Soluplus®

For better solubility and bioavailability

Now approved in Europe!

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)

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

Pre-clinical 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.

Regulatory Status – Overview

Country of regulatory submission	Application type	Regulatory status	Amount of Soluplus®
Germany France Italy Poland Romania UK Slovakia	Generic	Approved Public Assessment Reports CZ/H/685/001-002/DC Febuxostat Zentiva 80 mg film-coated tablets Febuxostat Zentiva 120 mg film-coated tablets CZ/H/692/001-002/DC Indren 80 mg film-coated tablets Indren 120 mg film-coated tablets	unknown
Argentina	Generic	Approved	unknown
Taiwan	Generic	Approved	unknown
Russian Federation	Generic	Approved	unknown
Poland France Germany UK USA India	Clinical Phase III	Clinical evaluation ongoing	unknown
Germany	New drug	Late pre-clinical phase	unknown
Brazil	Generic	Filed	unknown
Germany	New drug	Investigational Medicinal Product Dossier (IMPD) filed with the German Health Authority (BfArM)	unknown
Japan	Clinical Phase I	Under preparation	unknown
The Netherlands Denmark Finnland France Sweden Slovenia Slovac Republic Austria Czech Republic Italy Portugal Romania Poland Germany	Generic	Withdrawn by the applicant. The withdrawal was NOT based on a safety concern related to Soluplus®, but due to lack of bioequivalence (BE) to the reference drug.	312.5 mg/tablet

Get your sample today!
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