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Preformulation Studies for Tablets

Practical 19 - Bench practical

Aim

To characterise a drug and its compatibility with the intended dosage form before formulation development.

Principle

Preformulation connects material properties to manufacturing and performance risks. Relevant attributes include identity, solid state, solubility, ionisation, particle characteristics, stability and compatibility.

The investigation is driven by the intended route and dosage form. Oral solid development may emphasise flow and compactability, whereas a parenteral concept also requires consideration of aqueous behaviour, route-compatible excipients and sterile-product development.

Materials and Requirements

- Identified drug and candidate excipients
- Suitable solubility, thermal, spectroscopic and particle-characterisation methods
- Calibrated balances and controlled-condition containers
- Material and experimental-design records

Procedure

1. Define the intended dosage form, target product attributes and the questions the study must answer.
2. Review identity and available material information, then select tests that address actual development risks.
3. Determine equilibrium solubility under defined conditions and examine pH dependence when scientifically appropriate.
4. Assess particle size, morphology, flow or compaction behaviour for solid-dose development. Record the measurement method and limitations.
5. Compare the drug, individual excipients and selected mixtures by suitable methods such as FTIR and DSC, supported by relevant storage studies.
6. Prepare a risk matrix linking each result to a formulation or process decision. Identify experiments needed to resolve uncertainty.
7. Write the preformulation report with raw data, material grades, conditions and the rationale for the selected development approach.

Observations and Record

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

Attribute	Method and conditions	Result	Development implication
Identity / solid state	Record	Record	Assess
Solubility / pH	Record	Record	Assess
Particle / flow attributes	Record	Record	Assess
Compatibility / stability	Record	Record	Assess

Calculations

- Solubility = dissolved analyte mass / equilibrated liquid volume
- Recovery (%) = recovered measured amount / expected amount x 100

Worked Example

Illustrative equilibrium determination: 12.0 mg analyte is measured in 10.0 mL equilibrated supernatant after correcting the assay dilution.

Solubility = 1.20 mg/mL under the recorded pH and temperature.

A second condition giving 3.60 mg/mL shows a three-fold analytical difference. Stability and material-state changes must be checked before assigning the change solely to improved solubilisation.

Result and Interpretation

- Summarise the development risks and the evidence for the chosen formulation strategy.
- Spectral or thermal changes are investigated in context; a single shifted peak is not sufficient proof of incompatibility.
- Identify the conditions for which the results apply.

Precautions

- Avoid confusing kinetic dissolution with equilibrium solubility.
- Control temperature, equilibration and separation conditions.
- Assess analyte loss to filters or containers.
- Evaluate material and excipient grades relevant to the intended product.

Viva Questions and Answers

Why study preformulation?

It identifies material-related risks before committing to a formulation or process.

Does an FTIR change always prove a chemical reaction?

No; physical interactions and measurement conditions can also alter spectra.

Why specify dosage form?

Different routes and manufacturing processes require different material attributes.

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