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.

Regulatory Status - Overview

Country of regulatory submission	Application type	Regulatory status	Amount of Soluplus®
Taiwan	Generic	**Approved**	unknown
Russian Federation	Generic	Registration is expected in Q1 of 2018	unknown
Argentina	Generic	**Approved**	unknown
Poland	Clinical Phase I, II	Clinical evaluation ongoing	unknown
France			
Germany			
UK	Clinical Phase I, II	Clinical evaluation ongoing	
USA	Clinical Phase I, II	Clinical evaluation ongoing	unknown
India	Clinical Phase I, II	Clinical evaluation ongoing	unknown
Germany	New drug	Late pre-clinical phase	unknown
Germany	New drug	Investigational Medicinal Product Dossier (IMPD) under preparation	unknown
Japan	Clinical Phase I	Under preparation	unknown
The Netherlands	Gereric	Withdrawn by applicant. The withdrawal was not based on a safety concern related to Soluplus®, but due to lack of bioequivalence (BE) to the reference drug in an additional study considering fed and fasted conditions. For more details please refer to the Safety Expert Report.	312,5 mg/tablet
Denmark			
Finnland			
France			
Sweden			
Slovenia			
Slovac Republic			
Austria			
Czech Republic			
Italy			
Portugal			
Romania			
Poland			
Germany			

Pharmacopoeia Monographs and Titles

Soluplus® is not yet monographed in any pharmacopoeia. Upon approval the elaboration of a monograph will be initiated by BASF. A request for a pending USP-NF monograph will be submitted to the USP by the end of 2017.

Soluplus®

Regulatory Facts Sheet

BASF
We create chemistry

Soluplus®

For better solubility and bioavailability

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

Key Customer Benefits

- 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

Soluplus® at a glance

- 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:

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

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