OUT-OF-SPECIFICATION REPORT

OOS Report Number:

Phase Ia – Laboratory Investigation

Analyst Name:	**Date:**
Material Description: *(raw material, in-process, final product, stability, other and Lot #, if applicable)*	

Specification:	**OOS Result:**	**SOP #:**

Checklist:	**Yes**	**No**	**N/A**
1. Error in calculations or write/transfer error?			
2. Is there any dilution error?			
3. Were the appropriate and valid standards and reagents used? (incl. expiry date, storage)			
4. Was method followed? Analyst properly trained on method?			
5. Instruments meet established performance specifications and properly calibrated?			
6. Correct glassware (volumetric flasks, pipettes) used?			
7. Power failure?			
8. Spillage/contamination in standard/sample? Improper sample handling?			
9. Sample representative of lot? Sample correctly taken and prepared?			
10. Sample properly stored?			
11. Other: _____?			
12. Same result when same analyst repeats test?			
13. Same result when different analyst repeats test?			
14. Same result after testing hypothesis?			

Phase Ib – Laboratory Investigation Conclusion

OOS due to confirmed Laboratory Error?

☐ **YES** *If yes, explain corrective action taken:*

☐ **NO** *If no, proceed to Phase II or file a Supplier Complaint, if applicable. SCAR #:* _____

Is this a repeat error?	**Repeated test result after CA:**	**QA Release?**
☐ **YES** *If yes, how many times?* _____ ☐ **NO**		☐ **YES** ☐ **NO**

Phase IIa – Full-scale OOS Investigation

1. Statement of the reason of the investigation:
2. Summary of aspects of production process that may have caused the problem:
3. Results of documentation review, with assignment of actual or probable cause:
4. Results of review to determine if problem has occurred previously:
5. Description of corrective actions taken:

Phase IIb – Full-scale OOS Investigation Conclusion

Confirmed OOS? ☐ **YES** *If yes, proceed to close investigation.* ☐ **NO** *If no, begin a CAPA investigation. CAPA #* _____
Describe root cause(s) of confirmed OOS:
Disposition of OOS material(s):
Is a FDA field-alert report required to be issued? ☐ **YES** ☐ **NO**

Approval Signatures *(all applicable parties)*

	Name	Title	Signature	Date
Quality				
Production				
Operations				