Tergus
Think Topicals, Think Tergus

How Tergus Uses Process Control Systems for Batch-to-Batch Consistency

Semi-solid dosage forms, including gels, creams, and ointments, are not typically intended to be sterile, yet they are prone to microbial and other contamination risks during the manufacturing process. To mitigate these concerns, Tergus employs a range of process control systems that adhere to stringent quality standards. By implementing these systems, Tergus ensures consistent characteristics of semi-solid pharmaceuticals across multiple batches.

Tergus upholds the use of Standard Operating Procedures (SOPs) and Master Batch Records (MBRs), which are comprehensive written instructions outlining precise steps to follow during the production process. These play a crucial role in maintaining consistency from one batch to another by providing clear instructions that must be strictly adhered to.

One exemplary SOP implemented by Tergus is **SOP-FAC-3200** Control and Monitoring of Environmental Conditions for GMP Manufacturing Areas for Non-Sterile Products. This document delineates the control measures employed to minimize exposure risks, encompassing monitoring of Tergus':

- **Facility environment**
- **Architectural design and construction**
- **Organization and staging**
- **Personnel contamination and control**
- **Cleaning and disinfection**
- **HVAC systems**
- **Monitoring and control systems**
- **Water quality monitoring**
- **Compressed gases monitoring**
- **Raw material and product monitoring**

Additional examples of other Tergus SOPs that contribute to product consistency:

SOP-EQP-5100 Manufacturing equipment cleaning and cleaning verification	**SOP-MAN-6013** Stirrup creek gowning procedure	**SOP-MAN-6003** Drafting, revision, review and approval of batch records, master batch records and executed batch records
SOP-MAN-6002 GMP manufacturing line clearance and status tagging	**SOP-FAC-3209** Cleaning the stirrup GMP areas	**SOP-ADM-1001** Personnel training
SOP-MAT-4007 Sourcing and acquisition, receipt, storage, release and dispensing of manufacturing materials, including API	**SOP-EQP-5411** Operation and maintenance of temperature and humidity monitoring devices	**SOP-FAC-3206** Operation and administration of the Stirrup Creek Environmental Management System (EMS)

NOTE: This is NOT a comprehensive list

To further evaluate the production process's ability to consistently meet quality standards, Tergus conducts process capability studies, which involve statistical analyses. These studies collect data on the process output and compare it against desired specifications, enabling the determination of whether the process can consistently produce products that meet the necessary quality standards.

Continuous process improvement is an ongoing, agile endeavor aimed at identifying and eliminating sources of variability within the production process. Tergus achieves this through the implementation of new process control measures, updates to SOPs and PCSs, as well as modifications to the process itself, thereby eliminating sources of variability.

In summary, Tergus' process control systems, including SOPs, process capability studies, and continuous process improvement initiatives, ensure unwavering consistency in the characteristics of clients' semi-solid pharmaceuticals across all batches.

Discover how Tergus can help you meet your semi-solid drug manufacturing needs. Let's partner together, because getting there starts here. **terguspharma.com**

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