# **Soluplus®**

# For better solubility and bioavailability



Did you know that Soluplus also solubilizes drugs processed by wet granulation? Try Soluplus<sup>®</sup> 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** 

PRD number
Packaging size
Article number
Quality
Manufacturing sit

Manufacturing site Physical form

Polyvinyl caprolactampolyvinyl acetate-polyethylene glycol graft co-polymer

30446233 12.5 kg plastic drum

50477909 IPEC GMP

Ludwigshafen, Germany

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)
  - for a Letter of Authorization or a copy of the RIF please contact your sales representative.



#### **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)
  - 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.

















#### 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.

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