

Applications

- Dermatologic
- Ophthalmic
- Wound Care
- Vaginal
- Intra-oral
- Nasal
- Otic
- Rectal
- Buccal
- Transdermal

Formulations

- Alcoholic Gels
- Aqueous Gels
- Creams
- Lotions
- Ointments
- Solutions
- Sprays
- Suspensions
- Shampoos
- Foams



“I often tell colleagues that if topical formulation expertise is required, the road goes through Dow Pharmaceutical Sciences.”

- Vice President, Operations

Topical Product Development Since 1977
Our Focus - Your Success



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Focus

Topical products are much different than other dosage forms. With multiple ingredients and the unique properties of every API, problems can occur during formulation development, analytical method development, at scale-up, or after long term storage. At Dow Pharmaceutical Sciences, Inc., we focus exclusively on topical products, so we understand these problems and how to avoid or correct them. Our technical team will formulate your specific API into a stable, elegant, product that delivers drug to the target site, is scalable to commercial batch sizes, and is disease compatible - without vehicle effects that could negatively impact clinical results or patient acceptance.

Experience

As a result of focusing on topical products for 30+ years, Dow Pharmaceutical Sciences has developed more prescription topical formulations than any company in the world. We have experience with all types of NCEs, both small and large molecules, for dermatologic, ophthalmic, vaginal, buccal, nasal and other topical applications. Our success comes from experience and our unique formulation optimization process. Specialists in formulation, analytical, and drug transport collaborate to develop multiple formulation prototypes based on different excipient systems. Prototypes are screened for physical and chemical stability, and for tissue penetration in our state-of-the-art *in vitro* drug transport laboratory. Prototypes are optimized to result in one lead formulation and a back-up for further development.

The Dow Difference

In the past 3 years alone, Dow Pharmaceutical Sciences has successfully developed topical formulations for 65 pharmaceutical and biotechnology companies of all sizes – from start ups to multinationals. From our frequent meetings with the FDA dermatology division, we understand their requirements for CMC, non-clinical and clinical testing. During 2005-06, 14 topical prescription products were approved by the FDA. Formulation development for 8 of these 14 products was conducted by Dow. During 2003-04, Dow filed four eCTD NDAs, and all four were approved in 2005-06. As a Dow client, you gain access to our knowledge and expertise in topical products that will provide you an invaluable advantage towards success.

“Partnering with Dow Pharmaceutical Sciences to develop our topical formulation gives us our best chance of success. Most importantly, I can sleep at night!”

- Senior Vice President, Research and Development

Topical Product Development

Formulation optimization
In vitro penetration models
Analytical method development
Stability studies



Clinical Supplies

Packaging selection
Manufacturing (topicals)
Labeling (all dosage forms)
Distribution to clinical sites



Regulatory

Regulatory strategy
Non-clinical development plans
Clinical development plans
Electronic submissions to FDA



Clinical Trials

Solano Clinical Research (USA)
Bioskin (Europe)
Proof-of-Concept models



Consulting

Formulation assessment
Regulatory requirements