



We create chemistry

High Purity Excipients for Parenteral Formulation



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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
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

* Kolliphor® HS 15 is used in a recently FDA approved parenteral drug. For over ten years Kolliphor® HS 15 has been used in injectable drugs in both Canada and Europe.



More excipients for parenteral use to come.

Our service offer

For our parenteral excipients we provide comprehensive documentation including toxicological assessments, regulatory & quality packages, certificates and more.

Please contact us regarding your specific applications and needs:

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