

NOW AVAILABLE

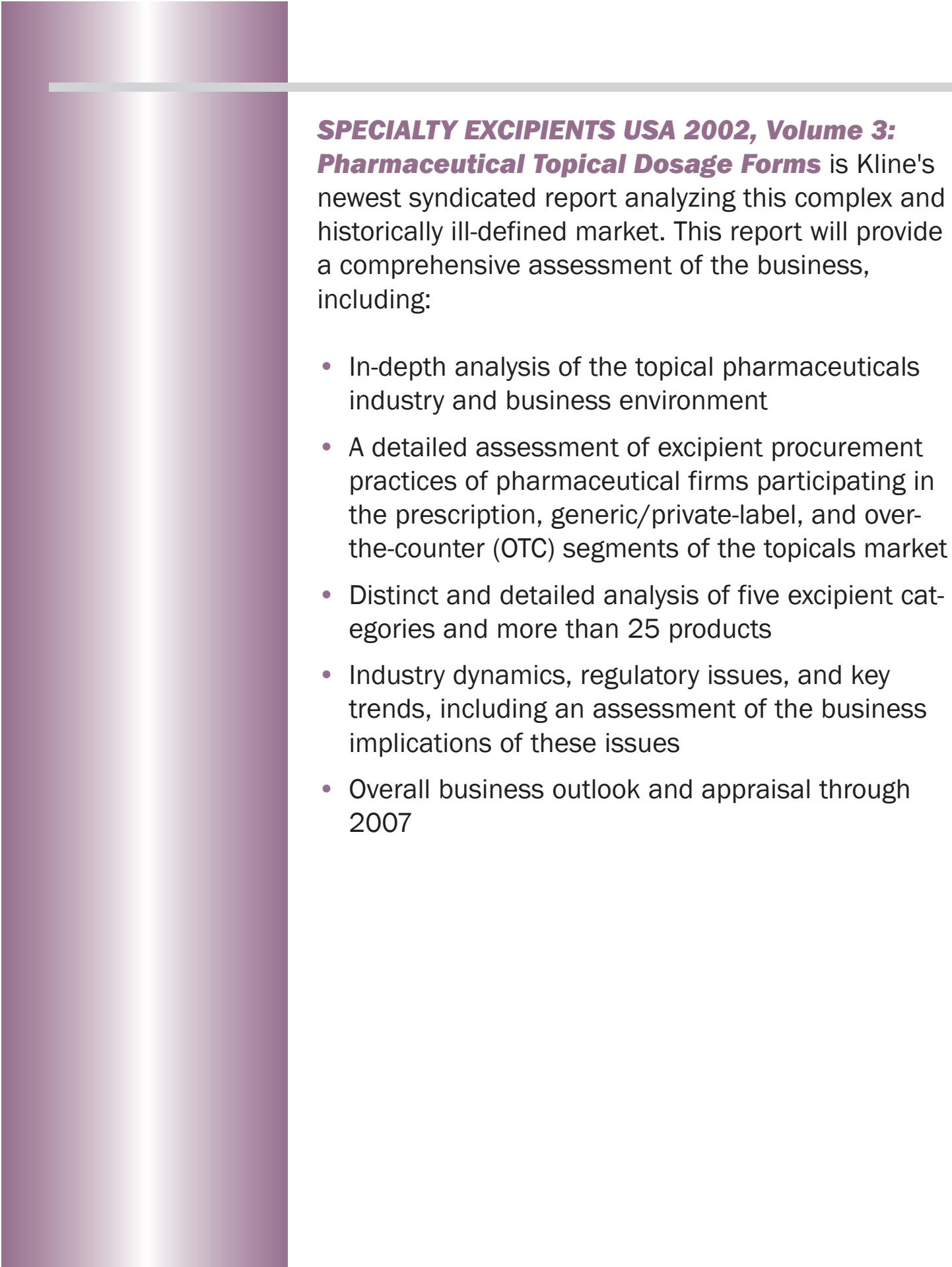
---

# SPECIALTY EXCIPIENTS USA 2002

Volume 3: Pharmaceutical Topical Dosage Forms



**KLINE & COMPANY, INC.**  
OVERLOOK AT GREAT NOTCH  
150 CLOVE ROAD, #410  
LITTLE FALLS, NJ 07424-0410  
(973) 435-6262  
[www.klinegroup.com](http://www.klinegroup.com)



***SPECIALTY EXCIPIENTS USA 2002, Volume 3: Pharmaceutical Topical Dosage Forms*** is Kline's newest syndicated report analyzing this complex and historically ill-defined market. This report will provide a comprehensive assessment of the business, including:

- In-depth analysis of the topical pharmaceuticals industry and business environment
- A detailed assessment of excipient procurement practices of pharmaceutical firms participating in the prescription, generic/private-label, and over-the-counter (OTC) segments of the topicals market
- Distinct and detailed analysis of five excipient categories and more than 25 products
- Industry dynamics, regulatory issues, and key trends, including an assessment of the business implications of these issues
- Overall business outlook and appraisal through 2007

## TABLE OF CONTENTS

1. EXECUTIVE SUMMARY
2. INTRODUCTION
3. OVERVIEW OF PHARMACEUTICAL TOPICAL INDUSTRY AND EXCIPIENT FUNCTIONALITY
4. SPECIALTY DELIVERY SYSTEMS
5. RHEOLOGY MODIFIERS
6. SPECIALTY EMOLLIENTS
7. SPECIALTY POLYMERS
8. PSEUDO COMMODITIES

*For sections 4 to 8, the following information is provided:*

- Description of physical properties, grades, prices, and use levels
- Estimated consumption in volume and value
- Customer base overview
- Supplier base, including estimated supplier sales and market share
- Channels of distribution
- Outlook through 2007
- Appraisal

### 9. PROCUREMENT PRACTICES

*This chapter provides subscribers with an assessment of specialty excipient procurement practices of leading pharmaceutical firms competing in the topicals business.*

*Included are key specialty excipient procurement criteria by prescription, OTC, and generic/private-label formulated topical products. Insights relating to pricing sensitivity in the pharmaceutical industry and the role and influence of purchasing departments will also be provided.*

- Selection criteria
  - Formulation characteristics
  - Excipient choice
  - Vendor selection
- The formulator as the decision maker
- The role of the purchasing department
- Use of distributors
- Key market trends
  - Industry
  - Products

### 10. REGULATORY ISSUES

*This chapter provides subscribers with an overview of key regulatory issues relating to specialty excipient consumption in topical pharmaceuticals.*

- Harmonization
- USP and NF
- FDA
- GMPs
- New excipients

### APPENDIX: List of Organizations Interviewed

## **OVERVIEW**

The U.S. market for specialty excipients for topical-dosage-form pharmaceuticals is unique and vastly different from oral solid-dosage-form pharmaceuticals. In fact, from a raw material standpoint, significant synergies exist between topical dosage forms and selected categories of cosmetics and toiletries. In other respects, however (in the regulatory environment, for example), the two businesses differ markedly.

For this study, topicals are defined as ointments, creams, lotions, gels, and suppositories that are applied directly to the affected area for local application and action. These include two basic types of product: (1) external topicals that are spread, sprayed, or otherwise dispersed onto cutaneous tissues to cover the affected area; and (2) internal topicals that are applied to the mucous membrane orally, vaginally, or on anorectal tissues for local activity.

Current and potential excipient suppliers are facing many strategic questions on this business, including:

- How should we segment this business?
- Where are the opportunities?
- Which producers of pharmaceutical topical dosage forms are the most innovative?
- What differences in procurement practices exist among producers of prescription, OTC, and generic/private-label topical dosage forms? How should we be positioned?
- How can we maximize value in this business?

## **THE REPORT**

A list of specialty excipients covered in this report is provided in Table 1, and the table of contents is provided on the previous page.

---

**Table 1**

**LIST OF SPECIALTY EXCIPIENTS COVERED IN THIS REPORT**

**Rheology Control Agents**

- Cellulosics
  - HPC
- Synthetics
  - Carbomer
  - Poloxamer
- Inorganics
  - MgAl silicate
- Gums
  - Xanthan gum
- Specialty emollients
  - Natural oils
    - Modified
    - Extracts
- Classic emollient esters

**Specialty Polymers**

- Silicones
  - Cyclomethicone
  - Dimethicone
  - Other

**Delivery Systems**

- Microcapsules

**Pseudo Commodities**

- Polyols
  - Fatty acids
  - Fatty alcohols
  - Fatty alcohol ethers
  - Surfactants
  - Waxes
-

---

## RESEARCH METHODOLOGY

Kline's research approach places the greatest emphasis on primary research to ensure that the foundation of business intelligence and insight is accurate and current.

During the course of the field research, we conducted in-depth discussions with knowledgeable industry participants to define and verify, in an exacting manner, the nature of the current and future competitive and business environment.

The project team conducted in-depth, in-person interviews with: (1) leading consumers of specialty excipients in the prescription, OTC, and generic/private-label segments of the pharmaceutical industry; (2) leading specialty excipient manufacturers, marketers, and distributors; and (3) pertinent government and regulatory agencies and trade associations.

The report also draws upon a search of recent trade and technical literature; analysis of statistical data from government agencies, trade associations, and industry organizations; and nonconfidential data from Kline's library and files.

We have found that Directed Discussions™, our professional-to-professional field research methods, are unmatched in their ability to gather hard-to-get market and competitive intelligence with a high degree of confidence.

Primary research comprises more than 90% of the overall research methodology for this syndicated report.

## SUBSCRIPTION OPTIONS AND PRIVILEGES

***SPECIALTY EXCIPIENTS USA 2002, Volume 3: Pharmaceutical Topical Dosage Forms*** is only available by subscription. Two subscription options are available to subscribers:

1. Three hard copies of report plus one day of consultation.
2. An online version of report, which includes unlimited online access to the report contents for members of the subscribing organization, one hard copy of the report, and one day of consultation.

Additional copies will also be made available for a nominal fee.

Details regarding subscription options and conditions are described in the attached subscription agreements. To subscribe now, please complete the subscription agreement and forward it to any of our offices. To obtain more details regarding the study, please contact us at any of our locations listed on the back cover.

---

# SUBSCRIPTION AGREEMENT

Please fax signed agreement to 973-435-3395

## SPECIALTY EXCIPIENTS USA 2002, Volume 3: Pharmaceutical Topical Dosage Forms

Please enter our subscription to your comprehensive study **SPECIALTY EXCIPIENTS USA, Volume 3: Pharmaceutical Topical Dosage Forms**. The standard subscription includes three copies of the finished report and one day of consultation time within the scope of the study. A subscription to the online version of the study includes unlimited online access to the report contents and one day of consultation time, plus one hard copy of the report. Additional copies of the report will be available for a nominal fee.

To protect our investment in this report and that of other subscribers, we agree that, for a period of three years after its date of issue, we will: (1) refrain from reproducing or copying this report in whole or in part by any means; (2) restrict its circulation to our own employees; and (3) use all reasonable precautions to prevent the disclosure of its contents to any other persons or organizations. We may, however, make this report available to any subsidiary company in which we hold more than half interest or to any parent company that holds more than a half interest in our firm. We may also use or disclose any information in this report that is public knowledge, that was already in our possession before receipt of the report, or that comes to us from third parties independently of this report.

Kline & Company, Inc. similarly agrees that it will use all reasonable precautions to prevent the disclosure of the contents of this report to any persons or organizations other than subscribers for three years after its date of issue.

We understand that **SPECIALTY EXCIPIENTS USA, Volume 3: Pharmaceutical Topical Dosage Forms** is available only by subscription. Subscription prices do not include sales tax. (NJ add 6% sales tax.) You will invoice us for the total amount, and we will pay this invoice within 15 days of receipt. Domestic ground shipping within the United States is included in the subscription price. Overnight and international shipping fees are optional and will be added to the total amount.

Study options	Standard price (U.S. funds)	Amount (please fill in price)
Three hard copies of the report	\$13,500	
Online access	15,000	
Additional copies	500 (each)	
	Subtotal	
	NJ only: 6% sales tax	
	<b>TOTAL (U.S. funds)</b>	

We have completed and signed this subscription agreement. Please indicate your acceptance of this subscription by countersigning and returning one copy for our files.

COMPANY _____	
SIGNATURE _____	DATE _____
NAME _____	
TITLE _____	
E-MAIL _____	
PHONE _____	

Send invoices to:

NAME _____
TITLE _____
ADDRESS _____
_____
E-MAIL _____
PURCHASE ORDER # _____

Shipping address (if different than billing address):

NAME _____
TITLE _____
ADDRESS _____
_____
E-MAIL _____

Kline use only:

ACCEPTED _____
SIGNATURE _____
NAME _____
TITLE _____
DATE _____

METHOD OF PAYMENT:

Send invoice







Card #: \_\_\_\_\_ Exp. Date: \_\_\_\_\_

Name (as it appears on credit card): \_\_\_\_\_

Signature (for credit card authorization): \_\_\_\_\_

---

## THE KLINE GROUP

### USA

**KLINE & COMPANY, INC.**  
OVERLOOK AT GREAT NOTCH  
150 CLOVE ROAD, #410  
LITTLE FALLS, NJ 07424-0410  
TEL: (973) 435-6262  
FAX: (973) 435-6291  
E-mail: [consult@klinegroup.com](mailto:consult@klinegroup.com)

### EUROPE

**KLINE EUROPE, S.A.**  
1 AVENUE GRIBAUMONT  
B-1150 BRUSSELS  
BELGIUM  
TEL: (32-2) 770-4740  
FAX: (32-2) 770-9440  
E-mail: [consult@kline-europe.com](mailto:consult@kline-europe.com)

### BRAZIL

**FACTOR DE SOLUÇÃO**  
AV. SÃO GABRIEL, 333 - CJ. 112  
ITAIM BIBI - SÃO PAULO - SP  
01435-001 BRAZIL  
TEL: (55-11) 30797843  
(55-11) 30790792  
FAX: (55-11) 30796197  
E-mail: [srebelo@factordesolucao.com.br](mailto:srebelo@factordesolucao.com.br)

