



We create chemistry

High Purity Excipients for Parenteral Formulation

Inspiring Medicines for Better Lives

 BASF Pharma Solutions

www.pharma.basf.com

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High Purity Excipients for Parenteral Formulation

The parenteral application requires excipients of the highest quality standards. Solubilizers and co-solvents are the most widely employed excipients in the formulation of parenterals.

BASF offers a wide range of high-quality solubilization excipients and has unparalleled experience in quality and regulatory affairs, as well as solubility enhancement strategies.



Quality & Regulatory

The quality and regulatory benchmarks BASF applies to its parenteral excipients are comprised of:

- Manufacturing according to IPEC-PQG GMP
- Compendial compliance covering current and proposed major global pharmacopoeia standards
- Endotoxin & microbial testing
- Elemental impurity limits as per ICH Q3D
- Stability studies as per ICH guidelines
- Regulatory documentation
- Registration & submission support
- Non-clinical safety data



Production

Our excipients for parenterals are produced in Germany by qualified and experienced employees in line with the appropriate high-quality standards including documentation, equipment, utilities and personnel.



Solubilization

We offer a range of highly effective solubilization excipients for parenterals. Our experts have access to industry-leading tools and analytics such as our in-house developed high-throughput formulation robot, comprehensive solubilization screening, supersaturation and crystallization precipitation kinetics, as well as biorelevant analysis. Coupled with a deep and profound understanding of our excipients, we are in an excellent position to enable our customers to tackle their solubilization challenges rapidly and efficiently.

Product	Functionality	Monograph title / Chemical category	FDA IID listing
Kolliphor® HS 15	Nonionic solubilizer and emulsifier (surfactant; HLB = 15)	Macrogol 15 Hydroxystearate (Ph.Eur.) and Polyoxyl 15 Hydroxystearate (USP/NF) / Polyethoxylated 12-hydroxystearic acid	Yes
Kolliphor® ELP	Nonionic solubilizer and emulsifier (surfactant; HLB = 12 – 14)	Macrogolglycerol ricinoleate (Ph.Eur.) and Polyoxyl 35 castor oil (USP/NF) / Polyethoxylated castor oil	Yes
Kolliphor® P 188 Bio	Nonionic solubilizer and emulsifier (surfactant; HLB = 29)	Poloxamer 188 (Ph.Eur. and USP/NF) and Polyoxyethylene (160) Polyoxylpropylene (30) glycol (JP)	Yes
Kollidon® 12 PF	Solubilizer by complexation	Povidone (Ph.Eur., USP/NF and JP) / Synthetic polymer	Yes
Kollidon® 17 PF	Solubilizer by complexation	Povidone (Ph.Eur., USP/NF and JP) / Synthetic polymer	Yes



**MORE
EXCIPIENTS
FOR
PARENTERAL
USE TO
COME.**



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<https://pharma.basf.com/speak-with-an-expert>**

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