Monograph Analysis of Pharmaceutical Drugs

Experiment 3 - Practical Notes

Name: _____ Roll no.: _____ Date: _____

Aim

To read and apply the identity, purity and assay requirements of an assigned medicinal substance.

Principle

A monograph defines a named material and its quality requirements; tests address distinct attributes and must be read with the relevant general instructions.

Requirements

- Institution-assigned current or syllabus-prescribed drug monographs and coded teaching analysis records.

Procedure

1. Establish scope

Enter title, edition, chemical form, formula mass and content basis.

2. Map tests

Classify description, identification, impurity/related-substance tests, water or loss on drying and assay.

3. Review methods

Record sample preparation, standards, measurement and acceptance rule for each assigned test.

4. Evaluate data

Apply the stated rules to supplied results and explain any failed or invalid test.

5. Conclude

A complete conformity conclusion needs all required results; a passing assay alone is not enough.

Observations and Record

Monograph element	Requirement / finding
Title / edition / form	_____
Identity	_____
Purity / related substances	_____
Water or drying basis	_____
Assay and overall conclusion	_____

Result

Record the completed observations, calculations and conclusion with units. State any limitation of the observation.

Precautions

- Use the correct edition and all cross-referenced general instructions.
- Do not create numerical acceptance limits absent from the assigned monograph.

Viva Questions and Answers

1. Does a high assay prove purity?

No. Different impurity and identity requirements also apply.

2. Why read general notices?

They define how the individual monograph requirements are interpreted.

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