

Annexure-VI

Out Of Specification (OOS) Investigation Report

Company Logo Here XX PHARMACEUTICALS LIMITED 117 Adams Street, Brooklyn, NY 11201, USA

OUT OF SPECIFICATION (OOS) INVESTIGATION REPORT

Specification Reference No. :	Valid from :
Analytical Method Reference No.:	Valid from :
Out of Specification Reference No.:	Out of Specification Date:
Enclosure:	

Investigation of OOS Results (Report Level 2):

Sample identification		
Product / Material Name :		
Product / Material Code :		
Batch No. /Lot No. :	Mfg. Date:	Exp. Date:

Repetition of Analysis (retesting) by Analyst-2

Assigned By/ Date:	Assigned To/ Date:
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Analysis	Results	Limit	Remarks
Test-1			
Test-2			
Test-3			
Test-4			
Test-5			
Average			
Analyzed By :		Date :	

Repetition of Analysis (retesting) by Analyst-1 in case of sample comply with Analyst -2

Assigned By/ Date:	Assigned To/ Date:
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Analysis	Results	Limit	Remarks
Test-1			
Test-2			

Test-3			
Test-4			
Test-5			
Average			
Analyzed By :		Date :	

Repetition of Sampling & Analysis			
Assigned By/ Date:		Assigned To/ Date:	
Analysis	Results	Limit	Remarks
Test-1			
Test-2			
Test-3			
Test-4			
Test-5			
Average			
Analyzed By :		Date :	

Measures:

Name	Designation	Signature	Date
Analyst			
Supervisor/ Manager, QC			
AGM, QA			