

Laboratory Investigation and Report Form
(Ref. SOP LAB-055.)

Part A

Product Description: Code No.

Process Order No. (BPN): Expiry Date

Test Description:

Limits: Release Specification:.....

Expiry Specification: (For stability)

Results of First Test:.....

Results of other tests (same strength) in that test run

BPN	results	BPN	results

Part B

Evaluation for Determinant Error (Lab Error)

Results of Investigation

Causalities				Comments
Expiry Dates Comply for Reference Standards	Yes		No	
Expiry Dates Comply for Solvents	Yes		No	
Expiry Dates Comply for Reagents	Yes		No	
Fresh Standard Made	Yes		No	
Using Correct Method	Yes		No	
New Mobile Phase (for HPLC)	Yes		No	
Solution Re-standardised	Yes		No	
Instrument Re-calibration Done	Yes		No	
Instrumentation maintained	Yes		No	
Correct Calculations for Product	Yes		No	
Correct Formula for Calculation	Yes		No	
Plate Count Done (For micro)	Yes		No	
Correct Sampling Procedure	Yes		No	
Other Sources of Error	Yes		No	

Determined Error Investigation	Pass		Fail	
Retesting to be Performed	Yes		No	

Sign/Date.....Laboratory Analyst

Sign/Date.....Laboratory Manager

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Part C

Results from Retest of original samples

Results for resample

Resample No.	Sampling Location	Result 1	Result 2
1			
2			
3			
4			
5			
6			
7			
8			
9			

Stability samples of the same finished goods code

BPN	Results

Repeat test on a recently passed sample, BPN:

.....

Current Result	Original result

Sign/Date.....

....

Laboratory Analyst

Deviation Report (DR) Required

Yes No

Deviation Report No.(if "Yes" above)

Comments:

Sign/date..... Technical Service Manager

Sign/date.....Laboratory Manager

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Part D Investigation of the Production Process (Examples)

Process		Checked			
1)	pH Adjustment Amount used <input type="text"/> Recommended amount <input type="text"/>				N/A
2)	Mixing Times at Manufacture	Yes	<input type="checkbox"/>	No	N/A
3)	Weighing	Yes	<input type="checkbox"/>	No	N/A
5)	Blending time	Yes	<input type="checkbox"/>	No	N/A
6)	Filling Times	Yes	<input type="checkbox"/>	No	N/A
8)	The Quality of the Raw Materials	Yes	<input type="checkbox"/>	No	N/A
8)	Cleaning of Vessel	Yes	<input type="checkbox"/>	No	N/A
10)	What Product/batch number was in the Manufacturing Vessel Prior to the product being investigated? Vessel No.				
11)	What Product/batch number was in the Filling/Holding Vessel Prior to product being investigated? Vessel No.				
12)	What Product/batch number was run on the Filling Machine Prior to the product being investigated Line number <input type="text"/>				
13)	If there are foreign peaks in the HPLC chromatogram, spike the sample with the product(s) from points 10, 11, & 12. Test by running on current Mobile Phase and the Mobile Phase specific to the contaminant in question.				
14)	Further Use of Investigative Problem Solving Skills				
15)	Trend Card Evaluation (attach stability profile) (attach release profile)				

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continued

16) **Calculation to check correct active weighed**
$$\frac{\text{Weight of active (g)}}{\text{Batch Size (L)}} \times \text{Factor to base (if required)} = \text{Theoretical Assay}$$

Calculation % deviation from Theoretical Label Claim
$$100 - \left[\frac{\text{Actual Result}}{\text{Theoretical Result}} \times 100\% \right] = \% \text{ from Theoretical Label Claim}$$

Conclusions, Assumptions, Comments

Sign/DateLaboratory Analyst
.....Laboratory Manager
.....Technical Service Manager