4.3.1 Following this SOP to conduct In-process and Finished Products analysis including testing and reporting.

4.3.2 Completing all training required prior to conduct any task.

4.3.3 Following procedure for Laboratory Investigation in case of any test failures, questionable, out of trend and out of specification results.

5.0 PROCEDURE

5.1 Receiving Samples in the QC Laboratory

5.1.1 Production personnel should deliver the sample to the QC laboratory sample booth, log the sample into Logbook Bulk and In-Process Sample Logbook, sign the Logbook and enter the required information as specified by the Logbook.

5.1.2 Upon receipt in the Laboratory, the Laboratory Administrator or designee should check the sample labels against the entry in the Logbook.

5.1.2.1 If the information on the label matches the entry in the Logbook, the Laboratory Administrator or designee sign off in the Logbook and the sample is logged into the Finished Goods database.

5.1.2.2 If the information on the label does not match the entry in the Logbook, the Laboratory Administrator or designee must notify the Laboratory Manager that the sample is not accepted in the Laboratory.

5.1.3 The sample should then be transferred to a designated area within the Laboratory.

5.2 Scheduling Test

5.2.1 The Laboratory Manager or designee needs to make sure to schedule work according to priority list provided by the marketing and supply. Otherwise samples should be tested on a first in first out basis.

5.2.2 Sample turnaround times are indicated below:

5.2.2.1 In-Process Blends, Bulk Capsules, Bulk Tablets (end of run/coated), Finished Liquid – 10 days from receipt.

5.2.2.2 In-Process tests – as soon as received (maximum 1 day).

5.2.3 Where microbiological testing is required, the microbiological samples are to be submitted to internal or external microbiology laboratory.

5.3 Testing and Reporting

Upon receipt of the sample for testing, the Laboratory Analyst must:

5.3.1 In the Finished products database: Change status from “logged in” to “under test”, enter analyst name and start date.

5.5 Document Filing

5.5.1 The Laboratory Workbook should be filed in the filing compactuses and product folder should be filed in the Products filing cabinet.

5.5.2 The completed Laboratory Documentation such as ***TEM-145*** *Finished Product Specification and Test Report* should be given to the Laboratory Administrator or designee for generation of a Certificate of Analysis (COA). Once the COA has been approved, the completed Product Test Record Form, Laboratory Document Check List and COA should then go to Quality Assurance for review.

5.6 Generation of COA

5.6.1 Upon receipt of the completed ***TEM-145*** *Finished Product Specification and Test Report ,* the Laboratory Administrator or designee should generate a COA from the appropriate template The COA should contain the following information:

Product Name
Lot Number
Date Manufactured
Date of Analysis
Reference to the Corresponding Material Specification
Test / Method / Specification / Result
Statement of Quality
Signature of the Authority.

5.6.2 The Laboratory Manager or designee should review and sign the COA.

5.6.3 When the Quality Assurance signature is not required the Laboratory Administrator or designee should scan the COA and store the electronic copy in the relevant product folder. The hardcopy of COA will be attached to the Product Test Record and send to QA. QA to file the hardcopy with the batch documents.

5.6.4 When the Quality Assurance signature is required the printed COA will be attached to the Product Test Record and forwarded to Quality Assurance department.

5.6.5 Quality Assurance Department to sign the COA, scan it and store the electronic copy in the relevant product folder. The hardcopy of COA will be attached to the Product Test Record and filed with the batch documents.

5.7 Reassay Procedure

5.7.1 Manufactured Semi Finished Goods

5.7.1.1 A reassay might be required if the bulk product is not packed within the specified time period listed in the Bulk Holding Periods**.**

5.7.1.2 If a reassay is required the Quantity and shelf life of the product is to be reviewed by the Supply planner. The product needs to have more than 2 years shelf life in the market and the value of the product should be higher than retest cost.

5.7.1.3 The Supply Planners will alert Laboratory Manager and Manufacturing Department if a reassay is required on a manufactured semi-finished good.

