

Preparation and Evaluation of Eye Drops and Eye Ointments

Practical 08 | Industrial Pharmacy I

Aim

To study Preparation and Evaluation of Eye Drops and Eye Ointments, and interpret the recorded observations.

Principle

- Ophthalmic solutions and ointments have different vehicles and release behaviour. Both require appropriate sterile processing, container integrity and ocular-product quality controls.
- A dosage form combines an active ingredient with excipients selected for processing, stability and performance.
- Preparation and evaluation are linked: changes in composition or process can alter the product quality attributes.
- Compare the roles of aqueous vehicles in drops and semisolid bases in ointments.
- Observe the approved preparation demonstrations and record the process controls.
- Review clarity and pH for drops, and uniformity and particle/grittiness observations for ointments.
- Examine assay, container integrity and the applicable completed sterile-quality records.

Materials and Apparatus

- Prepared ophthalmic teaching products, approved formulae and completed sterility, particle and product-quality records.
- Assigned active ingredient, excipients and the instructor-approved master formula.
- Balance, mixing/preparation equipment, packaging materials and the assigned evaluation apparatus.

Method

1. Read the master formula and identify the purpose of each ingredient.
2. Calculate the quantities for the assigned laboratory batch and check ingredient identity.
3. Follow the specified order of addition and preparation process, recording actual quantities and process observations.
4. Measure the yield or finished quantity and package the laboratory preparation as specified.
5. Evaluate the product attributes listed for this dosage form with documented methods.
6. Compare the observations with the assigned specification and explain any difference.

Observation Record

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

Observation / parameter	Record / finding
Dosage form	_____
Vehicle and ingredient roles	_____
pH or consistency	_____
Particles/grittiness	_____
Drug content	_____
Closure/sterile-process records	_____

Calculations and Interpretation

- Batch scale factor = desired quantity/master-formula quantity.
- Scale each ingredient by the same factor unless the approved formula specifies otherwise.
- Assay (%) = measured active amount/declared active amount × 100, on the same unit and product basis.

Result

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

Finding: _____

Conclusion: _____

Precautions

- Record changes in process or composition; do not conceal a deviation.
- Use the specification assigned to the exact product and dosage form.
- A teaching batch is for laboratory evaluation and is not released for patient use.

Viva Questions

1. Why identify excipient functions?

Each excipient can influence processing, stability, release or acceptability.

2. Why is appearance alone insufficient for evaluation?

It does not establish content, performance, stability or microbiological quality.

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