



SOLUBILITY ENHANCEMENT EXCIPIENTS MARKET OVERVIEW

Market Analysis and Overview

Webinar

October 12, 2021

Today's Speaker



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Project Manager,
Chemicals & Energy

Today's Presentation

- › **Introduction to Kline & Company**
- › Solubility Enhancement: Introduction
- › Global Pharmaceuticals Market
- › Need for Solubility Enhancement
- › Solubility Enhancement Technologies
- › Solubility Enhancement Excipients Market
- › Competitive Landscape
- › Appraisal and Outlook



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Our project teams are staffed with seasoned management consultants and operating executives from the chemicals industry.

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» Solubility Enhancement Excipients: Introduction

Solubility Enhancement Excipients: Market Analysis and Opportunities summarizes the results of Kline & Company's comprehensive study on a comprehensive analysis examining the market for solubility enhancement (SE) in pharmaceutical oral solid and parenteral dosage forms globally.

This report analyzes the growing need for SE technologies and the related consumption of SE excipients. Existing and developed technologies have been assessed, and consumption and supply of excipients have been analyzed.

The ingredient groups covered in this study include lipids, polymers, cyclodextrins, surfactants, and ion exchange resins.

Solubility Enhancement in Pharmaceutical Oral Solid and Parenteral Dosage Forms

Base Year: 2020 A comprehensive analysis examining the market for Solubility Enhancement in Pharmaceutical Oral Solid and Parenteral Dosage Forms globally.

To be published: Q2 2021

2nd edition The reports will focus on key trends, developments, changes, challenges, and business opportunities.

Global Coverage

SCOPE

- » Consumption of solubility enhancement excipients in GDP and parenteral dosage forms
- » Consumption of excipients by technology and methods used
- » 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
- » Consumption forecast of excipients to 2030

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➤ Methodology

- The report is primarily based on a series of interviews with approximately 40 individuals, including customers, suppliers, distributors, formulators, and government agencies globally. It also draws upon suppliers' product literature; an analysis of statistical data from government, trade, and industry associations; and non-confidential information from Kline's database.
- This analysis also draws on secondary sources such as: (1) product literature and websites of ingredients and excipients suppliers to the pharmaceutical industry; (2) a search of recent trade and technical literature; (3) an analysis of statistical data from government, trade, and industry organizations; and (4) non-confidential data from Kline & Company's previous work in this industry, including syndicated studies.
- All sales values are provided in United States dollars (USD). Value sales are at the manufacturers' level and not at the retail or distributor level, except when otherwise noted. Prices are based on average market values and are reported on a 100% active basis unless otherwise noted. Forecasts are calculated in constant USD, with no allowance for inflation.
- Unless otherwise specified, all volumes are reported on a 100% active basis, in kilograms or tonnes.
- The data presented in this report is as accurate as possible within the general scope of the survey but may vary by product and application. Overall, we believe that the data presented is within 10–15% of the true values.

Today's Presentation

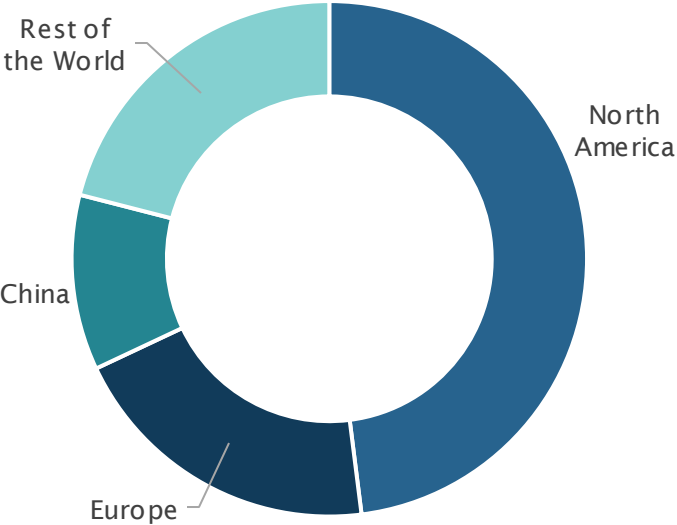
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The global pharmaceuticals market is around USD 1.3 trillion, with the North America and Europe leading the market.

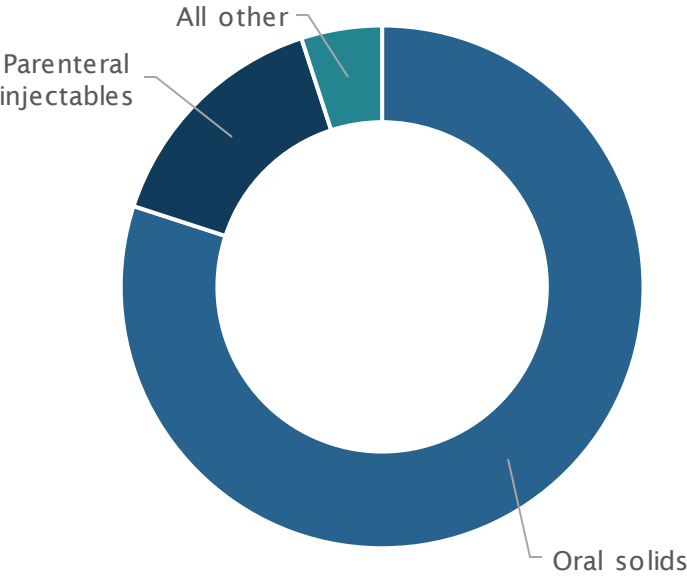
GLOBAL PHARMACEUTICAL MARKET, 2020

BY REGION



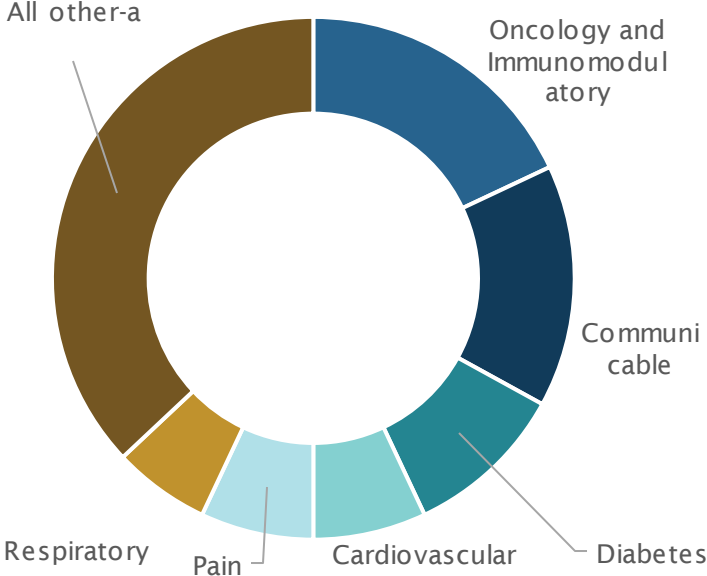
Total: USD 1.3 Trillion

BY DOSAGE TYPE



Total: USD 1.3 Trillion

BY THERAPEUTIC AREAS

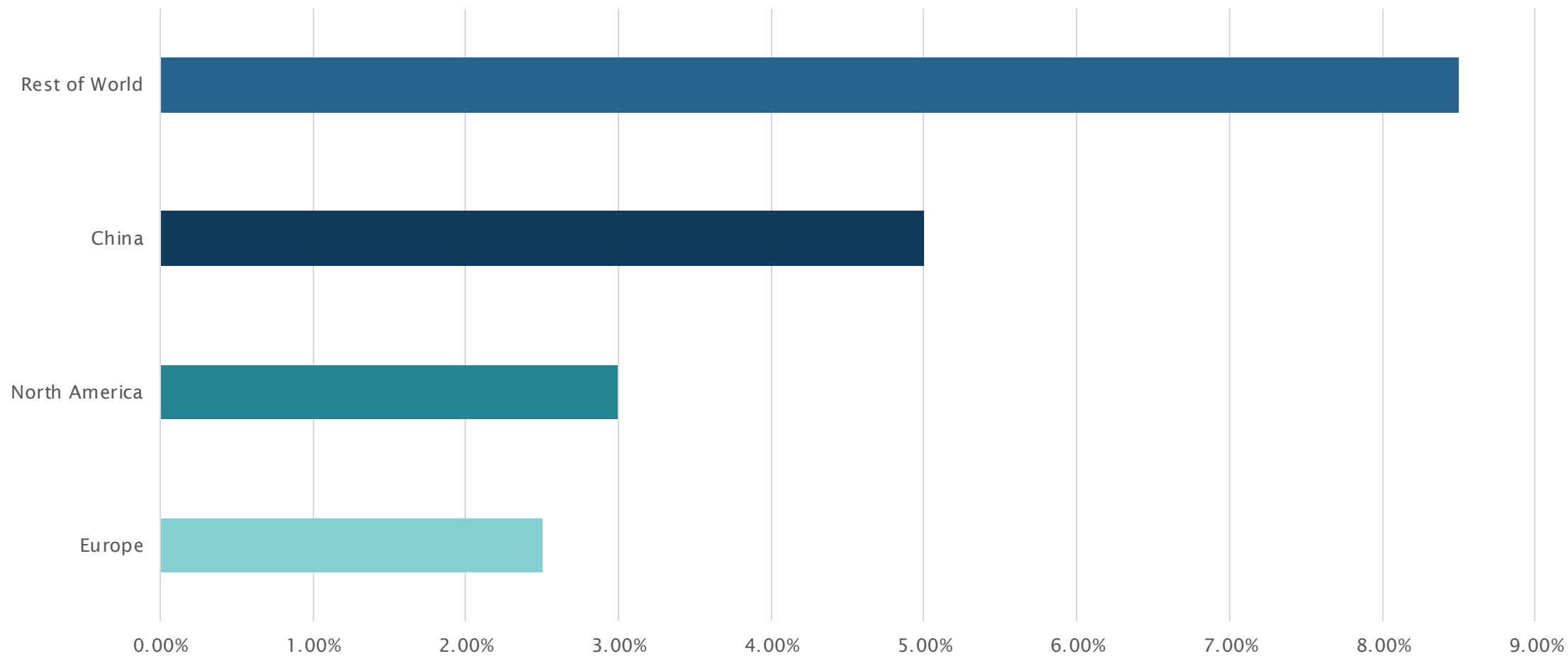


Total: USD 1.3 Trillion

a- Includes noncommunicable diseases such as chronic kidney disease, osteoarthritis, osteoporosis, Alzheimer's disease, and cataracts.

Global Pharmaceutical Industry Outlook

FORECAST OF PHARMACEUTICAL INDUSTRY BY REGION, 2020-2025



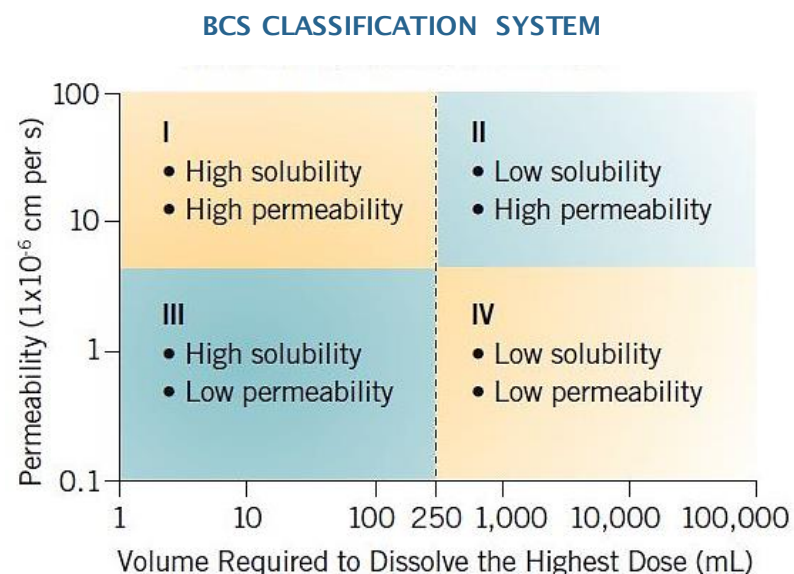
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Bioavailability of Active Ingredients

- The biopharmaceutical classification system (BCS) is a scientific framework for classifying a drug substance based on its aqueous solubility and intestinal permeability. It is a guide provided by the U.S. Food and Drug Administration (FDA) for predicting intestinal drug absorption.
- The most important classes of drugs are BCS Class II and Class IV, which have the issue of solubility.
 - These are largely oral solid drugs, with more than 85% of the drugs sold in the market being administered orally.
 - Due to the high importance of Class II and Class IV drugs to be formulated in oral solid doses, it is critical to improve their solubility to make them sufficiently bioavailable upon oral administration.



BCS CLASSIFICATION SYSTEM, 2020			
CLASS	SOLUBILITY	PERMEABILITY	ABSORPTION PATTERN
I	High	High	Well-absorbed
II	Low	High	Variable
III	High	Low	Variable
IV	Low	Low	Poorly absorbed

➤ Bioavailability of Active Ingredients (continued)

Reasons for Poor Bioavailability

- Poor aqueous solubility
- Inappropriate partition coefficient
- First-pass metabolism
- Degradation due to low pH in stomach
- Interaction with food
- Insufficient time for absorption

Need for
Solubility
Enhancement

- Approximately 40% of the current marketed drugs and approximately 70–90% of pipeline drugs fall into two solubility categories of BCS: Class II and Class IV.
- The number of poorly soluble molecules entering the drug development pipeline has been increasing each year.
- An estimate of more than 50 drug products were successfully developed in 2020. Advanced SE technologies, including amorphous solid dispersions, supercritical fluid processing, self-micro-emulsifying drug delivery system, nanocrystals, cyclodextrins, and lipid technologies, were used.

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Solubility Enhancement Technologies

CURRENT USE AND GROWTH OUTLOOK FOR SOLUBILITY ENHANCEMENT TECHNOLOGIES FOR ORAL SOLID AND PARENTERAL INJECTABLE DOSAGE FORMS, 2020

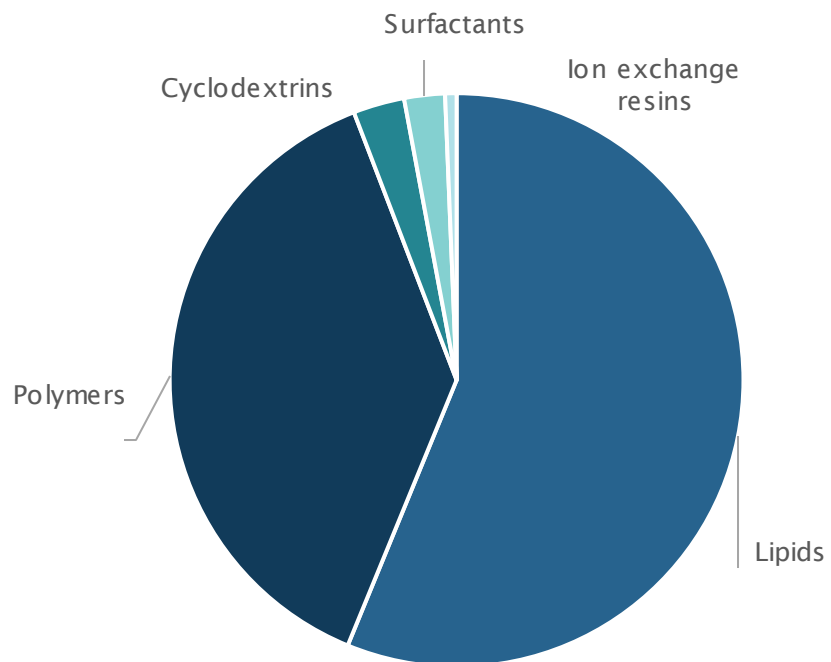
TECHNOLOGY	METHOD	CURRENT USAGE	GROWTH OUTLOOK
Particle size reduction	Micronization	Vast	Moderate growth
	Nanosuspension	Moderate	Moderate growth
Modification of crystal habit	Polymorphs and pseudopolymorphs	Moderate	Slow growth
Solid dispersions	Hot-melt extrusion	Moderate	Fast growth for oral solid dosage form
	Spray drying	Vast	Fast growth for oral solid dosage form
	Lyophilization	Small	Moderate growth for both dosage forms
Lipid solubilization	Lipid-based drug delivery systems such as SEDDS/SMEDDS	Moderate	Fast growth for both dosage forms
Chemical modification	pH adjustment	Moderate	Slow growth
	Salt formation	Moderate	Slow growth
Complexation with CDs	Complexation with CDs	Moderate	Slow growth for oral solids and high growth for parenteral injectable dosage form
Other	Prodrugs	Moderate	Slow growth
	Hydrotropy	Small	Slow growth

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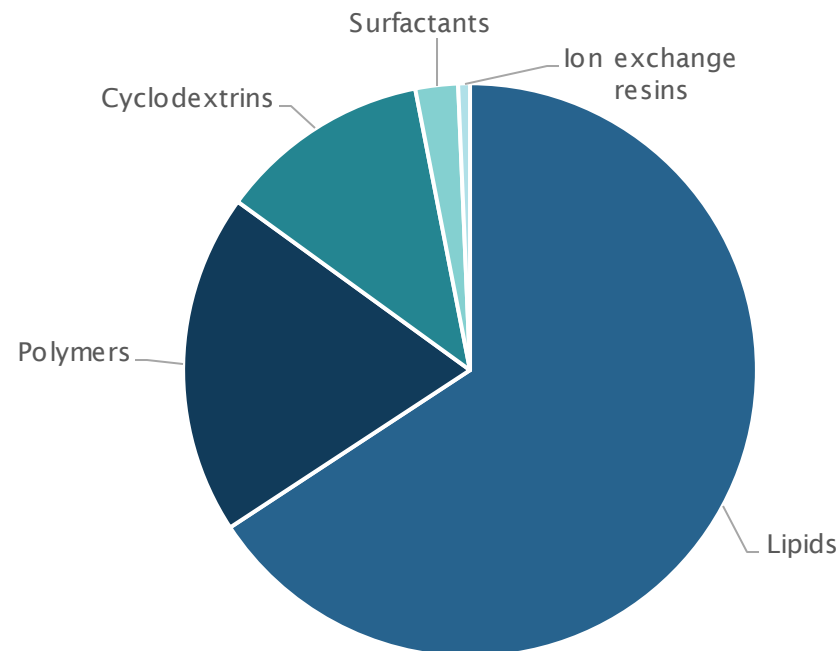
➤ The global solubility enhancement excipients market is USD 400–500 million

GLOBAL MARKET OF SOLUBILITY ENHANCEMENT
EXCIPIENT CATEGORIES BY VOLUME, 2020



Total: 6,000.0–7,000.0 Tonnes

GLOBAL MARKET OF SOLUBILITY ENHANCEMENT
EXCIPIENT CATEGORIES BY VALUE, 2020



Total: USD 400.0–500.0 Million

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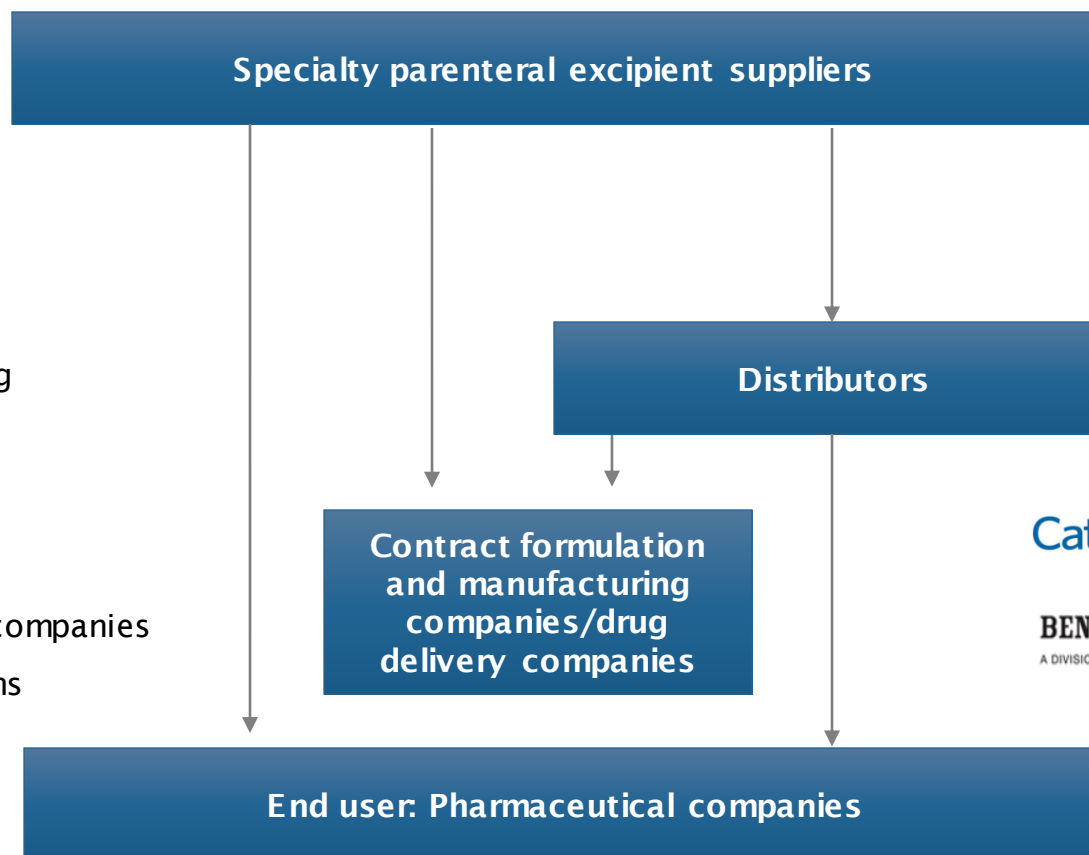
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Industry Structure for Solubility Enhancement Excipients

ROLE IN THE INDUSTRY STRUCTURE

- Manufacturers of SE excipients
- Some excipient suppliers using distributors to facilitate sales
- Contract formulators and manufacturers/drug delivery companies for pharmaceutical formulations
- Pharmaceutical companies

USUAL ROUTE TO MARKET



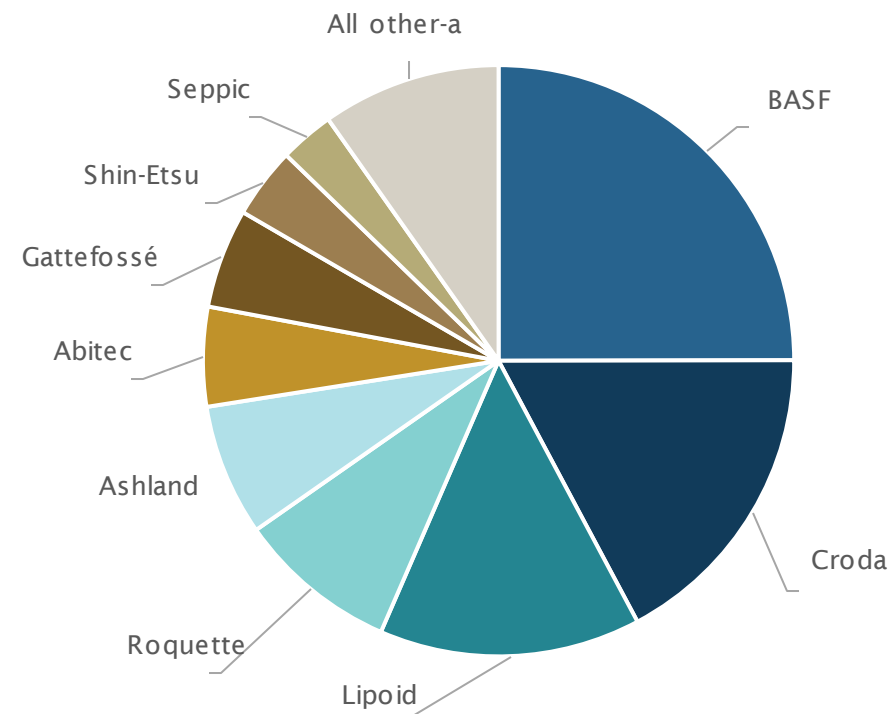
EXAMPLES



Competitive Landscape for Solubility Enhancement Excipients

- The market for SE excipients continues to be relatively concentrated.
- There are approximately 30 suppliers present in the global market for SE excipients.
- The supplier scenario of these excipients consists of different types. Some suppliers are present in only one excipient category, while others are present in multiple excipient categories.
- Further, some suppliers offer excipients for use in different technologies for SE, while others offer excipients for one technology.

GLOBAL MARKET OF SOLUBILITY ENHANCEMENT EXCIPIENTS BY SUPPLIER, BY VALUE, 2020



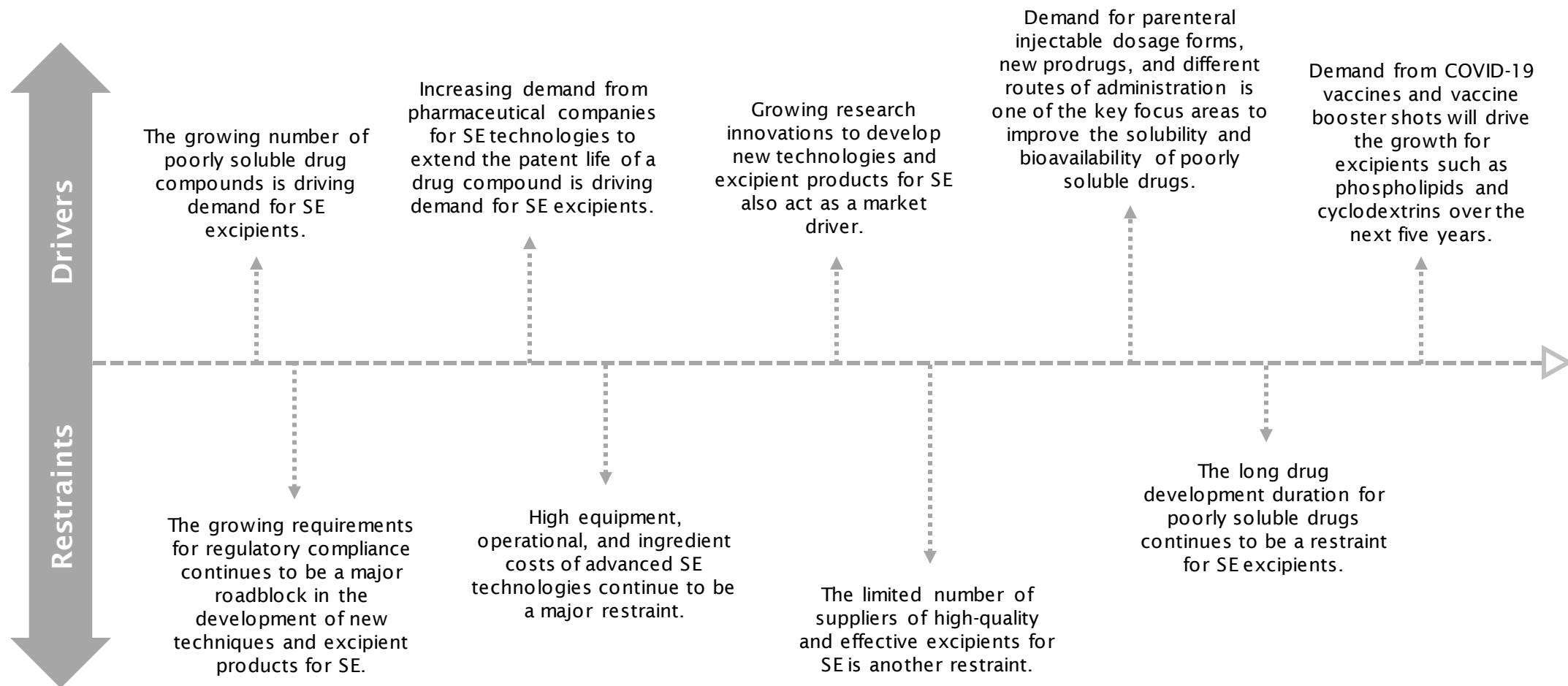
Total: USD 400.0-500.0 Million

a- Includes Cyclo Labs, Solvay, and Thermax, among others

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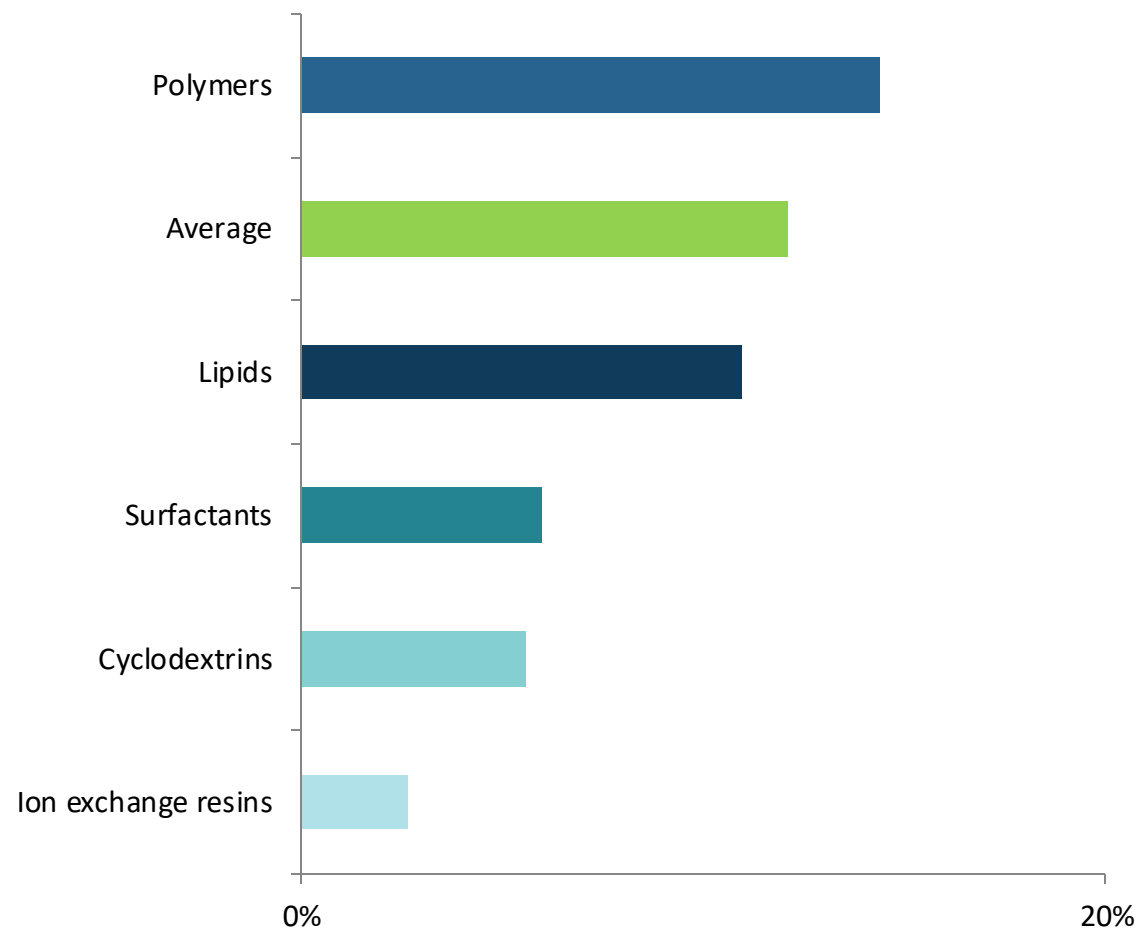
Market Drivers and Restraints for Solubility Enhancement



Global Solubility Enhancement Excipients Market Outlook

- The fastest-growing category of excipients for SE is polymers, due to their rapidly increasing consumption in solid dispersion techniques.
- The increasing use of self-emulsifying drug delivery systems (SEDDS) and self-micro-emulsifying drug delivery systems (SMEDDS) will drive the growth of lipid excipients during the forecast period.
- In 2020, the COVID-19 pandemic completely changed the market dynamics for cyclodextrins for parenteral injectable dosage form. Consumption was significantly higher due to its use in Remdesivir, a drug used to treat COVID-19.
- Surfactants are expected to grow at a relatively lower rate, as their independent consumption for enhancing solubility continues to be low.

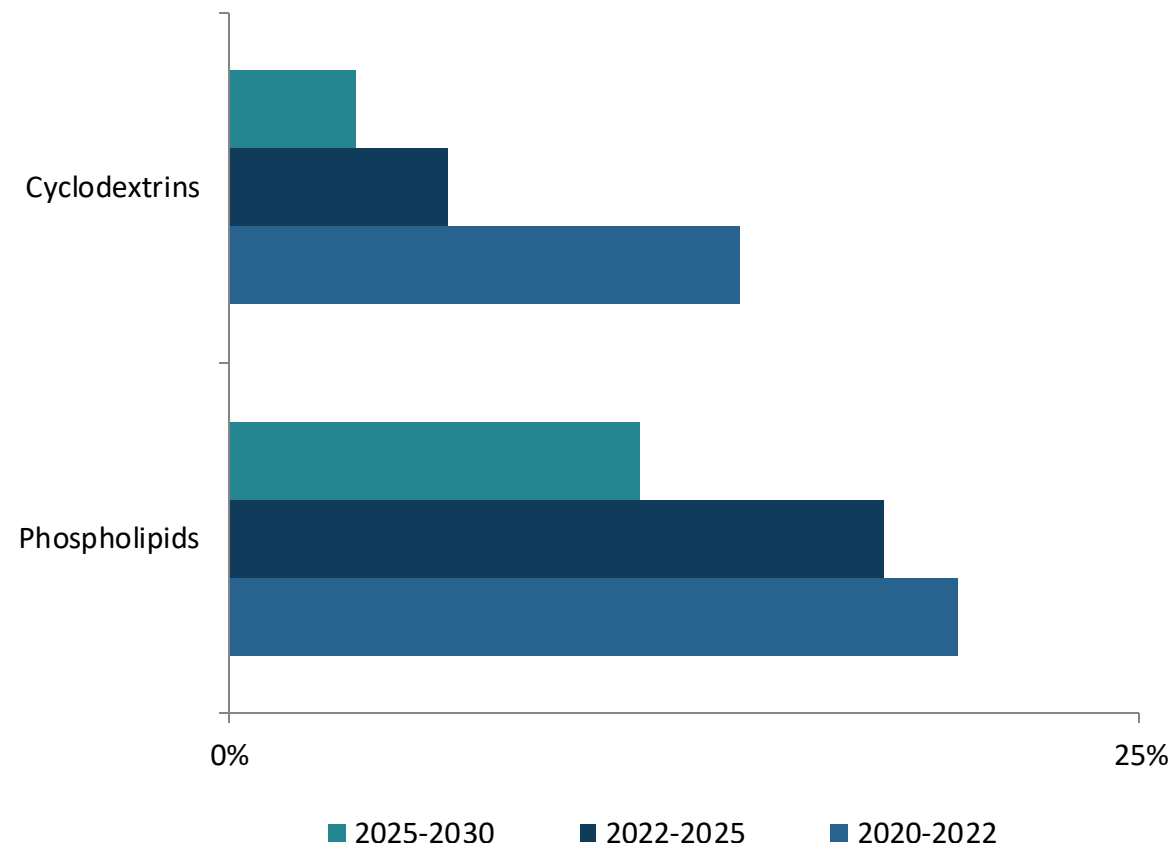
ESTIMATED GROWTH OF SOLUBILITY ENHANCEMENT EXCIPIENTS
BY CATEGORY, BY VOLUME, 2020-2030



➤ Impact of COVID-19 — Solubility Enhancement Excipients Outlook

- There are a few SE excipients that were used in COVID-19 treatment drugs and vaccines. This had a significant impact on the demand for these excipients globally.
- The demand for CDs in parenteral injectables has been on the rise due to their increasing use in vaccines such as COVID-19, Porcine Circovirus, influenza, Dengue Virus, Hepatitis C, and HIV.
- Phospholipids also play a very important role in the novel drug delivery systems (NDDS), as they are significantly used in the treatment of COVID-19.
- As a result, growth for CDs and phospholipids for SE was projected for three different scenarios over the forecast period.

ESTIMATED GROWTH OF SOLUBILITY ENHANCEMENT EXCIPIENTS FOR BY EXCIPIENT, 2020-2030





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