STANDARD OPERATING PROCEDURE	
Document number: PR-001	**Version:** 1
Title: Sample SOP – Review of Certificate of Analysis	**Effective date:** 09 January 2024

1. Purpose

The purpose of this standard operating procedure (SOP) is to define the review steps necessary to approve a commercial Certificate of Analysis (COA).

2. Scope

This SOP applies to review of commercial COAs for drug product intended for any approved market.

3. Definitions

Abbreviation	Definition
COA	Certificate of Analysis
SOP	Standard operating procedure
QA	Quality assurance

4. Responsibilities

The responsibilities for each role and/or function are defined in the following table.

Role	Line Function	Responsibility
Reviewer	Quality control	Confirms draft COA was completed correctly, results were transcribed correctly, and results were within specification.
Author	Quality control	Originator of draft COA who addresses issues found during review.
Functional Manager	Quality control	Receives notification of out of specification results found during review.

5. Procedure

5.1. Reviewer will receive an automated message from the documentation system when draft COAs are available for review.

5.2. Reviewer retrieves the draft COA from the documentation system. Printing of the document for ease of review is permitted.

5.3. Reviewer retrieves the quality control data package relevant to the drug product batch listed on the draft COA.

5.4. Reviewer compares each result on the draft COA with the reported result from the data package to confirm transcription was performed correctly.

5.5. Reviewer confirms each result on draft COA is within specification and reported in accordance with the specification (e.g., number of decimal places).

5.6. If Reviewer does not find any errors, and all results are within specification, go to Step 5.9.

5.7. For any errors on the draft COA:

5.7.1. If there are transcription, rounding, or other errors found, Reviewer will note these on the draft COA in the documentation system. After all notes are made, use the Review menu to send the draft COA back to the Author for corrections.

5.7.2. Once Author corrects draft COA and resubmits for review, Reviewer will verify all errors were corrected and proceed with review.

5.8. If an out of specification result is found, Reviewer will immediately notify Author and Functional Manager. Author will then follow SOP PR-002. The draft COA cannot be approved until the conditions of SOP PR-002 are met.

5.9. Reviewer confirms all results reported on draft COA are correct by selecting the Approve option in the Review menu.

5.10. Reviewer electronically signs draft COA. After this step, the COA will move to Quality Assurance (QA) review and approval in the documentation system according to SOP PR-003.

6. References

6.1. SOP PR-002, Investigation of Out of Specification Results

6.2. SOP PR-003, Release of Commercial Material

7. Version History

Version	Changes
1	None; new document.