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# Drug-Excipient Compatibility by DSC and FTIR

Practical 11 - Practical study

## Aim

To examine drug-excipient mixtures using DSC and FTIR with suitable controls.

## Principle

Thermal events and vibrational spectra provide complementary evidence. Peak shifts, disappearance or thermal changes can arise from dilution, melting, dissolution, moisture or physical mixing; they do not alone establish a chemical incompatibility.

## Materials and Requirements

- Drug, excipients and defined-ratio mixtures
- Qualified DSC and FTIR with preparation records
- Unstressed and stressed controls and supporting assay where required
- Approved method or teaching-data pack and a dated record sheet

## Procedure

1. Define the preparation or dataset, study question and method version. Record identities, units and the criteria to be used before examining the outcome.
2. Select justified mixture ratios, storage stress and matched individual-material controls.
3. Record DSC pan type, mass, atmosphere and scan programme and acquire comparable thermograms.
4. Record the FTIR accessory, background and preparation conditions and acquire matching spectra.
5. Compare features against controls, then use a stability-indicating assay or other orthogonal evidence to investigate meaningful changes.
6. Retain the original observations and calculations. State deviations, missing information and the limits of the conclusion; do not replace measured values with expected results.

## Observations and Record

Enter actual measurements or the supplied teaching data. Record the method, material identity, conditions and units.

| Preparation | Thermal event | Diagnostic IR feature | Supporting chemical evidence |
|---|---|---|---|
| Drug alone | Record | Record | Record |
| Excipient alone | Record | Record | Record |
| Mixture / stressed mixture | Record | Record | Record |

## Calculations

- Mixture drug fraction = drug mass / total mixture mass
- Compare thermal enthalpy on a consistent mass and composition basis.

### Worked Example

Illustrative mixture contains 10 mg drug and 10 mg excipient: drug fraction = 0.50.
A halved drug melting enthalpy per gram of mixture may reflect dilution; it is not by itself proof of reaction.

## Result and Interpretation

• Write a compatibility assessment distinguishing observation, hypothesis and confirmed chemical change.

## Precautions

• Use appropriate instrument and thermal handling controls.
• Do not label every peak shift an incompatibility.
• Retain spectra and thermograms with acquisition settings.

## Viva Questions and Answers

### Why include pure components?

They provide the baseline features for interpreting the mixture.

### Why can a DSC peak disappear?

Dissolution in molten excipient, dilution or a physical change can contribute.

### What confirms a chemical concern?

Suitable orthogonal chemical evidence, including degradation analysis.

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