- *WAR-085 Sampling and Inspection of Raw & Bulk Materials",*
- *WAR-100 Sampling of Raw Materials in Sampling Booth",*
- *WAR-105 Cleaning of Sampling Booths and Implements in the Raw Materials Quarantine Store".*

5.2 **70% Alcohol Sampling**

5.2.1 Materials required:

- 500mL x 5 sterilised jars (for microbiological testing)
- 120mL x 1 non- sterilised jar (for chemical testing)
- 1 sampling thief – sterilised
- 70% Alcohol
- Latex gloves
- Texta for labelling

5.2.2 Ensure correct gowning procedures are followed as per standard procedure for *"Personal Hygiene and Clothing Policy"* and *"Personal Protective Equipment Policy"* for entry into the manufacturing area.

5.2.3 Ensure latex gloves sprayed with 70% Alcohol are worn prior to sampling.

5.2.4 Label all sample jars with Sample Name, Batch Number, Date and Time Sampled and the Operator Name using the labelling Texta.

5.2.5 Spray the drum cap with 70% Alcohol and remove it.

5.2.6 Remove the sampling thief from the sterilisation bag and plunge into the drum ensuring the plunger of the sampling thief is down and submerged under the liquid so it fills.

5.2.7 Remove the sampling thief gently and pulling plunge up and expel the liquid into the sample jars. Repeat this process until all sample jars are full.

5.2.8 Tighten the lids of the sample jars to prevent leaking, take the samples to the QC Laboratory and affix proper labels to the sample jars.

5.2.9 Log the chemical sample into the *"QC Laboratory Raw Material Receival Logbook"* for chemical testing.

5.2.10 Send the microbiological samples to the Microbiology Lab for microbiological testing.

5.3 **Blend Sampling**

5.3.1 Check the sampling thief to ensure that it is clean before use.

5.3.2 The operator refers to the Product Manufacturing Instructions (MI) to determine what sampling plan is to be followed. One sample container, 49mm x 49mm Polypropylene securitainer, is filled for each sampling point required.

5.3.3 Label each sample container with the following information: Item Code, Product Name, Batch Number, Sample Position, Signature and Date.

5.6.5 The samples are delivered to the QC Laboratory and registered in the *"Bulk and In-Process Sample Logbook"*.

5.7 **Coated Tablet and Capsule Sampling**

5.7.1 The Operator collects all coated tablet samples.

5.7.2 The coating pan continually mix's the tablets. A representative sample is taken by transferring small scoops of tablets from the coating pan as the tablets are mixing, during the cooling down process of coating. Approximately 100grams are collected in a labeled plastic bag.

5.7.3 The plastic bag is labeled with the Item Number, Product Name, Lot Number, Date, Average Weight (as determined during In-Process testing), Signature and Date and marked "Coated".

5.7.4 The samples are delivered to the QC Laboratory and registered in the "Bulk and In-Process Sample Logbook".

5.8 **Re-Sampling**

5.8.1 Where a Raw Material, Blend, EOR, Coated or Bulk requires re-sampling the sampling steps are the same as described above for the original sample.

5.8.2 Re-sampling of a material is only permitted under certain circumstances where the integrity of the original sample is doubted, where insufficient original sample is provided to complete the required testing or for other special circumstance as authorised by the QA Manager.

5.8.3 *Form-010 Sample Request Form* must be completed for each re-sampling event.

5.8.4 The form must detail specifics of the re-sampling event including:

5.8.4.1 Number of samples to be taken.
5.8.4.2 Size of samples to be taken.
5.8.4.3 Location from which samples are to be drawn (original containers or new locations).
5.8.4.4 What testing is to be conducted. (No testing other than that specified on the "*Form-010 Sample Request Form*" or attached *Form-715 Analytical Testing Report for Non Standard Testing QA Inspection Sheet* is permitted.)
5.8.4.5 Any Deviation or Laboratory investigation Report relating to the reason for re-sampling must be referred to when making the decision to re-sample.

6.0 **DEFINITIONS / ACRONYMS**

None

7.0 REFERENCES

WAR-085 Sampling and Inspection of Raw & Bulk Materials
WAR-100 Sampling of Raw Materials in Sampling Booth

