Sample SOP Template for Dissolution Testing

\*\*Title:\*\* Standard Operating Procedure (SOP) for Dissolution Testing

\*\*Document Number:\*\* SOP-XX

\*\*Effective Date:\*\* \_\_ / \_\_ / \_\_\_\_

\*\*Revision Number:\*\* \_\_\_

\*\*Prepared by:\*\* \_\_\_\_\_\_\_\_\_\_\_\_

\*\*Reviewed by:\*\* \_\_\_\_\_\_\_\_\_\_\_\_

\*\*Approved by:\*\* \_\_\_\_\_\_\_\_\_\_\_\_

# 1. Purpose

To describe the procedure for performing dissolution testing on solid oral dosage forms.

# 2. Scope

Applicable to immediate-release and modified-release tablets and capsules.

# 3. Responsibility

Analysts and supervisors in the QC and R&D laboratories.

# 4. Procedure

- Verify equipment calibration and cleanliness.

- Select appropriate apparatus and speed.

- Prepare and degas dissolution media; measure pH.

- Warm media to 37 ±0.5 °C.

- Place dosage units carefully.

- Start timer and apparatus.

- Sample at defined time points; replace media.

- Filter samples immediately.

- Analyze samples by UV/HPLC.

- Calculate % dissolved; compare with acceptance criteria.

- Record all data and observations.

# 5. Deviation Handling

Document deviations; assess impact; notify supervisor; record corrective action.

# 6. Revision History

|  |  |  |  |
| --- | --- | --- | --- |
| Rev | Date | Changes | Prepared by |

# Pre-Run Checklist

|  |  |  |
| --- | --- | --- |
| Item | Checked (✓) | Comments |
| Media prepared and degassed |  |  |
| Media pH checked and recorded |  |  |
| Temperature set to 37 ±0.5 °C |  |  |
| Apparatus selected & verified |  |  |
| RPM verified with tachometer |  |  |
| Vessel centering & shaft height checked |  |  |
| Reference standard weighed & potency recorded |  |  |
| Sampling schedule prepared |  |  |
| Sinkers/filters ready |  |  |
| Labeling of vessels/samples completed |  |  |
| All observations to be documented |  |  |

\*Analyst signature:\* \_\_\_\_\_\_\_\_\_\_\_\_

\*Date:\* \_\_ / \_\_ / \_\_\_\_

# Observation & Deviation Log

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Time | Vessel | Observation (e.g., floating, sticking, foaming) | Action Taken | Analyst Initials | Reviewer Initials |

\*Complete in real-time; retain as part of batch record.\*