

Annexure-V

OUT OF SPECIFICATION (OOS) INVESTIGATION PROTOCOL

Company Logo Here XX PHARMACEUTICALS LIMITED 117 Adams Street, Brooklyn, NY 11201, USA
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OUT OF SPECIFICATION (OOS) INVESTIGATION PROTOCOL

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

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

Repetition of Analysis (retesting)	
Analyst	Number of determinations
i) Analyst 1	
ii) Analyst 2	
iii)	
Instrument	Comments
i) Instrument (ID:)	
ii) Instrument (ID:)	
Reagent	
i) Same reagents	
ii) Other reagents	
Others	

i) Analysis of reference sample	
ii)	
Repetition of sampling (re- sampling)	
i) Sampling plan	
Additional investigations	

Reasoning:

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