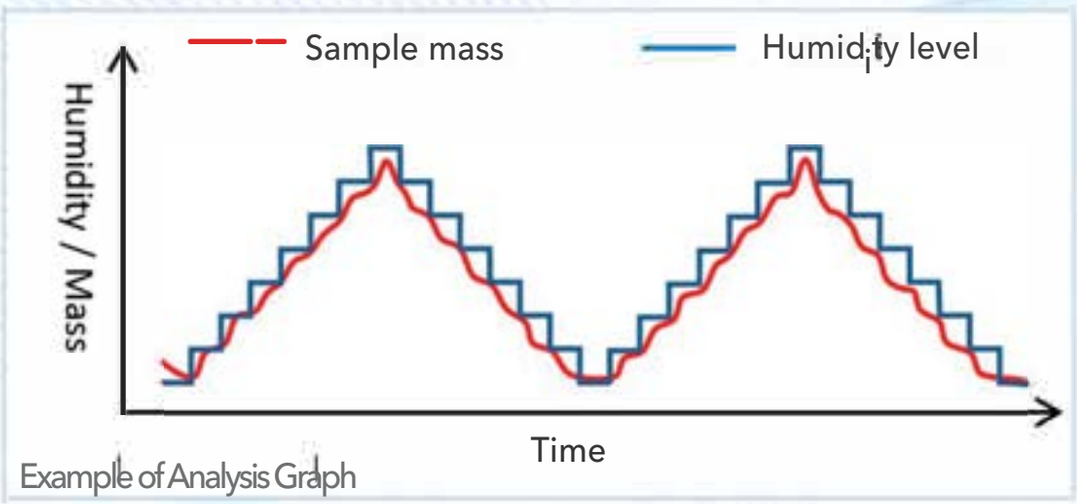
DYNAMIC VAPOUR SORPTION (DVS)

APPLICATIONS FOR FREEZE DRYING

One of the outsourcing services provided by Biopharma Group is Dynamic Vapour Sorption (DVS) which is a gravimetric technique that measures how quickly and how much solvent is absorbed by a sample. It does this by controlling and varying the vapour concentration surrounding the sample and measuring a change in mass in the sample.

The sample rests on a digital micro balance which detects the sorption/desorption of solvent vapor (typically water) through the increase or decrease in mass of the material as the relative humidity (RH) varies.



Example of Analysis Graph

Why DVS?

By understanding the changes induced by the solvent the DVS has a lot of applications across several industries related to material science, and especially in the pharmaceutical industry. Within the pharmaceutical industry it is an excellent tool for probing the physical properties and moisture induced changes which occur in drugs powder and drug products.

DVS in Freeze Drying

Usually, a freeze-dried drug formulation is only developed when drug is too unstable to be commercially viable as a ready-to-use solution. The development of freeze -dried formulation can be relatively expensive, time consuming and increases the product's expense for many pharmaceutical companies which increases the cost to the end user. Being able to understand the behaviour of a freeze dried product can aid in selecting suitable stabilisers (excipients), storage conditions, and determining the shelf life of the product in those storage conditions which can save time, energy and money during the development process.

Applications

By using DVS and other techniques in conjunction the following answers can be obtained for the development of a suitable freeze-dried formulation :

- Qualification of amorphous/crystalline content
- Water activity measurements
- Batch to batch comparison of excipients and drug product to ensure continuity
- Surface area and porosity determination of freeze dried cake structures
- Moisture sorption and desorption
- Investigate the effect of moisture induced changes within a material

Industries

Pharmaceutical

- Packaging applications e.g. blister packaging
- Material characterisation
- Pre-formulation and formulation
- Determining storage conditions

Personal Care

- Creams moisturisation studies
- Affect of thermal or chemical hair treatment

Food

- Caking of powders - visible changes with humidity
- Stability/shelf-life prediction

DVS Resolution
Dual Vapour Gravimetric Sorption Analyser

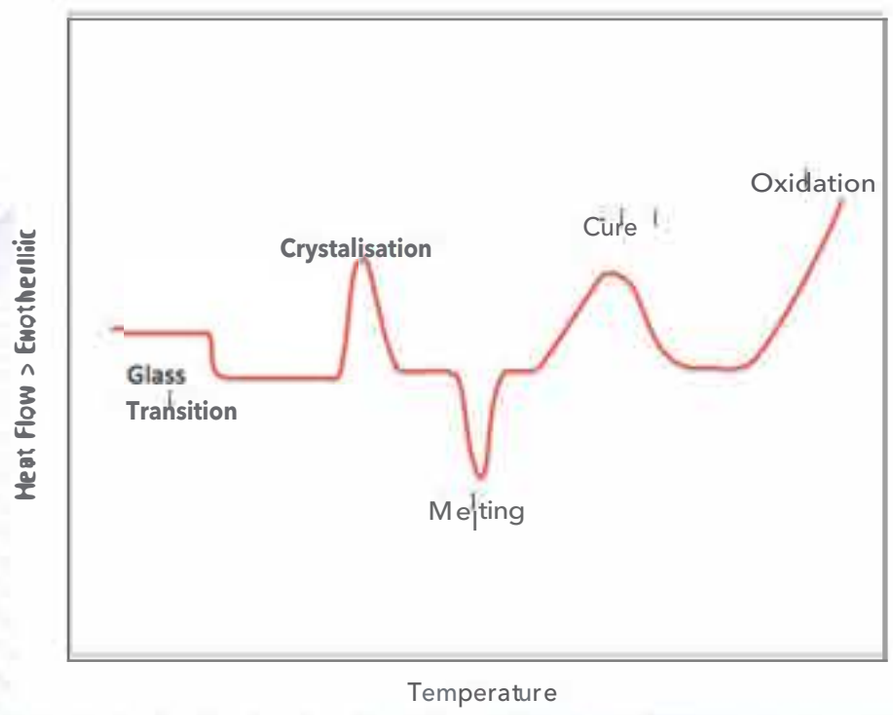
To request more details or discuss your requirements further, please contact our specialists at

www.biopharmagroupcdmo.com

DIFFERENTIAL SCANNING CALORIMETRY (DSC)

APPLICATIONS FOR FREEZE DRYING

One of the analytical services offered by Biopharma Group is called Differential Scanning Calorimetry (DSC) which detects thermal transitions of a material relative to the reference pan. DSC can be used and is historically considered a 'gold standard' for determining melting points, glass transitions, crystallisation, or other thermal events of a material. This technique has many applications in the developing and assessing freeze dried formulations and the freeze drying process.



During DSC analysis, the sample temperature is raised at a constant rate by heat input. The heat flow required to maintain this constant rate is then logged against temperature to generate the DSC trace, which shows the exothermic and endothermic events, such as crystallisation or melts of a material.

Modulated Differential Scanning Calorimetry (mDSC) is very similar to normal DSC measuring the difference in heat flow between a sample and reference pan as a function of temperature. However, instead of using a linear heating rate, a sinusoidal modulation (oscillation) is used. This allows phase transitions to be detected with greater sensitivity and resolution. Does allowing for the identification of different phase transitions.

Application

Applications of DSC and mDSC include:

- Characterisation the thermal behavior of solutions prior to freeze drying to determine critical process parameters
- Determine the melting behavior of complex organic materials, both temperatures and enthalpies of melting and can be used to determine purity of a material
- Determine the thermal stability of a material and predict ideal storage conditions
- Quantification of'amorphous and crystalline content of a material

Why is Glass Transition Important?

Many freeze dried formulations stabilise small molecules and large molecules such as vaccines, and therapeutic proteins by entrapping them in amorphous excipients. The amorphous phase of the excipients maintains the structure of the proteins and slow molecular motion slowing degradation.

Amorphous materials can undergo glass transitions upon heating which is defined as the temperature at which a amorphous material transitions from a brittle to rubbery state upon heating.

It is important to know the glass transition temperature as freeze dried formulations stored above the glass transitions can be observed to lose activity.

DifferentialScanning Calorimeter Instrument

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