Standard Operating Procedure

SOP Title: Root Cause Analysis Worksheet
Document Code: FORM-VA-005
Supersedes: [Previous Version if applicable]
Approved By: [Name / Title]
Review Date: [Annually or as needed]

Version: 1.0   Effective Date: 06May25

I. HEADER INFORMATION

Deviation / CAPA ID: _____
Date Opened: _____
RCA Facilitator: _____
Investigation Team Members:
  1. _____
  2. _____
  3. _____
Department(s) Involved: _____

II. PROBLEM STATEMENT

Describe WHAT happened, WHEN, WHERE, and IMPACT.

_____
_____
_____

III. "5 WHYS" ANALYSIS

WHY #	Causal Answer (why did the event occur?)
1	
2	
3	
4	
5	

Identified Root Cause: _____

IV. FISHBONE (CAUSE-AND-EFFECT) BRAINSTORM

List contributing factors under each category.
a) **People / Manpower**
- _____
- _____

b) **Methods / Procedures**
- _____
- _____

c) **Materials**
- _____
- _____

d) **Machines / Equipment**
- _____
- _____

e) **Environment / Facilities**
- _____
- _____

f) **Measurements / Data**
- _____
- _____

V. ROOT-CAUSE VERIFICATION

Evidence confirming root cause (data, tests, repeatability):

_____

_____

VI. RECOMMENDED CORRECTIVE & PREVENTIVE ACTIONS

Action #	Description	Owner	Target Date

VII. APPROVAL & FOLLOW-UP

Investigation Lead Signature: _____ Date: _____
QA Review Signature: _____ Date: _____
CAPA Board Approval: ☐ Yes ☐ No
Date Closed: _____
Verified Effective? ☐ Yes ☐ No

Version	Date	Change Description	Approved By
		Aligned with updated Quality Manual QM-VA-001 and Master Batch Record SOP.	[Name / Title]