




Advancing Topical Formulations Into GMP Manufacturing

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PHARMACEUTICAL CHEMISTRY DEVELOPMENT & MANUFACTURING



Overview

- Brief Introduction
- Testing & API Characteristics
- Formulation
- Microbiology
- Extraneous Preparation
- Safety
- Process Scale-Up
 - Container Closure Selection
- Summary

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About Us




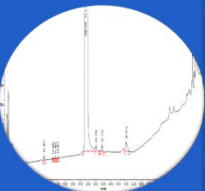
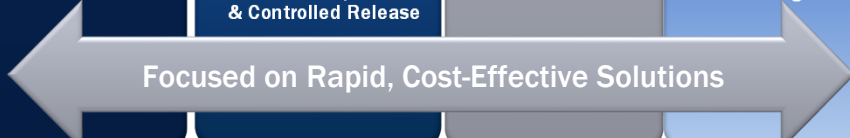


- Client-Centric Project Approach
- 17 Years of Service
- Privately Held & Fee for Service Focused
- 190 Employees & Growing
- 68,000 sq. ft. Facility
- 18,000 sq. ft. Dedicated to HP/C
- Diverse Mix of Clients
- Experience with Complex Formulations



Productivity Award
Quality Award
Regulatory
Reliability Award

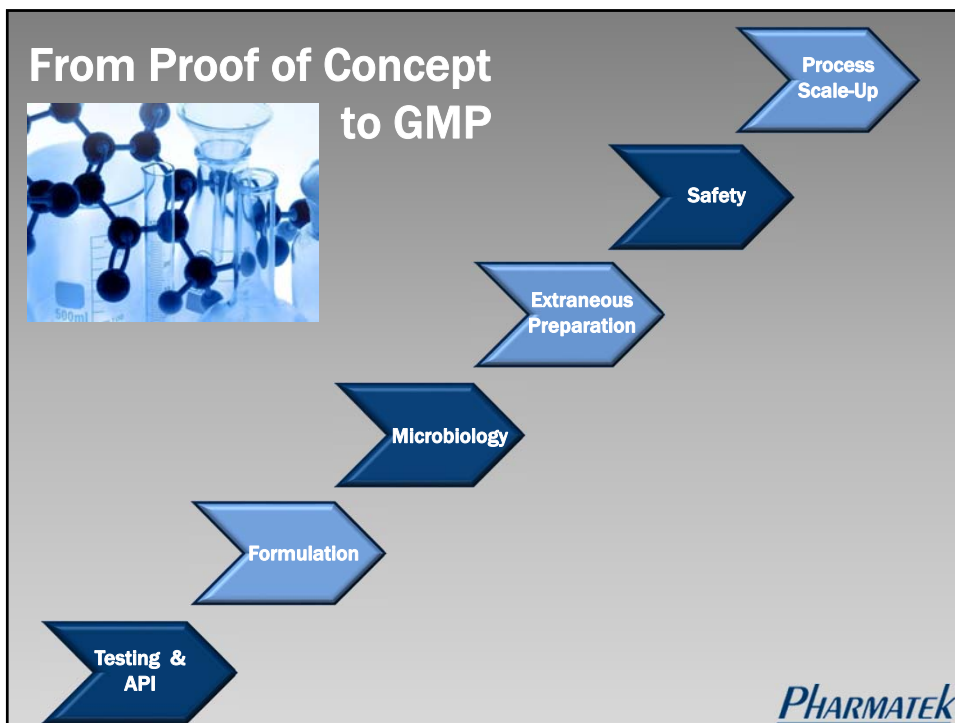


			
<p>Preclinical Development</p> <ul style="list-style-type: none"> • Animal Efficacy Formulations • Tox Formulations • Preformulation Testing • Compound Characterization & Selection 	<p>Formulation Development</p> <ul style="list-style-type: none"> • Formulation Screening & Prototype Development • First-in Man / Fit for Purpose formulations • Solutions for Poorly Soluble Compounds & Controlled Release 	<p>cGMP Manufacturing</p> <ul style="list-style-type: none"> • CTM Mfging • Scale Up • Clinical Packaging & Labeling • Distribution • Tech Transfer 	<p>Analytical Services</p> <ul style="list-style-type: none"> • Prototype Stability • API & Drug Product Method Development • Product Release • ICH Stability Testing • CTM Storage
 <p style="font-size: large; font-weight: bold; margin: 0;">Focused on Rapid, Cost-Effective Solutions</p>			



cGMP Manufacturing Services

- CTM Manufacturing/Packaging/Labeling
- FIM → Commercial
- CTM Storage & Fulfillment
- Highly-Potent/Cytotoxic Compounds
- Tech Transfer
- Engineering Batch
- Product Specifications
- Protocols & Batch Records
- CoAs



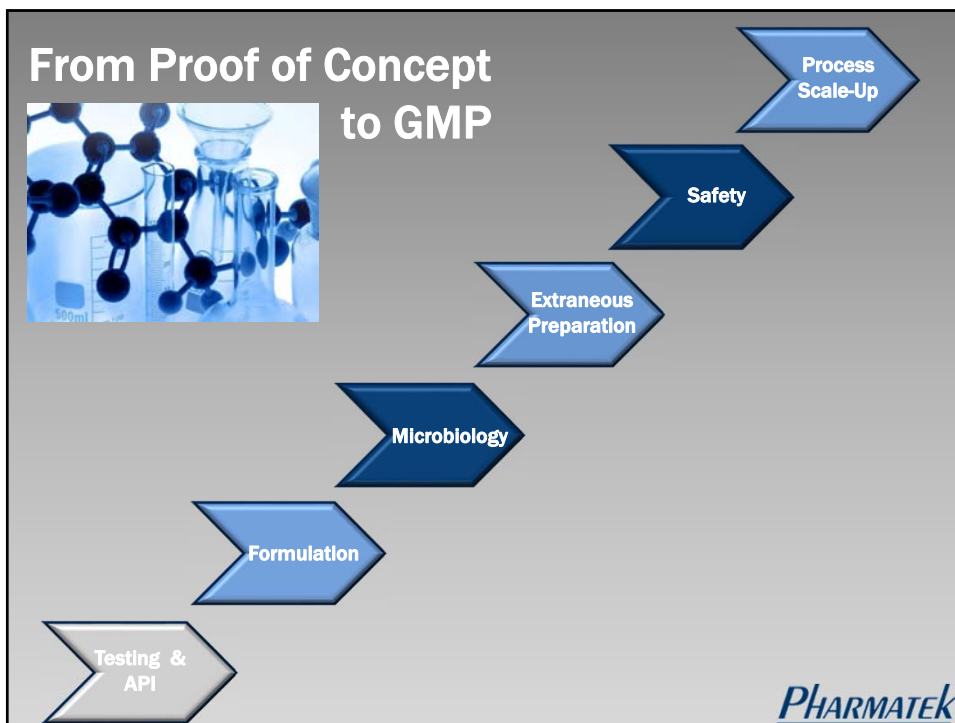



Analytical Testing & API

- Safety Classification (On-boarding)
- Stability Indicating Method
- Cleaning Method
- Polymorph
- Representative API




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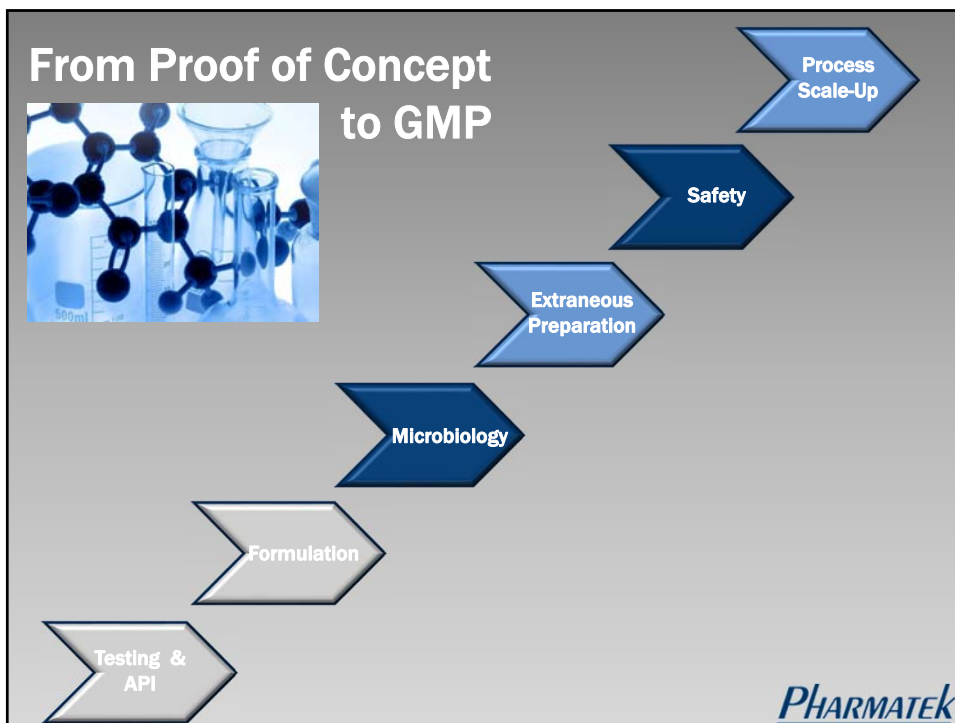


Formulation

- Stock Formulation
 - Data-Driven?
- Preservative (Assay)
- Stability Indicating Method
- Common Excipients & Sourcing
- Placebo Matching
- Patient preference (gel, cream



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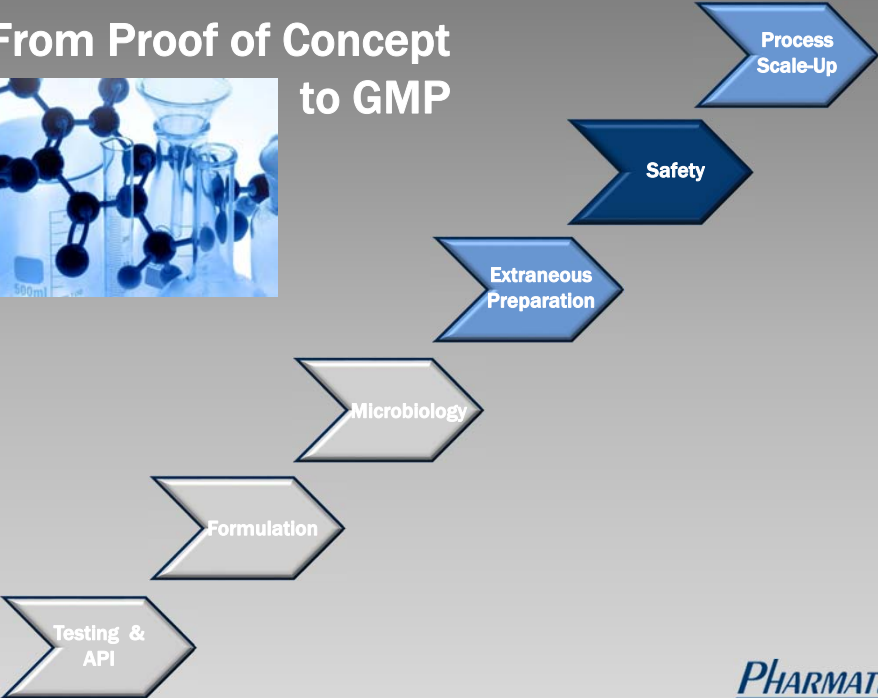



Microbiology


- Indication and Clean Room Classification
- AET and MET Testing
- Specific Assay for Preservative




From Proof of Concept to GMP



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graph TD; A[Testing & API] --> B[Formulation]; B --> C[Microbiology]; C --> D[Extraneous Preparation]; D --> E[Safety]; E --> F[Process Scale-Up];
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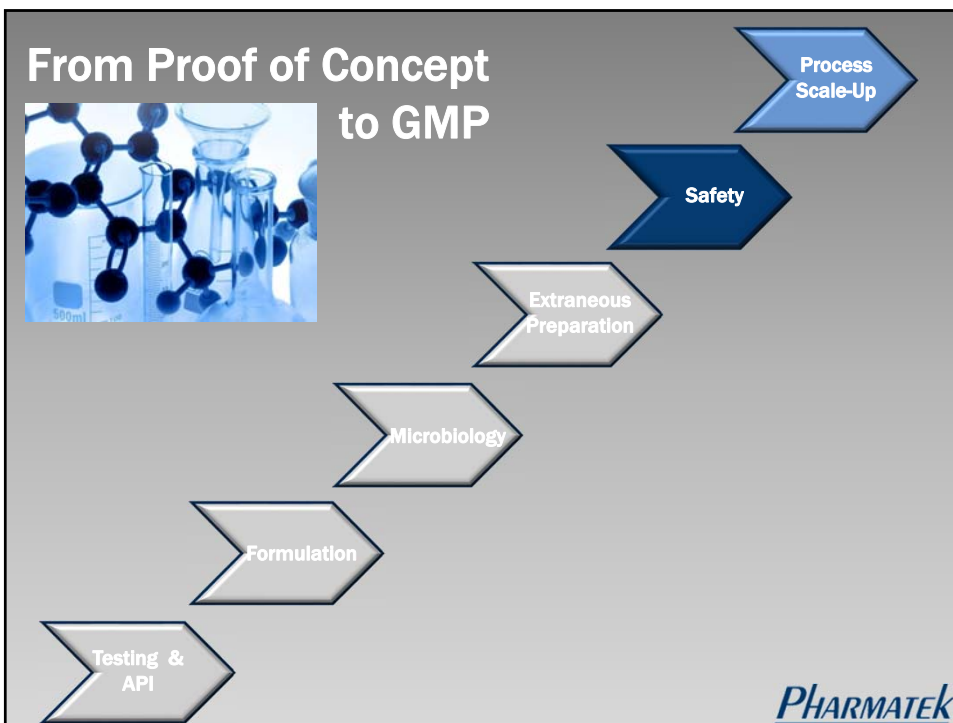
Extraneous Preparation

Compound Pharmacy

- Quick to Clinic
- Lower Cost
- Support with In-Use Stability
- Sourcing of Materials
- Align with Pharmacy Capability and Equipment



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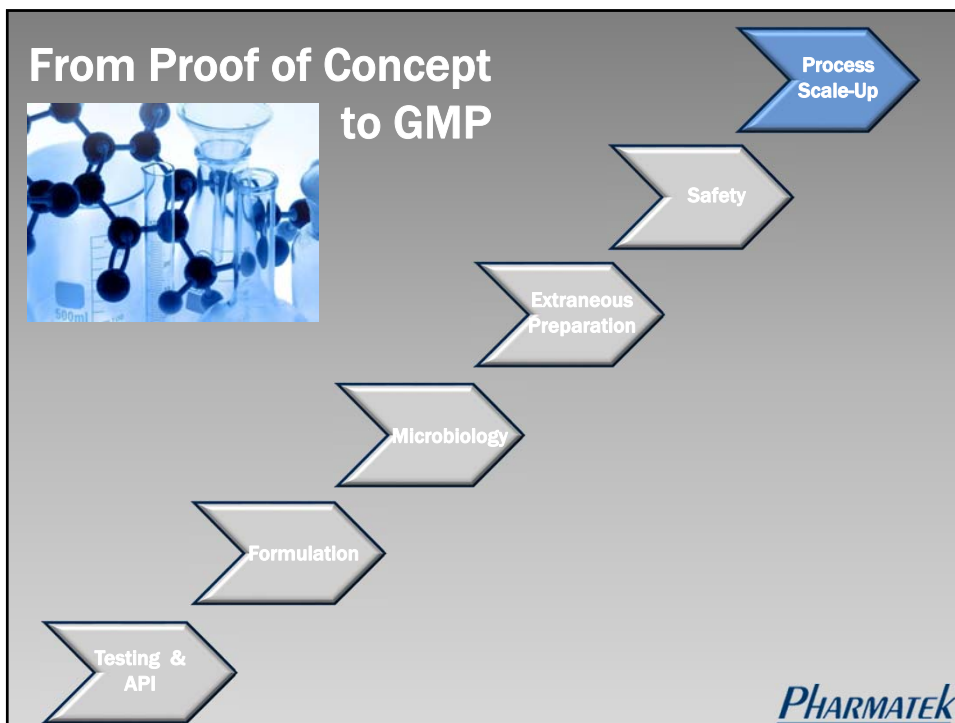
Safety

- Expertise for Handling HP/C
- Match OEL with Facility Design & Engineering Controls
- OEL ($\mu\text{g}/\text{m}^3$)
 - Employee Safety
- Match ADE to Cleaning Limits
- ADE ($\mu\text{g}/\text{day}$)
 - Patient Safety

**Once in solution avoid skin contact*









Process Scale-Up

- Mixing Vessels Based on Viscosity and Formulation Type
- Solvent Evaporation (Concentration and Release Results)
- Order of Addition
- pH (Time and Adjustment Strategy)



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Process Scale-Up

Dispense Technology

- Accuracy
- Single vs. Multi-Use Dosing
- Interface with delivery technology



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Container Closure

- May Not Be Elegant for Phase 1
- Single Use vs. Multi-Use
- Sourcing
 - Supplier Qualification and GMP Status
 - Time
- Compatibility and Stability



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Summary

- Select Data-Driven Formulation
- Robust Analytics
- Align with CMO to Match Corporate Goals
- CMC Leadership



**What works for one API may not work for another*

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THANK YOU

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