Soluplus®

For better solubility and bioavailability

Clinical safety data available!

Did you know that Soluplus also solubilizes drugs processed by wet granulation?
Try Soluplus® and experience a new dimension in solubility and bioavailability enhancement.

Soluplus® at a glance

- Outstanding solubilization properties, especially for poorly soluble APIs
- Enables bioavailability enhancement
- Ideal for hot melt extrusion and all standard granulation techniques
- Market proven solution for unique formulation challenges
- Amphiphilic structure: polymer and solubilizer perfectly combined in one product
- Molecular weight optimized for superior ASD stability
- Glass transition temperature optimized for easy processing

Product Details

Brand/Trade name	Soluplus®
Chemical name	Polyvinyl caprolactam-polyvinyl acetate-polyethylene glycol graft co-polymer
PRD number	30446233
Packaging size	12.5 kg plastic drum
Article number	50477909
Quality	IPEC GMP
Manufacturing site	Ludwigshafen, Germany
Physical form	Granules

Regulatory Documentation

- US-DMF #23504 (Type IV DMF, containing CMC information)
- Regulatory Information File (RIF) with equivalent content to an Open Part/Applicants Part of a DMF
- US-DMF #23626 (Type V DMF, containing pre-clinical safety data)

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

Now approved in Europe!

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, as well as two clinical study reports. Available under BASF secrecy agreement)

ℹ For a copy of the Tox Abstract, Safety Expert Report and our secrecy agreement please contact your sales representative.

Pharmacopoeia Monographs and Titles

Soluplus® is not yet monographed in any pharmacopoeia. Based on the approval in several EU member states, BASF has initiated the application of a monograph in the European Pharmacopoeia. A USP-NF monograph will follow upon approval in the USA.

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New clinical data available: Safe use of Soluplus® at high oral exposure rates

- ✓ Clinical phase 1 trial with 30 subjects
- ✓ Conducted in Germany in 2018, completed in 2019
- ✓ Approved by German Federal Ministry for Drugs and Medical Devices (BfArM)

Trial Setup

Composition of powder and applied dosage form (oral suspension) ratio

Drug formulation	Composition
Extrudate powder with API and Soluplus® (20/80 ratio)	125 mg API; 500 mg Soluplus® 250 mg API; 1000 mg Soluplus® 500 mg API; 2000 mg Soluplus®
Final formulation applied	Aqueous suspension (1% Carboxymethylcellulose sodium, 0.5% Polysorbate 80)
Study subjects received a maximum oral dose of 500 mg API and 2000 mg Soluplus® or matching placebo formulation containing max. 2000 mg Soluplus®.	

Ratio of oral administration – verum and placebo

Soluplus® concentration per dose	500 mg	1000 mg	2000 mg
Study subjects dosed with drug formulation	8	8	8
Study subjects dosed with placebo formulation	2	2	2

Results

- ✓ Adverse effects were mild to moderate and reversible
- ✓ Accumulation of symptoms observed only in combination with the drug

General Remarks

- Based on a toxicological assessment, doses of up to 8000 mg Soluplus® per healthy volunteer were regarded as safe.
- For a subject of 70 kg body weight, this translates into an oral Soluplus® exposure of 114 mg/kg.
- The protocol was submitted for approval to the German Federal Institute for Drugs and Medical Devices (BfArM), which agreed to the conduct of the study in May 2018.

For more information (e. g. clinical data, Tox Report), please contact your local sales representative.

Get your sample today!
pharma-solutions@basf.com