



**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	Yes	No	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		No	
3)	Weighing	Yes		No	
5)	Blending time	Yes		No	
6)	Filling Times	Yes		No	
8)	The Quality of the Raw Materials	Yes		No	
8)	Cleaning of Vessel	Yes		No	
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/Date .....Laboratory Analyst  
.....Laboratory Manager  
.....Technical Service Manager