Preparation of Tetracycline Hard Gelatine Capsules

Experiment 19 - Practical Notes

Name: _____ Roll no.: _____ Date: _____

Aim

To prepare, evaluate, package and label a hard-gelatine capsule training batch.

Principle

A uniform powder blend is divided into capsule shells. Fill mass alone does not establish drug-content uniformity.

Working Formula

Use the assigned current monograph for ingredient grades, amounts and specifications. Enter the working quantities before starting.

Ingredient	Purpose	Working quantity
Assigned tetracycline material / dummy blend	Training fill	_____
Assigned diluent / glidant	Blend and filling properties	_____
Hard gelatine shells	Container	_____

Scaling factor = required batch size / master batch size. Working ingredient amount = master amount × scaling factor.

Requirements

- Assigned master formula and ingredients
- Balance, measuring glassware and suitable mixing equipment
- Appropriate clean container and label

Procedure

1. Calculate

Record target strength, number of capsules and the specified potency adjustment.

2. Prepare the blend

Sieve as assigned and use geometric dilution for a uniform blend.

3. Fill

Select the prescribed shell size and divide the blend using the approved filling technique.

4. Close and inspect

Check shell closure, damaged capsules and powder loss.

5. Evaluate

Record fill masses and identify the separate content, disintegration and other monograph checks.

Evaluation and Label

- Check fill-mass variation, appearance, closure and the distinction between mass and drug-content uniformity.
- Label the name, strength where relevant, route, batch/date, storage and institution-assigned use period. Mark laboratory preparations as training material.

Observations and Record

Check	Observation
Appearance / consistency	_____
Final mass or volume	_____
pH or other assigned test	_____
Packaging / label check	_____

Worked Example

The numbers below are illustrative; enter your own observations in the record.

- Example only: 20 capsules containing 250 mg labelled drug each need 5,000 mg = 5 g drug before any specified potency correction or process allowance.

Result

The training preparation was obtained as _____. Final yield: _____. Assigned quality checks: _____. It was packaged and labelled for the intended route.

Precautions

- Control powder exposure and use the assigned training material.
- Do not infer clinical strength from total capsule mass.
- Keep shells protected from excess heat and moisture.

Viva Questions and Answers

1. Why scale every ingredient?

The proportions must remain constant when batch size changes.

2. Why record the method?

Mixing order, temperature and technique affect the product.

3. Which quality checks are needed?

Check fill-mass variation, appearance, closure and the distinction between mass and drug-content uniformity.

4. Why is a label required?

It identifies the product, route, directions, storage and the training batch.

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