# Dissolution Method Development - Pre-work Datasheet

This datasheet is used to summarize the critical physicochemical and formulation information required before selecting dissolution apparatus and conditions. It aligns with USP <1092>, ICH Q6A, and FDA dissolution method development recommendations.

## 1. API Identification

API Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Chemical Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

CAS Number: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Polymorph / Salt Form: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Lot/Batch No.: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

## 2. Solubility vs pH Profile

|  |  |  |
| --- | --- | --- |
| pH | Solubility (mg/mL) | Notes |
| 1.2 |  |  |
| 4.5 |  |  |
| 6.8 |  |  |
| Other |  |  |

## 3. pKa and Ionization

pKa1: \_\_\_\_\_\_\_\_\_\_\_ pKa2: \_\_\_\_\_\_\_\_\_\_\_

Ionization Characteristics: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

## 4. Dose/Solubility Ratio

Dose Strength (mg): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Lowest Solubility (mg/mL): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Dose/Solubility Ratio: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Sink Condition Achieved? □ Yes □ No

## 5. Formulation Details

Dosage Form: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Strengths: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Particle Size (if API): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Other Notes: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

## 6. References / Sources

1. USP <1092> The Dissolution Procedure: Development and Validation

2. ICH Q6A Specifications: Test Procedures and Acceptance Criteria

3. FDA Dissolution Methods Database