

### Humidity Control for General Pharmaceutical

Moisture is a major menace for the general pharmaceutical industry because it causes hygroscopic materials to deteriorate, organic corrosion, biochemical reactions, activates injurious activity of microorganisms, impairs product accuracy and uniformity in formulations.

### Effects of Uncontrolled Humidity

#### Processing

**Powder Milling:** Water vapour makes material resilient and difficult to grind. The material clings to the grinding machine defying pneumatic conveyance from one process to another .

**Compounding of Tablets:** Unwanted moisture impedes required reactions, forms undesirable end products which results in poor quality and shorter shelf life.

**Tablet Compression:** Powdered material can be compressed under high pressure only in dry state. Moisture causes lumping and caking, decomposes the drug, lessens the medicinal value and causes failure of the tableting process.

**Tablet Coating:** Incorrect cooling and drying of the sugar solution can result in rough, translucent and uneven coating.

**Glandular/ Liver Extracts:** These require low relative humidity conditions after drying.

#### Manufacturing

**Effervescent Tablets:** Moisture in manufacturing areas affects surface finish.

**Cough drop:** Material sticks to the stamping machine when humidity is high.

#### Storage:

Aluminum is moisture sensitive in nature and can result in packing of moisture with the tablet

#### Packaging

**Dry Powder / Vial filling:** powder to sticks to the conveyor, preventing air veying and filling operation.

**Strip Packaging:** Moisture in the packaging area can lead to moisture absorption in the tablets and capsules, hence reducing the expected shelf life and effect.

### Causes of Uncontrolled Humidity

Damp weather conditions and presence of water source near to factories( because of large water usage in various process , leads to high level of humidity in the environment.

Also most of the factories are situated in the cold environment, which have wet atmospheric conditions

### General Recommendation

Various pharmaceuticals have different conditions and these should be maintained for optimum product and longer shelf life.

**Cough drop:** Humidity to be maintained is 30% RH.

**Penicillin:** Temperature and humidity has to be rigidly controlled within  $\pm 0.25^{\circ}\text{C}$  and  $\pm 3\%$  RH during penicillin incubation.

**Injection / Ampoule:** RH should be less than 45% while sterile ampoule powders require a RH of 35% or lower.

**Soft Gelatin Capsules:** Gelatine can be dried by circulating dehumidified air into the room maintained at 20% RH at  $320^{\circ}\text{C}$ .

### Bry-Air Solution

Bry-Air Dehumidifiers can maintain RH as low as 1% or even lower at constant level, regardless of ambient conditions during production, processing, storage and packaging. Bry-Air dehumidifiers are CNC fabricated with powder coated finish incorporating high performance Metal Silicate Fluted media, which is bacteria static, non-toxic and thus, ideal to meet GMP requirements of the pharmaceutical industry.

