Excipients for parenteral formulations of small molecules

Excipients for parenteral formulations of small molecules

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 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 by qualified and experienced employees in line with the appropriate high-quality standards including documentation, equipment, utilities and personnel.

Product	Functionality	Monograph title/Chemical category	FDA IID listing
Kolliphor® ELP	Nonionic solubilizer and emulsifier (surfactant; HLB = 12–14)	Ph.Eur.: Macrogolglycerol ricinoleate; USP/NF: Polyoxyl 35 castor oil / Polyethoxylated castor oil	Yes
Kolliphor® HS 15	Nonionic solubilizer and emulsifier (surfactant; HLB = 15)	Ph.Eur.: Macrogol 15 hydroxystearate; USP/NF: Polyoxyl 15 hydroxystearate / Polyethoxylated 12-hydroxystearic acid	Yes*
Kollidon® 12 PF	Solubilizer by complexation	Ph.Eur., USP/NF, JP: Povidone / Synthetic polymer	Yes
Kollidon® 17 PF	Solubilizer by complexation	Ph.Eur., USP/NF, JP: Povidone / 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 drug formulations in both Canada and Europe.