

Excipients for Parenteral Use

BASF's portfolio of high-quality solubilization excipients

Discover BASF's wide range of excipients for parenteral use meeting the highest quality standards as well as BASF's unparalleled experience in quality and regulatory affairs.

Product Details

Product	Functionality	Monograph title/Chemical category	FDA IID listing	Product benefits
Kollidon® 12 PF	Solubilizer by complexation	Povidone (Ph. Eur. and USP/NF)/ Synthetic polymer	Yes	Rapid renal elimination without polymer accumulation in the body due to low molecular weight Proven tolerability in wide range of drug applications
Kollidon® 17 PF	Solubilizer by complexation	Povidone (Ph. Eur., USP/NF and JP/JPE)/Synthetic polymer	Yes	Innovative PeroXeal™ packaging concept limiting peroxide formation
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	Highly purified Kolliphor® EL grade (Polyoxyl-35-castor oil) Particularly suitable for formulations containing extremely sensitive APIs
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*	Low histamine release for fewer side-effects Thermally stable and suitable for heat sterilization

* 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.

Stability after Sterilization

Proven stability after sterilization using sterile filtration and standard autoclaving.

Quality and Regulatory

The quality and regulatory benchmark BASF applies to its excipients for parenterals comprises of:

- ✓ Manufacturing according to IPEC-PQG GMP
- ✓ Elemental impurity limits acc. to ICH Q3D
- ✓ Compendial compliance covering current and proposed major global pharmacopoeia standards
- ✓ Regulatory documentation, registration and submission support available
- ✓ Endotoxin and microbial testing
- ✓ Non-clinical safety data

Get your sample today!
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