



2nd Edition

Solubility Enhancement in Pharmaceutical Oral Solid and Parenteral Dosage Forms

To Be Published 2nd Quarter 2019

Base Year: 2018

Forecasts to 2028

Regional Coverage: Global

The major challenge faced by the pharmaceutical industry is currently poor solubility, hence the low bioavailability of most new drugs being developed. More than 80% of the entire drug candidates in the R&D pipeline, notably with the influx of large number of biologics, are reported to be poorly soluble in water. This leads to serious problems for the efficiency of pharmaceuticals both in injectable and OSDF dosage forms, which translates into a major challenge for drug formulators. At the same time, this is creating sustainably growing market opportunities for solubilization technologies in general, and more particularly for excipients that aid in solubility enhancement.

This Program Will Help Subscribers to Answer Key Questions such as:

- What are the technologies for solubility enhancement and what is their current use?
- What are the pros and cons of each technology in use?
- What are the sales of excipients for solubility enhancement?
- How does the choice and consumption of excipients vary between injectable and OSDF for solubility enhancement?
- Which excipient suppliers are active on the market, which products are they supplying, and what are their relative market shares?
- What is the average price of various excipients for solubility enhancement?
- How is the technological landscape expected to evolve?
- What is the forecast consumption of excipients for solubility enhancement from 2018 to 2028?
- Which could be the new excipients used in solubility enhancement in the forecast period?



Tentative Report Contents*

Introduction

Executive Summary

Introduction to Solubility Enhancement

- Global pharmaceutical industry: overview
- Regulatory scenario
- Current situation of poorly bioavailable active ingredients

Solubility Enhancement Technologies

- Overview of the technologies
- Role of SE technologies in the oral solid and parenteral dosage forms
- Advantages, disadvantages, and comparative assessment of the technologies
- Commercial examples of technologies in the solubility enhancement market
- Excipients used in the technologies
- Upcoming technologies
- Outlook

Comparative Assessment of SE technologies by dosage forms (OSDF versus parenteral)

- Current situation and outlook

Solubility Enhancement Excipients

- Introduction
- Grades and prices
- Consumption of excipient in the oral solid and parenteral dosage forms
- Competitive landscape
- Commercial examples of drugs using excipient in solubility enhancement market
- Novel/upcoming excipients for solubility enhancement
- Outlook

Comparative Assessment of SE excipients by dosage forms (OSDF versus parenteral)

- Current consumption and outlook

Competitive Landscape

- Introduction
- Industry structure
- Supplier market share in the oral solid and parenteral dosage forms
- Competitive landscape
- Short Profiles on major suppliers
- Major drug delivery companies
- Major customers

Appraisal and Outlook

- Major trends in oral solid and parenteral dosage forms
- Drivers and Restraints in solubility enhancement market
- Outlook and forecast for the solubility enhancement market

* Subject to charter subscriber input





Table 1: Technology Scope		
Technology	Process	Method
Particle size reduction	Micronization	Spiral jet mill micronization
		Fluidized-bed jet mill micronization
		Supercritical fluids-based technique
	Nanonization	Nanoprecipitation
		Media milling
		High-pressure homogenization
Lipid solubilization	Several	Supercritical fluids technology
		Self-Emulsifying Drug Delivery System (SEDDS)
Modification of crystal habit	Polymorphs	
	Pseudopolymorphs	
Solid Dispersions	Spray drying process	
	Hot-melt extrusion process	
Complexation	Complexation with cyclodextrins	
Cryogenic techniques	Lyophilization	
Use of Liposomes and proliposomes		
pH adjustment		
Salt formation		
Cosolvency		
Hydrotopy		
Coprocessed excipients		
Use of Ion exchange resins		
Solid Lipid Nanoparticles		
Liquisolid Technology		
Use of Silica		
Use of Dendrimers		



Table 2: Product Scope

Excipient category	Excipient type	
Surfactants	Cremophors	
	Polyethylene glycols (PEG)	
	Polysorbates	
	Poloxamers	
	Solutol HS 15	
	Polyoxyl stearates	
	N-methyl-2-pyrrolidone	
	Ethanol	
	Glycerin	
	Lecithin	
	Docusate sodium (DSS)	
	Sodium lauryl sulfate (SLS)	
	Polymers	Copovidone
		HPMC
Polymethacrylates (PMAs)		
HPMCAS		
Povidone (PVP)		
HPC		
Polyvinyl caprolactam-polyvinyl acetate-polyethylene glycol copolymer		
PEO		
HPMCP		
Lipid-based excipients (including water-insoluble surfactants)		
Cyclodextrins		
Mesoporous Silica		
Dendrimers		

NOTE: This is a tentative scope, any excipients with significant consumption for solubility enhancement will be covered.



Scope

This report provides a detailed independent appraisal of the current and forecast demand of excipients for solubility enhancement by major products, supplier sales, technology and market trends and explores market opportunities and challenges for manufacturers of these excipients worldwide. The study provides:

- Consumption of solubility enhancement excipients in OSDF and parenteral dosage forms
- Consumption of excipients by technology and methods used
- Consumption forecast of excipients to 2028
- Competitive landscape for the excipients for solubility enhancement
- Technology and process analysis for solubility enhancement techniques
- Detailed analysis of key drivers and restraints of the excipients consumption for solubility enhancement
- Detailed analysis of key drivers and restraints of the technologies for solubility enhancement

Key Benefits

This study will assist suppliers of pharmaceutical excipients in identifying opportunities within the global market of solubility enhancement. It will also serve as an invaluable tool in the strategic planning process.

- Develop business strategies by understanding the trends and developments that are driving the global solubility enhancement excipients market
- Identification of key growth areas by excipient type, application dosage form, and technologies of their use to enable development of targeted sales and marketing strategies
- Develop market-entry and market expansion strategies
- Identify the competition from alternative technologies
- Competitive intelligence for use in benchmarking
- Forecasting scenarios from which to base solid strategic business plans



Methodology

Kline’s approach places principal emphasis on primary research techniques to ensure that the foundation of business intelligence and insight is accurate, current, and reliable. Building on our 50-plus years in the business and leveraging our worldwide network of offices, our teams of seasoned professionals draw upon pragmatic industrial and commercial experience to understand and interpret global impacts and local perspectives.

Primary Research

We Know Who to Talk to. We Know How to Listen.



A high number of in-depth discussions are conducted by each analyst. All interviews are done with true industry insiders.

Kline’s analysts draw upon pragmatic experience to understand global impacts and local perspectives. Our interviews engage experts across all pertinent fields and sectors including:

- Industry associations
- Government/regulatory agencies
- Marketers/manufacturers
- Distributors
- Formulators/customers

Secondary Research

We Know Where to Look – Mining the Details.



Analysis is further supplemented by secondary research, consisting of constant tracking of annual company reports, national statistics bureaus, trade/ industrial/professional associations, and the like.

Relevant developments are diligently followed and their impact closely monitored. Reports also draw upon non-confidential data from Kline’s internal database, consisting of over half a century’s syndicated research.

Comprehensive Market Intelligence

We Know How to Verify.



Data are rigorously analyzed, cross-checked, distilled, and validated. Kline’s proven methodology allows exceptionally effective, precise, and reliable market

intelligence, giving subscribers a solid foundation on which to grow, refine, and expand their business with confidence.

Kline Credentials

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