

THE NECESSITY OF CLIMATE CONTROL FOR PHARMACEUTICAL LABS

DRY AIR PLAYS A VITAL ROLE IN PHARMACEUTICAL DEVELOPMENT.

From the earliest stages of research and development to large-scale production of the final product, specific climate conditions must be maintained at every step of the process.



MANUFACTURING PROCESS UNIT OPERATIONS

The drug manufacturing process comprises a series of unit operations, such as:

MILLING

Grinds drug powder into small particles

- **INCREASES** homogeneity
- **IMPROVES** dosage uniformity
- **INCREASES** bioavailability
- **BOOSTS** solubility of the drug compound

A pharmaceutical mill can grind out **840 KG OF POWDER PER HOUR**

GRANULATION

Binds small particles together to form larger granules

- **PREVENTS** “demixing” of components
- **IMPROVES** flow characteristics of powders
- **IMPROVES** compaction properties for tablet formation

70% OF TABLETS are made using wet-granulation processes

TABLET PRESSING

Compresses powder into tablets of uniform size and weight

- **GRANULES** are measured into a die
- **TWO PUNCHES** are pressed together
- **ENOUGH FORCE** is applied to fuse the material

COATING

Covers drug with an external coating

- **PROTECTS** contents from stomach acid
- **PROTECTS** stomach lining from aggressive drugs
- **DELAYS RELEASE** of medication
- **MAINTAINS** shape of tablet



A pharmaceutical press can produce from **250,000 to 1,000,000+ tablets an hour**

CONDITIONS NEEDED FOR PHARMACEUTICAL PRODUCTION

EACH STEP in the manufacturing process requires different climate conditions—and so do different types of drugs



All medications must be stored at **68-78°F**



Many break down at temperatures above **86°F**



Tablet press operations require **20-35% RH**



Some printing processes require **95-98% RH**



Enzyme-based diagnostics are especially sensitive to **10%+ RH**

RELATIVE HUMIDITY (RH) below 45% ALLOWS STATIC CHARGES TO BUILD UP, CAUSING:



Drying or Crumbling



Sticking Together



Decreased Drug Performance



Packing Problems



Coating Difficulties

CLIMATE REQUIREMENTS FOR PHARMACEUTICAL FACILITIES

68-78°F

Required warehouse temperature to maximize shelf life

45%

Relative humidity needed for most production facilities

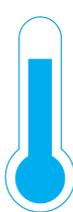
36-46°F

Temperature for high-risk products requiring precisely controlled refrigerators

CLIMATE VS. TEMPERATURE CONTROL

CLIMATE CONTROLLED

Manufacturer controls heating, air-conditioning and humidity of the unit



TEMPERATURE CONTROLLED

Manufacturer can regulate air-conditioning or heating (*not both*)

TEMPERATURE CONDITIONED

Manufacturer regulates both air-conditioning and heating from within or outside the unit

PHARMACEUTICAL CLIMATE CONTROL SOLUTIONS



Moisture and temperature control ensure that essential pharmaceutical processes meet the highest quality standards in accordance with GMP. **POLYGON PROVIDES CLIMATE CONTROL SOLUTIONS SUCH AS:**

DEHUMIDIFICATION



Desiccant dehumidification is ideal for maintaining **35-40% RH**



In small enclosures, humidity can be reduced to **less than 5%**

COOLING & HEATING



Achieve the **IDEAL TEMPERATURE** for any pharmaceutical facility



Maintain **PRECISE CONTROL** regardless of weather conditions

REMOTE MONITORING



2 or more wireless sensors measure **HUMIDITY AND TEMPERATURE**



Environmental changes are **DETECTED 24/7**

BENEFITS OF CLIMATE CONTROL

AGGLOMERATION AND STICKING OF PARTICLES

INCONSISTENT MOISTURE CONTENT

MOISTURE REGAIN

Dehumidification during tablet production **PREVENTS:**

PRODUCTION SHUTDOWN AND FREQUENT MAINTENANCE

DISFIGUREMENT AND CRUMBLING



Infographic Designed by Mad Fish Digital / Copyright © 2016 Polygon

Sources: http://www.ktron.com/industries_served/pharmaceutical/milling_and_micronization.cfm, <http://www.pharmtech.com/granulation-method-and-process-monitoring-matter?pageID=2>, https://en.wikipedia.org/wiki/Tablet_press, <http://www.thechildren.com/health-info/conditions-and-illnesses/heat-and-medication-humidity-and-soaring-temperatures-can-alter>, <http://www.condair.co.uk/knowledge-hub/humidification-in-pharmaceutical-manufacturing>, <http://www.cwenvironmental.co.za/index.php/en/products/climate-control/production-process-temperature-and-humidity-control/pharmaceutical-production-climate-control>, <http://pionline.com/articles/public/page114nonprint.pdf>, https://www.testouk.com/resources/media/global_media/campaigns/pharma_savens_logger/TS_PS_Savens_Pharma_EN.pdf, https://library.e.abb.com/public/1a32bafcb8ddeb1c125798300557c56/AD_FandC_005-EN.pdf, <http://www.polygongroup.com/services/climate/pharmaceutical-and-healthcare-industry/>