



## Kolliphor® ELP

The highly purified solubilizer for sensitive and parenteral applications

Learn more  
about  
Kolliphor®  
ELP

**Did you know that Kolliphor® ELP, the highly purified grade of Kolliphor® EL, was developed specifically for sensitive applications that require enhanced stability?**

### Kolliphor® ELP at a glance

Kolliphor® ELP delivers reliable performance as a non-ionic solubilizer and emulsifier. With its exceptionally high purity, it offers an ideal solution for developers seeking trusted excipients for injectable formulations.

- ✓ Widely used in approved drugs worldwide, including paclitaxel and vitamin K injections
- ✓ Excellent compatibility with other ingredients
- ✓ Highly purified and endotoxin-controlled



### Product details

Brand/Trade name	Kolliphor® ELP
Chemical name	Macrogolglycerol ricinoleate Polyoxyl-35-castor oil PEG-35 castor oil
Monograph compliance	Ph. Eur, USP-NF
CAS number	61791-12-6
PRD number	30554034
Packaging size	60 kg steel / PE combi drum
Article number	50868562
Quality	IPEC GMP
Manufacturing site	Ludwigshafen (Germany)
Physical form	Paste at room temperature Liquid at approx. 30°C
pH	5 – 7
HLB	12 – 14
CMC	Approximately 0.02% (w/w) at 37 °C

## What distinguishes Kolliphor® ELP as an enhanced alternative to Kolliphor® EL?

- ✓ Tighter specifications for water content, potassium ions, and free fatty acids to support greater consistency, purity, and formulation stability.
- ✓ Minimizes free fatty acid content—including ricinoleic, oleic, and palmitic acids—to prevent phase separation, reduce particle formation, limit clarity changes, and preserve solubilization efficiency.
- ✓ Ensures suitability for use in parenteral applications via endotoxin control and microbial testing.

The key differences outlined in the table highlight why Kolliphor® ELP is optimally suited for sensitive or demanding formulations:

Parameter	Kolliphor® ELP	Kolliphor® EL
Appearance	Almost white paste	Yellow liquid
Viscosity, 25 °C	600 – 750 mPa*s	700 – 850 mPa*s
Water	≤ 0.5%	≤ 2.8%
Potassium	15 ppm	Not specified
Ricinolic acid	≤ 0.2%	Not specified
Oleic acid	≤ 0.1%	Not specified
Palmitinic acid	≤ 0.1%	Not specified
Free fatty acids C12-C18	≤ 1.0%	Not specified

## Regulatory documentation

- US-DMF # 2981 (Type IV, containing CMC information)
- Regulatory Information File (RIF) with equivalent content to an Open Part/Applicants Part
- Canada # 1992-046

**i** For a Letter of Authorization or a copy of the RIF, please contact your sales representative.

## Pharmacopoeia monograph and titles

Kolliphor® ELP meets the requirements of the current monograph of Ph. Eur. “Macrogolglycerol ricinoleate” and USP-NF “Polyoxyl-35-castor oil”.

## Preclinical safety data

Summary of the design and results of the pre-clinical studies are available.

**i** Request the Tox Abstract through your sales representative or RegXcellence®.

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