Physico-Chemical Characterization of Lyophilizates

- Headspace Moisture Analysis (HMA)

  HMA, also known as Frequency Modulated Spectroscopy (FMS), is a non-invasive technique for determining the headspace moisture of lyophilized samples. HMA measures the absorption of a laser at a wavelength of 1,400 nm that passes through the gaseous headspace of a vial containing a lyophilized drug product. A calibration curve with a known water vapor concentration standard is used to determine the water content in the headspace.

  HMA can be used for formulation development, lyophilization process development and quality control testing of lyophilized products. Low residual moisture is important for the long-term stability of lyophilized pharmaceuticals and is therefore an important parameter when conducting stability studies. In addition, HMA is used for container seal integrity testing.

- Freeze-drying Microscopy (FDM)

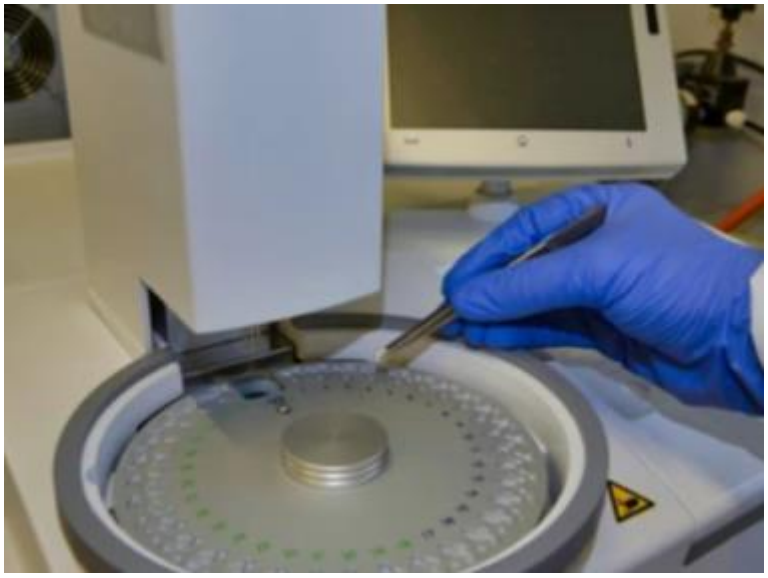
  Freeze-drying microscopy is a valuable technique for studying formulations to determine the temperature of critical products during the freeze-drying process. FDM is primarily used in freeze-drying process development and formulation development in conjunction with differential scanning calorimetry to determine optimal freeze-drying conditions.

- Differential Scanning Calorimetry (DSC)

  In the context of lyophilization process development, DSC is an important and commonly used technique to determine the glass transition temperature of the maximum cryoconcentrated solute (Tg'). This value is important to optimize the primary drying conditions. The glass transition temperature (Tg) of a freeze-formed amorphous product can also be determined by DSC and used to define the storage conditions of the final drug product.

- Karl-Fischer Titration (KFT)

  KFT is an extremely accurate technique for residual moisture determination, usually independent of the excipients in the lyophilized drug product.

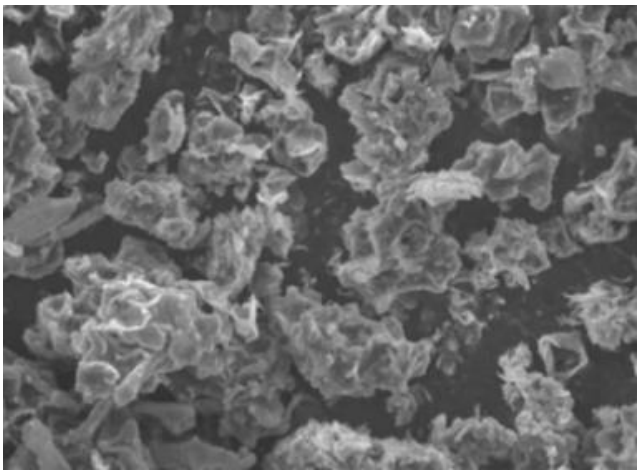


- Gas Adsorption Analysis Based on the Brunauer-Emmett-Teller (BET) Theory

  BET analysis is used in lyophilization process development and formulation development. It provides valuable insight into the structure of lyophilized samples and helps determine optimal lyophilization conditions.

- Scanning Electron Microscopy Coupled Energy-dispersive x-ray Spectroscopy (SEM-EDS)

  SEM-EDS combines the advantages of two valuable analytical techniques: Scanning Electron Microscopy (SEM), a versatile visualization technique. Energy Dispersive X-ray Spectroscopy (EDS), a powerful technique for elemental analysis.



- X-ray Powder Diffraction (XRD)

  X-ray powder diffraction (XRD) is a powerful technique for determining the amorphous or crystalline state of proteins in lyophilized drug products.

  Source: https://www.formulationbio.com/physico-chemical-characterization-of-lyophilizates.html