

 **BASF**  
We create chemistry

# Excipients for Parenteral Use



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The parenteral application requires excipients of 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
Kollidon® 12 PF	Solubilizer by complexation	Povidone (Ph.Eur. and USP/NF/JP) / Synthetic polymer	Yes
Kollidon® 17 PF	Solubilizer by complexation	Povidone (Ph.Eur., USP/NF and JP) / Synthetic polymer	Yes
Kolliphor® ELP	Nonionic solubilizer and emulsifier (surfactant; HLB = 12-14)	Macroglycerol ricinoleate (Ph.Eur.) and Polyoxyl-35-castor oil (USP/NF) / Polyethoxylated castor oil	Yes
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® 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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