First Hope

COMPLETE NOTES

Click here to visit our website

PHARMACY PRACTICAL NOTES

# Complete subject and semesters are available on FirstHope app only.

Scan or click here

Click here to get the app >

Available on Google Play

JOIN THE FIRSTHOPE COMMUNITY

## Join our Telegram channel

Click here to join Telegram >

Scan or click here

@FirstHopeNotes

### Instagram

@firsthope.official

Click here to follow >

### YouTube channel

FirstHope-Pharmacy / Live streams

Click here to watch >

### WhatsApp channel

Follow FirstHope on WhatsApp

Click here to join >

### FirstHope website

firsthope.co.in

Click here to visit >

**B.Pharm / D.Pharm / M.Pharm / Pharm.D**

Complete subjects and semesters are available in the FirstHope app.

# Comparison of Dissolution Profiles Between Brands

Practical 7 - Bench practical

## Aim

To compare two product release profiles using matched conditions and an appropriate comparison method.

## Principle

A dissolution test measures transfer of drug into a defined medium under controlled hydrodynamic conditions. A profile provides information across time and may reveal lag, burst release or incomplete release.

Temperature, apparatus, medium, speed, sampling and analytical method are selected for the product and study purpose. An in-vitro profile alone does not establish a clinical duration of action.

## Materials and Requirements

- Qualified dissolution apparatus and the specified vessels
- Product-specific medium and calibrated temperature measurement
- Validated sampling and assay arrangement
- Reference standard and dosage units

## Procedure

1. Record product, batch, dose, apparatus, medium composition and volume, agitation, temperature and sampling schedule.
2. Verify apparatus readiness and the method-required medium preparation and deaeration conditions.
3. Introduce units using the prescribed technique and collect individual-vessel samples at the planned times.
4. Use the validated sampling location and filtration procedure. Replace withdrawn volume where specified and document the exact scheme.
5. Measure concentrations within the established assay range using appropriate standards and blanks.
6. Correct for removed drug and dilution. Plot individual and mean cumulative release, retain variability and compare with the applicable criteria.

## Observations and Record

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

| Time | Measured concentration | Corrected released mass | Release percentage |
|---|---|---|---|
| Initial | Record baseline | Calculate | Calculate |
| Time point 1 | Record | Calculate | Calculate |
| Time point 2 | Record | Calculate | Calculate |
| Final planned point | Record | Calculate | Calculate |

## Calculations

- For equal-volume replacement: Mn = V x Cn + v x sum(Ci for earlier samples)
- Release (%) = Mn / initial drug amount x 100

### Worked Example

Illustrative V = 900 mL and replacement sample volume v = 10 mL. Concentrations at three times are 0.010, 0.020 and 0.030 mg/mL.

Corrected mass at the third point = 900 x 0.030 + 10 x (0.010 + 0.020) = 27.3 mg.

For a 50.0 mg initial amount, release is 54.6%. This calculation assumes the stated replacement scheme and a stable dissolved analyte.

### Profile comparison

- Use the same sampling schedule and method, and retain individual-vessel data for both products.
- For a valid conventional f2 comparison, apply the relevant guidance on unit numbers, variability and late time points. Product-specific conditions take priority.
- f2 = 50 log10(100 / sqrt(1 + mean((R - T)^2))). A value within the conventional similarity range is interpreted only when the prerequisites for that comparison are met.

## Result and Interpretation

- Report the entire profile, individual-unit variability and the actual conditions.
- Compare controlled-release products using an appropriate product-specific design and acceptance approach.
- Distinguish incomplete release from analytical loss or an unsuitable test condition.

## Precautions

- Maintain method-specified temperature and hydrodynamics.
- Control sampling time, filter recovery and volume replacement.
- Avoid treating pooled samples as evidence of individual-unit uniformity.
- Investigate apparatus or assay failures before interpreting the profile.

## Viva Questions and Answers

### Why correct for sampling?

Withdrawn fluid removes drug that contributes to cumulative release.

### Why examine individual units?

A similar mean can conceal large unit-to-unit variation.

### Does faster dissolution always mean a better controlled-release product?

No; performance must match the intended release target.

First Hope

COMPLETE NOTES

Click here to visit our website

PHARMACY PRACTICAL NOTES

# Complete subject and semesters are available on FirstHope app only.

Scan or click here

Click here to get the app >

Available on Google Play

JOIN THE FIRSTHOPE COMMUNITY

## Join our Telegram channel

Click here to join Telegram >

Scan or click here

@FirstHopeNotes

### Instagram

@firsthope.official

Click here to follow >

### YouTube channel

FirstHope-Pharmacy / Live streams

Click here to watch >

### WhatsApp channel

Follow FirstHope on WhatsApp

Click here to join >

### FirstHope website

firsthope.co.in

Click here to visit >

**B.Pharm / D.Pharm / M.Pharm / Pharm.D**

Complete subjects and semesters are available in the FirstHope app.