

# 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 <span style="border: 1px solid black; display: inline-block; width: 80px; height: 1.2em; vertical-align: middle;"></span> Recommended amount <span style="border: 1px solid black; display: inline-block; width: 80px; height: 1.2em; vertical-align: middle;"></span>				N/A
2)	Mixing Times at Manufacture	Yes <span style="border: 1px solid black; display: inline-block; width: 40px; height: 1.2em; vertical-align: middle;"></span>	No <span style="border: 1px solid black; display: inline-block; width: 40px; height: 1.2em; vertical-align: middle;"></span>		N/A
3)	Weighing	Yes <span style="border: 1px solid black; display: inline-block; width: 40px; height: 1.2em; vertical-align: middle;"></span>	No <span style="border: 1px solid black; display: inline-block; width: 40px; height: 1.2em; vertical-align: middle;"></span>		N/A
5)	Blending time	Yes <span style="border: 1px solid black; display: inline-block; width: 40px; height: 1.2em; vertical-align: middle;"></span>	No <span style="border: 1px solid black; display: inline-block; width: 40px; height: 1.2em; vertical-align: middle;"></span>		N/A
6)	Filling Times	Yes <span style="border: 1px solid black; display: inline-block; width: 40px; height: 1.2em; vertical-align: middle;"></span>	No <span style="border: 1px solid black; display: inline-block; width: 40px; height: 1.2em; vertical-align: middle;"></span>		N/A
8)	The Quality of the Raw Materials	Yes <span style="border: 1px solid black; display: inline-block; width: 40px; height: 1.2em; vertical-align: middle;"></span>	No <span style="border: 1px solid black; display: inline-block; width: 40px; height: 1.2em; vertical-align: middle;"></span>		N/A
8)	Cleaning of Vessel	Yes <span style="border: 1px solid black; display: inline-block; width: 40px; height: 1.2em; vertical-align: middle;"></span>	No <span style="border: 1px solid black; display: inline-block; width: 40px; height: 1.2em; vertical-align: middle;"></span>		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 <span style="border: 1px solid black; display: inline-block; width: 40px; height: 1.2em; vertical-align: middle;"></span>				
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