INJECTABLES, DIALYSIS & SPECIALTY API

ROQUETTE
Offering the best of nature™

AN UNWAVERING COMMITMENT TO ENABLING
LIFE-SAVING PHARMACEUTICALS

Improving patient health is your top priority. Ensuring your formulations' safety is ours. That's why we commit to securing the highest purity ingredients for use in reliable parenteral preparations.

For the last 50 years, Roquette has pioneered the development and production of high-quality ingredients for parenteral preparations. As a leading global supplier and unparalleled expert in pyrogen-free active pharmaceutical ingredients (APIs), we are confident our products offer the purity your injectable and dialysis solutions require.

By ensuring our production processes and quality systems are in compliance with the most stringent internationally accepted GMP standards (ICHQ7), we offer reliability and full traceability within our vertically integrated and transparent supply chain. Our commitment to delivering safe, traceable ingredients for challenging applications is what sets Roquette apart, and our drive to continuously innovate in the parenteral preparations market is why our customer base continues to grow.

OUR LEGACY

Technical expertise is empowered by our diverse global Research and Development network.

For years, Roquette has been the market and technical leader in starches and polyols, with over 60 patents and new product launches. Now we are expanding to other excipient chemistries to provide unique solutions to the technical challenges you face.

OUR MISSION

Provide technical expertise to all stages of pharmaceutical development

Instill in our customers a sense of confidence by delivering world-class ingredients and raw materials

Remain consistent in our ability to help customers develop and elevate life-saving pharmaceuticals

UNCOMPROMISED EXPERTISE

For decades, we've been providing technical service expertise supported by our signature lab in Lestrem, France. In 2017, we opened a 750 sq. ft. facility in Singapore, and we are growing our capabilities in the United States. Ask us about your specific project for excipient solutions and robust application support.

ENDURING QUALITY

Roquette quality systems are based from ICHQ7*, IPEC guidelines and ISO 9001, and offers EXCiPACT certification at the main manufacturing facility in Lestrem, France. Our approach to providing customers with high-quality drug development solutions always begins with rigorous uality processes and product.

SUSTAINABLE SUPPLIER

By encouraging local supply, using geothermal energy sources, and optimizing means of transportation, we combine economic profitability with a low environmental footprint.

INSPIRED INNOVATION

Our global R&D team and pharmaceutical application experts understand the challenges you face and can readily meet your evolving needs for innovative and patient friendly dosage solutions.

*APIs manufactured under ICHQ7, excipients manufactured under IPEC

Pyrogen-free products for life-saving solutions

Our ability to develop high-quality, pyrogen-free ingredients for injectables and dialysis preparations has set and advanced pharmaceutical industry standards worldwide. Understanding the need for putting patient health and well-being first, we provide a comprehensive range of safe and reliable products to the pharmaceutical industry.

> *"Parenteral preparations may require the use of excipients, for example to make the preparation isotonic with respect to blood, to adjust the pH, to increase solubility, to prevent deterioration of the active substances or to provide adequate antimicrobial properties, but not to adversely affect the intended medicinal action of the preparation or, at the concentrations used, to cause toxicity or undo local irritation."*

LYCADEX® PF

LYCADEX® PF (pyrogen-free dextrose monohydrate) is a physiological sugar for use as an excipient or API. As an API, it functions as a carbohydrate energy source for parenteral preparations. It is a great choice for hemodialysis and peritoneal dialysis preparations due to its osmotic agent properties. Furthermore, as an isotonic agent, it can act as an excipient for small and large volume parenteral and R_x injectables.

PEARLITOL® PF

PEARLITOL® PF (pyrogen-free mannitol) is an API, which serves as an osmotic diuretic agent—causing the removal of excess water from the blood—or as a way to reduce elevated pressure in the brain (cerebral oedema) and eyes (acute glaucoma). Since its physical and chemical properties allow it to act as a bulking agent, it's recognized as an excipient of choice for freeze-dried powder amenable to injection or infusion.

NEOSORB® PF

NEOSORB® PF (pyrogen-free sorbitol) has many uses including parenteral preparations, chirurgical irrigating solutions, and R_x injections. In addition to being an isotonic agent excipient, it can serve as an API (carbohydrate source) or as an osmotic diuretic. When used as an irrigating fluid in surgical procedures, sorbitol, its base component, can prevent intra- and extracellular dehydration.

SODIUM GLUCONATE PHARMA

Sodium Gluconate Pharma, a pyrogen-free organic salt, has a low endotoxin content, making it suitable for small or large parenteral preparations as a physiological electrolyte or as a buffer agent in R_x injectables.

KLEPTOSE® HPB/HP

KLEPTOSE® HPB/HP are hydroxypropyl betacyclodextrin parenteral-grade, pyrogen-free materials used as encapsulating agents for R_x injectables. Additionally, they provide active substance stabilization improvement against light and oxidation in parenteral preparations, as well as enhanced solubilization of APIs for improved bioavailability.

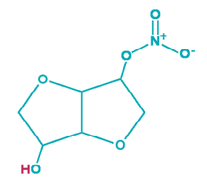
KLEPTOSE® HPB-LB

KLEPTOSE® HPB-LB parenteral grade is a multi-compendial product that complies with European and U.S. Pharmacopeia, and has standards that not only comply with but are even higher than Chinese Pharmacopeia. Part of the wider KLEPTOSE® product range, KLEPTOSE® HPB-LB supports local and global pharmaceutical manufacturers in overcoming registration filing challenges in China, as well as the rest of the world, without the need to develop multiple drug solutions. This can accelerate speed to market and provides a competitive advantage.

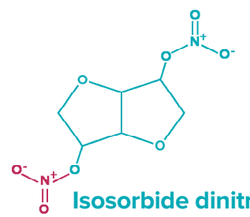
API for oral administration

ISOSORBIDE C PHARMA

ISOSORBIDE C PHARMA, a specialty API for oral administration, acts as an osmotic diuretic used for the treatment of internal ear dysfunction, such as in Meniere disease. Additionally, it can serve as an intermediate for API production of isosorbide mononitrate and isosorbide dinitrate.



Isosorbide mononitrate – ISMN



Isosorbide dinitrate – ISDN

Figure 1: ISOSORBIDE C PHARMA contributes to ISMN and ISDN production, both of which are vasodilators used in the treatment of ischaemic heart disease and heart failure.

INJECTABLES, DIALYSIS & SPECIALTY API SOLUTIONS

		LYCADEX® PF	PEARLITOL® PF	NEOSORB® PF	SODIUM GLUCONATE PHARMA	KLEPTOSE® HPB/HP	KLEPTOSE® HPB-LB	ISOSORBIDE C PHARMA
DEFINITION	**Name**	Dextrose monohydrate	Mannitol	Sorbitol	Sodium gluconate	Hydroxypropyl betacyclodextrin	Hydroxypropyl betacyclodextrin	Isosorbide
	Formula	$C_6H_{14}O_6$, H_2O	$C_6H_{14}O_6$	$C_6H_{14}O_6$	$C_6H_{11}NaO_7$			$C_6H_{10}O_4$
	Molecular weight	198.17 g/mol	182.17 g/mol	182.17 g/mol	218.13 g/mol	1135 + 7*MS*58.1	1135 + 7*MS*58.1	146.114 g/mol
	CAS	14431-43-7	69-65-8	50-70-4	527 - 07 - 1	128446-35-5	128446-35-5	652-67-5
	EINECS	200-075-1	200-711-8	200-061-5	208-407-7	420-920-1	420-920-1	211-492-3
	Appearance	Powder	Powder	Powder	Powder	Powder	Powder	Powder
FUNCTIONS	**As an API**	Carbohydrate source because it is rapidly and directly adsorbed by the organism, without prior enzymatic breakdown Osmotic agent for dialysis	Osmotic diuretic agent Diagnostic agent for kidney function Adjunct in the treatment of an acute renal failure Reduces intracranial pressure, treat cerebral oedema Reduces intraocular pressure Detoxifier	Irrigating fluid for surgical procedures, to prevent extra- and intracellular dehydration Carbohydrate energy source	Physiological compatible electrolyte for pharmaceutical injectable preparations and for dialysis solutions			Osmotic diuretic used for the treatment of internal ear dysfunction, such as in Meniere disease
	As an excipient	Isotonic agent	Freeze-dried powder for injection or for infusion Isotonic agent	Isotonic agent	Physiological compatible pH regulation agent	Solubilizes drugs Stabilizes drugs against light or oxidation Reduces irrigation at injection site	Solubilizes drugs Stabilizes drugs against light or oxidation Reduces irrigation at injection site	
TESTS	**LAL**	Yes	Yes	Yes	Yes	Yes	Yes	No
	On rabbits	Yes	No	No	No	No	No	No
COMPLIANCE	**EP**	Yes	Yes	Yes	NA	Yes	Yes	NA
	USP/NF	Yes	Yes	Yes	Yes	Yes	Yes	NA
	JP	Yes	Yes	Yes	NA	NA	NA	Yes
	CHP	Yes	Yes	Yes	NA	No	Yes	NA
	CEP	R1-CEP 1996-030-Rev 04, for both Lestrem and Keokuk plants	R1-CEP 2000-039-Rev 00	R1-CEP 2001-113-Rev 01	NA	RO-CEP-2015-264-Rev 00	No	NA
	USA DMF	Type II, n° 4697 Type II, n° 11059	Type II, n° 12879	No DMF	No DMF	Type IV, n° 9420	No	NA
	CHP DMF	Y20190000012	Y20170001658	IDL n° H20170214	NA	No	F20170000001	NA
PACKAGING		25 kg and 50 kg bags 1000 kg or 900 kg big-bags	25 kg bags	25 kg bags 900 kg big-bags	25 kg drums	25 kg drums	25 kg drums	25 kg cardboard box

LEARN MORE ABOUT ROQUETTE INJECTABLES & DIALYSIS PRODUCTS AT

www.roquette.com | pharma@roquette.com

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