

Annexure-IV
OUT OF SPECIFICATION (OOS) INVESTIGATION CHECKLIST

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

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 1):

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

OOS Result		
Stage :		
Test :	Results :	Limit :
Analyzed By :		Date :

Checklist			
Possible cause	YES	NO	Not Applicable
Documentation			
i) Calculation error			
ii)			
iii)			
Procedure			

i) Incorrect procedure			
ii) Deviation from procedure			
Working Standard			
i) Correct standard			
ii) Expiration date OK			
iii) Storage OK			
iv) Initial weight OK			
v) Dilution OK			
vi)			

Possible cause	YES	NO	Not Applicable
Condition of sample			
i) Correct sample			
ii) Storage OK			
iii) Initial weight OK			
iv) Dilution OK			
v)			
vi)			
Balance (Balance ID :)			
Code No. of Balance :			
i) Calibration OK			
Instrument (Instrument ID :)			
Code No. of Balance :			
i) Calibration OK			
ii) Parameter set Correctly			
iii) Injector Correct			
iv) Detector correct			
v)			
vi)			
System Suitability Test (SST)			
i) System suitability test carried out			
ii) SST OK			
iii)			
iv)			
Reagent			
i) Physical appearance OK			
ii) Validity OK			
Volumetric standard solution.			

i) Physical appearance OK			
ii) Validity OK			

Diagnosis	YES	NO	Not Applicable
Apparent evaluation fault			
OOS Testing level 2			

Measures:

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