Annexure I

Deviation Form

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

Deviation Form

Deviation Ref No.:

Section A: RECORD OF DEVIATION (To be filled by initiator immediately i.e. 1/2 day of incident)

Deviation No. & Date of Report			Date of incident:			
Department			Initiators Name:			
Designation			Signature:			
Time of incident:	Observer:		Witness:			
Source of Deviation (possible source of departure) Put √ at right	SOP		Product/RM/PM Specification		Human error	
	BMR/BPR		Control direction		Validation/ Stability protocol	
	Equipment & Facility		Documentation error		Calibration failure	
	Storage condition		Environmental limit		Reprocess	
	Yield & Reconciliation		Instruction given by contract manufacturer			
	Other (specify):					

Identification of implicated system	Product Name:	Batch No:
	Material Code:	Equipment/Facility name & identifier:
	Equipment location:	

Details of event: (Generally initiator will define the following in details: o How was the deviation found and by whom? o Over what time period has the deviation occurred o What deviation in the process occurred? Provide as much detail as possible drawing on the experience of the investigators assembled.)	

Immediate (Remedial) Action (Put √ where it is applicable)				
Operat on Suspended		Modification of the process/procedure/Equipment		
Segregation of material		Reject/discard	Adjustment	
Others (specify details):				

Name of person(s) who performed specific remedial action(s). Date of completion of remedial action:	
Signature of Functional Head:	**Date**:

Section B: Assessment of Risk (To be filled by Quality Compliance Manager & Department Manager within 1 day of incident)

Available Information for impact assessment (Batch Document, Log book, Line clearance any other policy)			
Reference of information:			
Assessment Factors:	**Yes**	**No**	**Details**
Will impact on strength, identity, purity and stability of the product			
Have effect on both local/USFDA/EU regulatory compliance			
Immediate impact on any implicated batches			
Possible impact on other batches			
Patient /Customer safety			
Current status of impacted batch			
Detection point of failure (detected by chance/detected during checking/detected at the point of error)			
whether the implicated batch is on the market or within XX's control	□ Yes □ No		
Any immediate ac ion is required further	□ Yes □ No Details:		
Prevent manufacture of defective product	□ Yes □ No		

Prevent defective product to reach market	□ Yes □ No
Any impact on batch release	□ Yes □ No
Any other risks (If requires Risk Assessment tool i.e. FMEA will be used for Major/Critical deviation)	
Criticality	**□Critical □ Major □ Minor**
Communication with Contract Manufacturer	□ Yes □ No
Recommendation of Contract Manufacturer	

Quality Compliance Recommendation:

Target Date: Respo
sible

Requirement of investigation: □ Yes □ No

Justification (only if investigation is not required):

Quality Compliance Manager : Date

SECTION C: INVESTIGATION & IDENTIFICATION OF ROOT CAUSE (Department Manager: Within 15 days)

Investigation reference No:	Start date : Completed on:
** Separate Approved Investigation report is to be attached*	

SECTION D: CAPA APPROVAL

Requirement of CAPA: □ Yes □ No If yes, put the CAPA reference No:

Requirement of any immediate action:		
Action	Completed Date	Responsible

SECTION E: CLOSING

Completion of all identified/recommended action/QA Follow up:	
Release date of impacted batch/Equipment or facility ready to use: **Signature of Quality Compliance Manager**	
CLOSED	**Manager, Quality Assurance** **Date**