

Form-310 Issue date:

Raw Material Out of Specification Investigation and Report Form (Ref. SOP LAB-055)

Raw Material Description:			Code No:		
Manufacturer's Batch No:			Lab batch no:		
Limits for this Test Reason for Investigation:					
Results:					
Part A					
Sign/Date			Laboratory Analyst		
Part B Evaluation for Determ	inant Error (La	ab Error)			
Results of Investigation	(,			
Instrument Re-calibration Done	Yes	No			
Solution Re-standardised	Yes	No			
Fresh Standard Made	Yes	No			
Using Correct Method	Yes	No			
Balance Calibrated	Yes	No			
New Mobile Phase	Yes	No			
Instrumentation Maintained	Yes	No			
Correct Calculations for Product	Yes	No			
Correct Formula for Calculation	Yes	No			
Other Sources of Error					
one courses of Error					
Sign/Date:			Laboratory Analyst		



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Part C Results of the Retesting

Tunt of Trooping of the	no recouning	•					
Results for Second Test	on 1		2	3			
composite in Triplicate							
Result from RM Trend Ca	ard						
Results from Manufactur	er's C/A			_			
Results from Previously	Passed						
Retention Sample							
Lab. No. of Previously Pa							
Troising Campio							
Results for Original Individual Lab. Samples (when applicable)		Results for Resample of (when applicable)	the Bulk RM				
Lab Sample 1		Lab Sample 1					
-			-				
Lab Sample 2			Lab Sample 2				
Lab Sample 3			Lab Sample 3				
Lab Sample 4			Lab Sample 4				
Lab Sample 5			Lab Sample 5				
Lab Sample 6			Lab Sample 6				
Lab Sample 7			Lab Sample 7				
Lab Sample 8			Lab Sample 8				
Lab Sample 9			Lab Sample 9				
Deviation Report Require	ed Y	es	No				
Deviation Report Number							
Comments							

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Sign/Date.....Laboratory Manager