

Standard Operating Procedure

Title: Sampling and Inspection of Raw and Bulk Materials

Department	Warehouse	Document no	WAR-085
Title	Sampling and Inspection of Raw and Bulk Materials		
Prepared by:		Date:	Supersedes:
Checked by:		Date:	Date Issued:
Approved by:		Date:	Review Date:

1.0 DOCUMENT OWNER

Warehouse / Quality Manager

2.0 PURPOSE

Detail the procedure for inspecting and sampling of receipted raw materials (RM); bulk materials (BM) or Semi-Finished goods (e.g. tablets, pastes, capsules) and [active pharmaceutical ingredients](#) (API) at GMP site.

3.0 SCOPE

Covers receipted RM, BM and API at the GMP site and contracted processing sites for manufacturing of pharmaceuticals.

4.0 RESPONSIBILITY \ BUSINESS RULES

Refer to section 6 for all definition and acronyms.

4.1 Only those trained in inspection and sampling can carry out these procedures. The Warehouse Operators who are trained in sampling and inspection are termed as QA Sampling Inspectors.

4.2 All RM, BM and API are sampled in the laminar flow booth located in the quarantine section of the receiving warehouse. When this booth is under maintenance, the laminar flow booth in the dispensary can also be used.

4.3 Only one lot of any item may be sampled at any one time with a cleaning step between lots.

4.4 Drugs of dependence or others covered by special security requirements are to be sampled in the presence of a witness.

4.5 All RM, BM and API are sampled in accordance with sampling plans and sampling guidelines approved by Quality.

4.6 Lot dispositions (change from the initial Quarantine status to A, B, C, R or H status) for RM, BM and API are carried out by approved QUALITY personnel, based on C of A, Warehouse documents, NIR results and samples provided by QA Sampling Inspectors in the Warehouse.

4.7 Trained and authorized QA sampling inspectors in the Warehouse place lots in N status if specified in the RMSTR (Raw Material Specification - Test Report), unless quality disallow placing any specific item/lot or material from a given manufacturer or supplier in N status.

4.8 The sequence of sampling carried out in the Sampling Booth is as follows:

Samples for microbiological testing are first drawn, followed by samples for chemical testing. The host material from where these samples are drawn is removed from the Sampling Booth and only then; NIR vials are filled in the Sampling Booth per requirement, from chemical samples already drawn.

4.9 Any re-sampling activity is carried out strictly in accordance with instructions from Quality.

4.10 All RM, BM and API deliveries are stored in appropriate areas before and after sampling. Physical transfers of material within the Warehouse are reflected in the ERP system (Enterprise Resource Planning Software) through prompt transfer transactions by Warehouse Operators in ERP system.

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5.1.8 Locate sampling plans; reduced / normal / tightened. It is to be noted that the first delivery of a given RM item from any manufacturer is always on a tightened sampling plan.

5.1.9 Note the number of containers in the delivery of an RM. Consult the appropriate sampling plan to be used for the delivery per the advice of Quality.

5.1.10 From the number of containers in the delivery of an RM, using the appropriate sampling plan, note the number of containers to be sampled. For example, if a given RM from a supplier is on a reduced sampling plan, a delivery containing 50 bags would need 2 bags of the delivery to be opened for sampling.

5.1.11 For BM, refer to sampling plan to select the number of containers and for sampling quantity.

5.1.12 Sample every container of each lot of API and comply with any special instructions provided by Quality for any specific lot or delivery.

5.1.13 Check the quantity of sample to be drawn indicated on the RMSTR for a given RM. If the sample quantity indicated is 40 grams, the total sample to be drawn for the lot is a minimum of 40gms. If 2 bags are to be sampled, per sampling plan, it is required to draw at least 20gms from each bag into separate sample containers for each of the two bags. Quality would advise their specific requirements for testing of any item / lot as required. The maximum sample quantity for any given RM is 3 times that in the RMSTR.

5.1.14 As API's are very expensive, the RMSTR quantities are adhered to unless otherwise advised by Quality for specific reasons.

5.1.15 Ensure that the requisite containers of the lot to be sampled (for RM / BM / API) are placed on captive alloy or plastic pallets. At random, select the needed number of containers to be opened for sampling from amongst the delivered pallets and place them on pallets before attempting to take them into the Sampling Booth.

5.1.17 Collect the requisite sampling implements (e.g. sterile / certified clean: spoons, ladles, spikes). Check RMSTR / MSDS and select requisite safety apparel / breathing protection. Collect requisite sampling containers and related items (e.g. bottles, sterile containers, plastic bags, cable ties, plastic patches. Collect and organize other items that are essential for carrying out sampling (e.g. lint free cloth, 70% alcohol).

5.1.19 Ensure the requisite sampling implements are within the expiration period before use.

5.2 Documentation of Sampling and Sampling in the Sampling Booth

5.2.1 Inspect the Sampling Booth and the Sampling Booth logbook. Ensure that the booth is clean and is ready for sampling. Turn on the laminar flow booth. Wait for 10 minutes before checking the readings in Step 5.2.2.

5.2.2 Read the RH and temperature gauges located on the laminar flow booth. Ensure that these are between 25-40% and below 25 deg C respectively. If the readings are outside the range, do not commence sampling. Contact Engineering for corrective actions.

5.2.3 Check if the airflow indicator on the Sampling Booth panel displays in the green zone (60-105 Pa) and the dust filter air gauge also indicates in the green zone (0-250Pa). Check and ensure that the airflow indicator mounted just inside the Sampling Booth room entrance also reads between 12-50Pa. If all these readings are favourable, sampling can be undertaken in the Sampling Booth. Sampling is always carried out in the indicated zone of laminar flow within the Sampling Booth.

5.2.4 Fill out details of date received, Purchase order, site lot number, manufacturer's lot number, supplier name, manufacturer's name, quantity delivered, number of containers, inspection level, sample size, sample code number on the relevant sections of the RMSTR already printed per Step 5.1.2 above.

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aseptic sampling. The containers being sampled are always placed between the Operator and the inlet face of the Sampling Booth. Sampling is done carefully to limit any spillage or dusting.

5.2.16 Once sampling is carried out, check again that all the containers are sealed. Collect all the used sampling implements; place them in a plastic bag after wiping them clean of visible residue with 70% alcohol and clean cloth. Collect all sample containers and take them out of the Sampling Booth. Clean the outside of the containers of RM / BM / API recently sampled with a clean cloth and dispose all the used cleaning cloths in the S4 waste bin. Vacuum the outside of the containers / pallets of any spills and wipe the pallets with 70% alcohol to remove any spills before removing the pallet with containers out of the Sampling Booth.

5.2.17 If NIR samples are required (this will be specified in the RMSTR), ensure that the source containers of the RM / BM / API have been removed from the Sampling Booth. Take the recently drawn chemical samples back into the Sampling Booth with a specific number of empty NIR vials and fill the NIR vials with material drawn from the chemical samples. Re-seal the chemical sample containers and the NIR vials. Record the details in the Sampling Booth logbook to denote the end of sampling.

5.2.18 Clean the Sampling Booth per [SOP WAR 105 "Cleaning the Sampling Booth and Implements in the Raw Material Quarantine Store"](#) and record cleaning start and end times in the logbook. Cleaning verification is carried out and recorded in the logbook. The Sampling Booth is then marked "Clean" on the display board outside and is ready for the next sampling activity.

5.2.19 After the sampling, put away the containers of RM / BM / API into the appropriate areas in the Warehouse.

5.2.20 If quality require a Deviation Report for any given item / lot due to planned or unplanned deviations, QA Sampling Inspectors assist in preparation of a Deviation ([QMS-035 Pharmaceutical Deviation Report System](#)).

5.3 Complete Sampling Documentation and ERP System Entries

5.3.1 Record details of sample date, Site lot number, manufacturer's lot number, description of material and inspection level and your signature in the sampling history chart for the item in the item file.

5.3.2 Log on to ERP System using your personal sign on and password. Input sampling details with quantity of samples drawn. Ensure that the correct inventory units of measure are used (e.g. grams, Thousands, number). Ensure that you confirm in ERP System that sampling is completed for the given lot.

5.3.3 Complete the requisite sections of the RMSTR. Attach the same to a copy of the "Form 850 - Inspection of Goods on Delivery" (Appendix B) after signing the sampling section. Attach the Certificate of Analysis for the lot from the manufacturer and the aseptic and chemical samples drawn. Ensure that the labels on the samples are correct. If NIR samples are involved, proceed to analyse the NIR vials in the NIR instrument located in the QA Sampling Inspector's office as per Step 5.4. The NIR results have to be attached to the samples before the samples and documents are submitted to the Quality Laboratory.

5.4 NIR Scanning, Placement of Lot in N status and Sample Submission to the Quality Laboratory

5.4.1 Carry out NIR scanning of the samples drawn in accordance with appropriate SOP. Attach the printed ID report, along with documents in Step 5.3.3.

5.4.2 Dispose the NIR vials with their contents into the S4 sharps bin placed conveniently in the office.

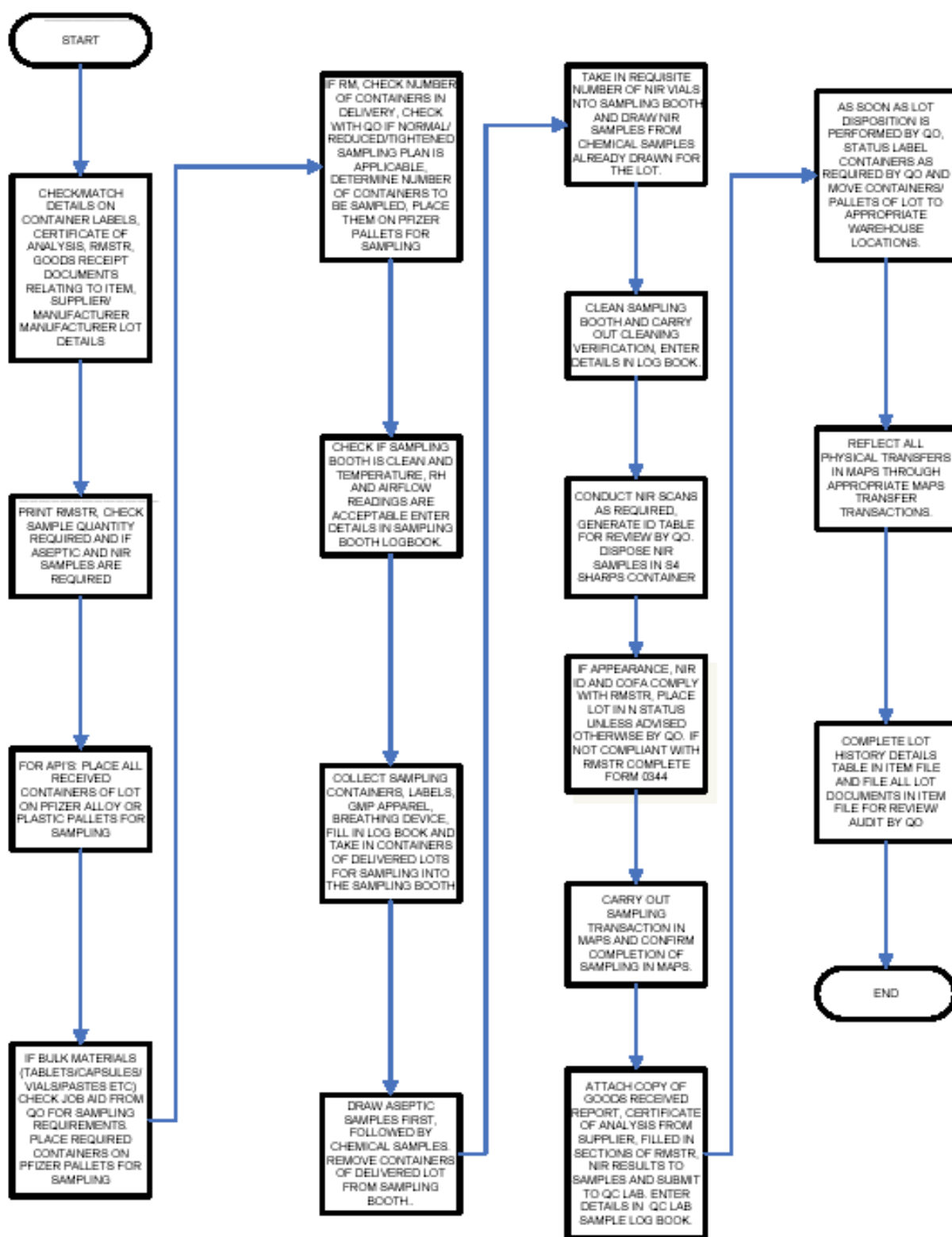
5.4.3 Review Appearance and NIR ID results. Record appearance and NIR ID details on RMSTR in the relevant sections. Review Certificate of Analysis from manufacturer/Supplier for the lot against RMSTR. If no mismatch is noticed, sign in the relevant section of RMSTR to confirm that you have

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5.5.5 Flowchart for Process

APPENDIX A



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6.0 DEFINITIONS / ACRONYMS

API	Active Pharmaceutical Ingredients that have chemical activity and are the main therapeutically active agents. Examples include Prazosin Hydrochloride, Sildenafil Citrate or Amlodipine Besylate)
BM	Bulk Materials. They are also called Semi Finished Goods. These Include tablets, capsules, pastes, vials with biological or chemical activity.
EHS	Environmental Health and Safety
ERP System	Manufacturing, Accounting, & Planning System
MSDS	Material Safety Data Sheet
NIR	Near Infrared
QA	Quality Assurance
RH	Relative Humidity
RM	Raw Materials. Includes additives, diluents, binders, disintegrants, lubricants, coating agents or colors; (e.g. starch, Magnesium Stearate, Opadry white, Microcrystalline cellulose, Sodium Lauryl Sulphate).
RMSTR	Raw Material Specification - Test Report
ERP	Enterprise Resource Planning