

## Recommendation of the Animal Welfare Committee

### Requirements of vehicles and excipients used in solutions for parenteral injection (parenteral preparations)

Extract from the European Pharmacopoeia: “Parenteral preparations are sterile preparations intended for administration into the human or animal body by injection, infusion or implantation. (...) The excipients do not adversely affect the intended medical action or, at the concentrations used, cause toxicity or undue local irritation.” (European Pharmacopoeia 10.5, 10th edition, 2020, p. 5702).

Vehicles and excipients for the preparation of injection solutions for parenteral administration should meet the specifications of the European Pharmacopoeia and be tested for particulate contamination, sterility, absence of pyrogen and uniformity (European Pharmacopoeia, 10th edition 2020, p. 5702-5703).

“Only alkali-refined oils are used in the manufacture of parental preparations” (European Pharmacopoeia 10.0, 10th edition 2020, p. 901).

Plant oils tested according to the German Food Code are not suitable for parenteral injections, because they are neither sterile nor free of particulate matter nor standardized. They do not therefore conform to the standards of Good Scientific Practice or meet the medical requirements of injection solutions.

The Animal Welfare Committee recommends as alternatives e.g. the following solubilizers: Kolliphor® EL: Macroglycerol Ricinoleate Ph. Eur., Polyoxyl 35 Castor Oil USP, 500g

Or the following substances for intravenous feeding:

ClinOleic 20% emulsion for infusion 250 ml, Baxter Deutschland GmbH, (80% olive oil, 20% soybean oil)

Lipofundin 20%, B. Braun Melsungen, (soybean oil)

Lipidem B. Braun Melsungen, (medium-chain triglycerides 100.0 g. Refined soybean oil 80.0 g). Intralipid 20% (20% soybean oil)

From a medical perspective, the use of plant oils for oral injection is possible according to the German Food Code, but from a scientific perspective it is not recommended due to the lack of standardization.

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