



Kolliphor® HS 15

The potent nonionic solubilizer

Did you know that Kolliphor® HS 15 is now listed in the IID and used in a FDA approved parenteral drug?

Kolliphor® HS 15 is your highly effective solubilizer and emulsifying agent of choice to formulate poorly soluble APIs in oral and parenteral dosage forms.

- ✓ Newly IID-listed excipient
- ✓ Low histamine release for fewer side-effects
- ✓ Thermal stability
- ✓ Monographed in Ph. Eur. and USP-NF



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Product Benefits

- IID-listed and FDA approval of parenteral application containing Kolliphor® HS 15
- Low histamine release, for fewer side-effects
- Thermal stability, suitable for heat sterilization
- Lower hemolytic activity compared to other polyoxyethylene-based surfactants
- Monographed in Ph. Eur. and USP-NF

Product Details

Generic name	Macrogol 15 Hydroxystearate, Polyoxyl 15 Hydroxystearate
CAS number	70142-34-6
PRD number	30554050
Packaging size	50 kg plastic drum
Article number	50253404
Manufacturing site	Ludwigshafen (Germany)
Physical form	paste at room temperature, liquid at approx. 30 °C
pH	6–7
HLB	14–16
CMC	0.005%–0.02%

Regulatory Documentation

- US-DMF #9501 (Type IV DMF, containing CMC information)
- Regulatory Information File (RIF) with equivalent content to an Open Part/ Applicants Part of a DMF
- US-DMF #23531 (Type V DMF, containing pre-clinical safety data)
- CEP #2006-095
- Canada #1999-036

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

Pharmacopoeia Monographs and Titles

Kolliphor® HS 15 meets the requirements of the current monograph of Ph. Eur. “Macrogol 15 Hydroxystearate” and USP-NF “Polyoxyl 15 Hydroxystearate”.

Preclinical Safety Data

- Tox Abstract (summary of the design and results of the pre-clinical studies performed)
- Safety Expert Report (detailed description of the pre-clinical safety data)
- Safety Assessment Summary of Kolliphor® HS 15 as an oral excipient in pediatric populations
- Safety Assessment Report of Kolliphor® HS 15 as an oral excipient in pediatric populations

i For further information on the preclinical safety data and our secrecy agreement please contact your sales representative.

Get your sample today!
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