

At Dow Pharmaceutical Sciences Inc., We Focus Only On Topical Products.



Full Complement of Services

Clinical Manufacturing

### Dosage Forms

- Gels
- Lotions
- Creams
- Ointments
- Solutions
- Sprays
- Suspensions
- Suppositories



**Dow Pharmaceutical Sciences, Inc.**

The D in Topicals R&D

Since 1977

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## Small scale GMP manufacturing of Phase I and II *topical* clinical supplies

### Focus on Topicals

Topical products are our focus. We have broad experience taking semisolid and liquid topical dosage forms through process development, scale-up and technology transfer - so we are very good at solving the problems that can occur. In the past 3 years alone, we have manufactured clinical supplies for ~ 75 clients. Clinical batch sizes range from 1 kg - 36 kg for creams and ointments, up to 60 L for lotions and gels, and up to 160 L for solutions. Packaging can be done in a wide variety of containers (plastic, metal, glass) under a variety of conditions. We also provide clinical labeling and distribution services.

### Quality

Quality manufacturing is critical. With many client inspections and four recent FDA pre-approval inspections, we have had no 483 observations. Our Quality Assurance group independently reviews and approves documentation including master batch records, procedures, cleaning verifications, process validations, product specifications and batch releases. In-process controls include pH, batch uniformity, weight checks, capping torque, etc. Environmental monitoring ensures low bio-burden levels and effectiveness of cleaning and sanitation procedures.

### Flexibility

Because we focus on clinical manufacturing as opposed to commercial manufacturing, our group can more flexible. Every client is important to us, and we pride ourselves on fast and friendly service. We understand that changes in timing and batch size can occur when manufacturing clinical supplies and we respond rapidly. No batch size is too small; we manufacture from small pilot scale to large scale-up. We often assist with tech transfer to our client's commercial manufacturer of choice.

### Equipment

Equipment includes jacketed triple-action semisolids processor, homogenizers, propeller mixers, jacketed tanks, metering pump, bottle fillers and sealers. We have facilities designed for processing flammable products. Dow has -20°C, 5°C and controlled room temperature storage for APIs and drug products to meet stringent client needs.

