

Preformulation Studies of an Assigned Drug

Practical 01 | Industrial Pharmacy I

Aim

To study Preformulation Studies of an Assigned Drug, and interpret the recorded observations.

Principle

- Preformulation links the properties of the drug substance to dosage-form choices. Paracetamol, aspirin or another assigned drug can be compared for solubility, particle properties, moisture behaviour and compatibility.
- The property is obtained from a defined observable under controlled conditions.
- Replicate measurements, instrument checks and consistent units are needed before comparison.
- Aspirin can hydrolyse in the presence of moisture; any increase in apparent dissolution must not be mistaken for unchanged-drug stability.
- Poor powder flow can affect filling, while slow dissolution may require a separate formulation strategy.

Materials and Apparatus

- Assigned drug, balance, pH meter, microscopy or particle-size apparatus, solubility assay and prepared compatibility records.
- Assigned test material and calibration or comparison material.
- The apparatus specified for this property, a balance or volumetric equipment where relevant, and a record sheet.

Method

1. Identify the drug form and the dosage form being considered.
2. Measure the assigned physical properties under stated conditions.
3. Study solubility in the specified media and record pH and temperature.
4. Review the assigned thermal, spectral or other compatibility comparisons with excipients.
5. Tabulate property results and link each to a processing, stability or release concern.
6. Propose a dosage-form approach supported by the observations.

Observation Record

Complete this record using actual laboratory findings or the provided teaching data.

Observation / parameter	Record / finding
Drug identity	_____
Solubility and pH	_____
Particle characteristics	_____
Moisture result	_____
Compatibility observations	_____

Calculations and Interpretation

- Report each measured property with its method and units.
- For an assay-based solubility result, correct the measured concentration for all dilution steps.

Result

Record the actual finding, calculated value with units where relevant, and a conclusion supported by the observations.

Finding: _____

Conclusion: _____

Precautions

- Keep temperature and test conditions consistent across comparative readings.
- Record raw readings before rounding calculated values.
- Do not compare results obtained with different methods as if they were interchangeable.

Viva Questions

1. What is the purpose of preformulation?

To understand drug properties before selecting the formulation and manufacturing approach.

2. Why control the test conditions?

A change in conditions may alter the measured property independently of the intended variable.

3. Why retain replicate readings?

They show repeatability and help identify an anomalous measurement.

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