DECODING PHARMA

QUALITY ASSURANCE DEPARTMENT

STANDARD OPERATING PROCEDURE	
Department: Quality Assurance	**SOP No.:**
Title: Vendor Management	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

1.0 OBJECTIVE:

To lay down a Procedure for "Vendor Management".

2.0 SCOPE:

This Procedure is applicable for approval of vendors for raw materials and packaging materials required for manufacturing and packaging of drug product at .....

3.0 RESPONSIBILITY:

Head Purchase/Designee: shall be responsible for searching of vendors, receiving vendor samples, organizing vendor audit in co-ordination with Quality Head. Purchase shall be responsible for Approval/Rejection of vendor due to commercial aspect.

Head QC/Designee: shall be responsible for analysis and evaluation of results of vendor samples.

Head QA/Designee: shall be responsible for Review and evaluation of filled vendor registration form and supporting information or data in co-ordination QC from purchase and conducting vendor audits and review, approval or rejection of vendor.

Head Quality: shall authorize the Vendor Approval/Rejection based on quality and compliance aspect.

4.0 ACCOUNTABILITY:

Head Quality Assurance shall be accountable for ensuring compliance of this Standard Operating Procedure.

5.0 DEFINITION:

Vendor: 'Vendor' is often a generic term, used for suppliers of industries from retail sales to manufacturers to city organizations. 'Vendor' generally applies only to the immediate vendor, or the organization that is paid for the goods, rather than to the original manufacturer or the organization performing the service if it is different from the immediate supplier.

6.0 PROCEDURE:

6.1 Need and Identification of Vendor/Supplier:

Need of the new vendor/material would be due to new product development, improvement in quality, product discontinuation from existing vendor, commercial reasons, vendor rejection, business continuity plan etc. Head/Designee-Purchase shall prepare comprehensive list of vendors, supplying the required material. The sources of vendors can be obtained from the buyer's guide, Internet, personal contacts, information from other buyers, etc.

6.1.1 Head/Designee-Purchase shall collect the history of vendors from other buyers, advertisements, personal contacts in respect of both commercial and technical aspects.

6.1.2 Sort out the list of vendors best suited for supply based on the collected Information.

6.1.3 Vendor shall be informed about the requirement and based on vendor confirmation for the willingness to supply the material.

6.1.4 Purchase shall send the "**Vendor Registration Form**" (**Annexure-II & Annexure-XII)**

6.1.5 Vendor shall fill and send the vendor registration form or provide self-assessment/ evaluation form, Samples from three different Lots of raw materials and one for packing materials along with respective COAs with sufficient quantity of raw material for QC testing and Production trial batches (if required) as per mutually agreed specification of .....

6.1.6 The vendor shall provide all required supporting documents to ..... purchase as mentioned in **Annexure-VII.**

6.1.7 Educate the vendor, if required, on cGMP, product specifications, quality standards etc.

6.2 Vendor Approval Procedure:

(For New Material)

6.2.1 QA will share the specification with the purchase department for the required quality of RM and PM.

6.2.2 Purchase department search out for the vendor in accordance with lay down specifications.

6.2.3 Purchase will initiate the vendor development procedure by taking the approval from QA through vendor development intimation slip as per **Annexure-IX.**

6.2.4 Purchased department will arrange filled vendor registration form / supporting documents and required samples from three different batches of raw materials and one sample of packing materials for the initial assessment of the vendor.

6.2.5 On receipt of the above, Executive/designee-QA shall record the sample details in Vendor Sample Record **(Annexure-I)** of **SOP**.

6.2.6 Manager/designee-QA shall review and evaluate the vendor registration form with other information and data as per requirement.

6.2.7 Manager/designee-QA will assess the testing requirement of sample and based on that the received sample shall be hand over to QC to arrange sample analysis either internally or by external agency for testing as per approved/ established specification.

6.2.8 On completion of testing, report of sample testing (COA) shall be submitted to QA for further review, evaluation and approval process of the vendor.

6.2.9 Manager QA shall forward the sample to take the trials.(If Required)

6.2.10 Production and quality control shall compile the report and submit it in QA for further review and evaluation.

6.2.11 Manger QA/ Designee will review and evaluate the supporting data, information and duly filled Vendor registration form / self-assessment evaluation form from the vendor, internal reports of QC or Approved contract laboratory and reports of Production trials on Vendor samples (where applicable).

6.2.12 Based on the review and evaluation, Quality Head shall indicate the need for vendor's plant audit. In case it is not required, justification will be given based upon the criticality of the material / type of use / impact on product.

6.2.13 In case need for Vendor site audit would have been indicated, The Quality Head will consider the following requirement

6.2.13.1 In case of API/Primary packaging material: All vendors shall be audited once in two years or can be approved based on technical information.

6.2.13.2 In case of Excipients: All vendors shall be audited once in three years or can be approved based on technical information.

6.2.13.3 In case of the secondary and tertiary packaging material, all the vendors shall be audited once in three years or can be approved based on review of technical documents.

6.2.14 **Vendor audit:** Vendor audit shall be done by a qualified auditors

6.2.15 Criteria for qualification of auditor is,

6.2.15.1 Person must have relevant experience of pharmaceutical industry

6.2.15.2 Must be qualified internally by quality head or by any valid external agency.**(Annexure-X)**

6.2.15.3 Must be well versed with auditing skills

6.2.15.4 Must be aware of SMH procedure for vendor evaluation.

6.2.15.5 Understanding for the regulatory requirements

6.2.16 Auditor shall be identified based upon above mentioned criteria.

6.3 The qualified auditor, plan the vendor site audit as per the schedule**(Annexure-XV)**

6.4 The Auditor shall make a descriptive vendor evaluation report by considering all the key elements as mentioned in the **Annexure-III**

6.5 Vendor audit report shall be evaluated and certified **(Annexure-III)** by Quality Head and authorized by Head Quality.

6.6 Head-Purchase shall obtained compliance report from the Vendor and follow up with supplier till the closure of all the audit observations pointed out during audit

6.6.1 At this stage the vendor is considered as "Approved". Manager/designee-QA shall include the vendor details in the "**Approved Vendor List**" **(Annexure-IV** for raw materials and **Annexure-V** for packaging materials). and same shall be circulated to the Quality Control, Purchase, Warehouse,

6.6.2 Any new source for RM and PM shall be introduced through change control procedure after successful evaluation of vendor

6.7 QA department shall maintain the individual **Vendor History Card (Annexure-VI & Annexure-VIII)** of all the vendors and shall be rated for their commercial supplies made annually.

6.7.1 Based on trend data, percentage rejects shall be calculated for each vendor and "Quality rating " shall be done to the vendors

6.7.2 The quality score shall be done as follows;

6.7.3 For example, if a vendor has supplied 25 batches / lots to the plant and 2 out of 25 batches / lots were rejected by QC, the percentage rejects shall be; 2/25 X 100 = 8 % (percentage rejects).

6.7.4 The quality score shall be calculated by subtracting percentage reject from 100 % i.e. 100-8 = 92 %

6.7.5 Quality score of minimum 90 shall be required for the vendor to qualify.

6.8 If rating of any vendor goes below the quality acceptance level (Quality score ≥90 %) then the vendor shall be informed for the same

6.8.1 If any supply found below the quality acceptance level or any other issue firstly caution letter shall be issued to the concern vendor.

6.8.2 If after the caution letter issued any supply found below the quality acceptance level then warning letter shall be issued to the concern vendor.

6.8.3 If any supply received from below the acceptance quality level after the warning letter then concern vendor shall be black listed.

6.8.4 Vendor shall be communicated for Caution Letter/Warning Letter as per format present in **(Annexure-XIV).**

6.9 Based on the impact evaluation vendor may be removed from the approved vendor list.

6.10 Future supplies shall not be procured from the rejected vendor. Re-Approval of the rejected vendor shall be done as per the new vendor approval procedure.

6.11 Vendor approval represented through flow chart. **(Annexure-XI).**

6.12 Collect the entire updated vendor's/new vendor's added on in existing vendor list through Annexure and update the final list on yearly basis.

6.13 Disqualification of Vendors

6.13.1 Vendors failing to meet the GMP requirements and those consistently (up to three batch) failing to meet quality standard shall be disqualified and blocked for supply of material by QA. However vendor can immediately be disqualified, in case of any critical failure e.g. failing of potency (Assay is found out of specification), microbial test (Failure in pathogens).

6.13.2 If the corrective action is taken by the vendor to resolve the quality problems and non-compliances the vendor shall be re-approved for the supply.

6.13.3 Disqualification/Re-approval of Vendor shall be done as per prescribing **(Annexure-XIII).**

6.14 Documentation:

6.14.1 In case of Principle to Principle product, all the vendor shall be evaluated and approved as per SMH's SOP. Approved vendor list shall be updated and circulated accordingly.

6.14.2 In case of Loan Licensing product /Technology transfer of the product from contract manufacturing customer approved vendor list shall be considered as per contract givers there approved vendor list/EOD and customer wise separate list will be maintained & circulated to concern department.

6.14.3 Vendor shall inform ..... timely for any change in their process, quality or major modification in facility.

6.14.4 All audit reports, vendor history card and relevant documents shall be retained in the QA department for life time.

6.14.5 After vendor approval Quality Agreement between manufacturer/supplier and ..... shall be done as per approved procedure.

7.0 ABBREVIATIONS:

SOP	Standard Operating Procedure
QA	Quality Assurance
QC	Quality Control
cGMP	Current Good Manufacturing Practice
USP	United States Pharmacopoeia
BP	British Pharmacopoeia
EP	European Pharmacopoeia
IP	Indian Pharmacopoeia
VRF	Vendor Registration Form

EOD	External Origin Documents
WHO	World Health Organization

8.0 ANNEXURE:

ANNEXURE No.	TITLE OF ANNEXURE	FORMAT No.
Annexure-I	Vendor sample record.	
Annexure-II	Raw materials vendor registration form	
Annexure-III	Vendor evaluation report.	
Annexure-IV	Approved vendor list-raw materials.	
Annexure-V	Approved Vendor List-Packaging Materials.	
Annexure-VI	Vendor History Card.	
Annexure-VII	List of documents required for the vendor evaluation of RM and PM.	
Annexure-VIII	Summary sheet for vendor status (approved/ rejected)	
Annexure-IX	Vendor development intimation slip.	
Annexure-X	Auditor qualification certificate.	
Annexure-XI	Flow chart of vendor approval.	
Annexure-XII	Packing materials vendor registration form	
Annexure-XIII	Disqualification /Re-Approval	
Annexure-XIV	Caution letter/Black List	
Annexure-XV	Vendor Audit Planner	

9.0 DISTRIBUTION :

- Master Copy — Quality Assurance Department
- Controlled Copy No. 01 — Quality Assurance Department
- Controlled Copy No. 02 — Quality Control Department
- Controlled Copy No. 03 — Production Department
- Controlled Copy No. 04 — Warehouse Department

- Controlled copy No. 05 Purchase Department

10.0 REFERENCE:

In-House

ICH Q7

PIC/S Guide to Good Manufacturing Practice for Medicinal Products PE 009-11, Part I and II.

11.0 REVISION HISTORY:

Revision No.	Change Control No.	Details of Changes	Reason of Changes	Effective Date	Done By
00	Not Applicable	Not Applicable	New SOP		

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ANNEXURE- I

VENDOR SAMPLE RECORD

S.No.	Date	Vendor Name & Address	Sample Details	Samples given to QC on	Issued by	Received by	Result	Remarks

ANNEXURE- II

RAW MATERIALS VENDOR REGISTRATION FORM

Name of the Vendor	
Address of the Vendor	
Name/s of partners/directors	
Address of factory	
Telephones Nos. (Office)	
Telephone Nos. (Factory)	
Name of the contact person (Factory)	
Email I.D.	

INFORMATION OF GMP INSPECTIONS:

Details of inspections conducted in last 3 years:

Name and address of Inspection authority / customer	Date of inspection	Outcome of inspections

S. No.	Description	Y	N	NA
1.0	**QUALITY MANAGEMENT SYSTEM**			
1.1	Is there quality unit(s) that is independent of production? **(Attach the QMS organogram)**			
1.2	Are persons authorised to release intermediates and APIs ?			
1.3	Does all quality related activities recorded at the time they are performed?			
1.4	Is deviation from established procedures documented and explained? Are Critical deviations investigated, & the investigation and its conclusions documented?			
1.5	Are all raw and packaging materials released or used after the satisfactory completion of evaluation by the quality unit(s)?			

1.6	Are Procedures exist for notifying responsible management in a timely manner of regulatory inspections, serious GMP deficiencies, product defects and related actions (e.g., quality related complaints, recalls, regulatory actions, etc.)?			
1.7	Is Quality unit is Releasing or rejecting all products manufactured for use outside the control of the manufacturing company?			
1.8	Are there established system to release or reject raw materials, intermediates, packaging and labelling materials?			
1.9	Are all completed batch production and laboratory control records of critical process steps are reviewed before release of the product for distribution?			
1.10	Are there approved specifications and master production instructions for all the products?			
1.11	Are there written procedure for self-inspection?			
1.12	Is written procedures available of change control?			
1.13	Is there procedure available for review and approval of validation protocols and reports?			
1.14	Is there written procedure available for handling of market complaint?			
1.15	Is there written procedures available for maintaining and calibrating critical equipments?			
1.16	Is there written procedures available for preventive maintenance of all the critical instruments and equipments?			
1.17	Is written procedure available for assigning shelf life of the products?			
1.18	Is procedure available for performing product quality reviews?			
2.0	**PRODUCTION**			
2.1	Is there procedure available for preparing, reviewing, approving and distributing the instructions for the production of intermediates or finished products?			
2.2	Are written procedures available for reviewing all production batch records and ensuring that these are completed and signed?			
2.3	Is written procedure in place to ensure that all production deviations are reported and evaluated and those critical deviations are investigated and the conclusions are recorded?			
2.4	Is written procedures for cleaning and disinfection of production facilities?			
2.5	Is written procedures available for premises for installation and maintenance?			
2.6	Is written procedure available for equipment qualification, facility qualification and modifications and documentations?			
3.0	**PERSONNEL & HYGIENE**			
3.1	Is there suitable qualified, experienced staff employed? **(Attach the list of technical staff)**			

3.2	Are written procedure available for assigning job responsibilities of the employees?			
3.3	Is written procedure available for training of personnel?			
3.4	Specify minimum training hours for the employees?			
3.5	Is written procedures available for hygiene of employees?			
3.6	Is a written procedure available for wearing of protective covering during working?			
3.7	Are lockers provided in the change rooms?			
3.8	Is entry restricted in manufacturing of followings: Smoking, eating, drinking, chewing and the food?			
3.9	Is written procedures available of health check-up?			
4.0	**CONSULTANTS**			
4.1	Are any Consultants advising on the manufacture or quality is hired?			
5.0	**BUILDING**			
5.1	Are the layouts available of Buildings and facilities used in the manufacture?			
5.2	Are Buildings and facilities having adequate space for the orderly placement of equipment and materials to prevent mix-ups and contamination?			
5.3	Is flow of materials and personnel through the building or facilities should be designed to prevent mix-ups or contamination?			
5.4	Are there defined areas or other control systems for the activities receipt, identification, sampling, and quarantine of incoming materials, pending release or rejection?			
5.5	Are there adequate, cleaning, washing and toilet facilities provided for personnel?			
5.6	Are all the areas where finished product is exposed and LAF are validated to meet the required class? **(Specify the class of the areas)**			
6.0	**UTILITIES**			
6.1	Are all utilities drawings are available?			
6.2	Is capacity suitable to support the production activity **(List the capacities)**			
6.3	Is water system qualified for the manufacturing use? Is Written procedure available ?**(Attach schematic layout of water system and raw and purified water specification)**			
6.4	Is HVAC system qualified for the use? Is Written procedure available?			
6.5	Provide the list detailing the class of manufacturing area maintained?			

6.6	Are all drains are identified and provided with air break?			
6.7	Are highly sensitizing materials such as penicillin's (or) cephalosporin's or products having an infectious nature or high pharmacological activity or toxicity or any potent dosage products are manufactured in the premises?			
6.8	Is written procedures available for avoiding cross contamination?			
6.9	Are all areas provided with adequate lightning? Specify the specification employed?			
6.10	Is written procedures available for identification of utility lines? Specify the colour codes used?			
7.0	**PROCESS EQUIPMENT**			
7.1	Are all manufacturing equipment are identified and labelled?			
7.2	Are all equipment are qualified for the intended use?			
7.3	Are all equipments coming in contact with product are of SS316 or of suitable material?			
7.4	Are all equipments are provided with food grade lubricants and no any such contamination is identified?			
7.5	Are drawings of the all equipments are maintained?			
7.6	Are written procedures available for operation and cleaning of equipments?			
7.7	Are equipments are identified by status labelling?			
7.8	Are equipments are re-cleaned if time lapsed for the suitable use?			
7.9	Are equipments are validated for the cleaning procedure suitability?			
8.0	**CALIBRATION**			
8.1	Are all critical equipments, gauges are calibrated?			
8.2	Are there written procedures available for calibration and recording of same?			
8.3	Is written procedures available for status labelling of the calibration status?			
8.4	Are equipment calibration is performed using standards traceable to certified standards?			
9.0	**COMPUTERIZED SYSTEMS**			
9.1	Is there software is used for the record maintaining?			
9.2	Is there written procedures available and records maintained for validation of the software system?			
10.0	**DOCUMENTATION AND RECORDS**			
10.1	Are documents prepared, reviewed and approved in paper form or electronic form			
10.2	Are written procedures available for documents history?			
10.3	Are scale up reports are maintained?			
10.4	Is written procedure available for retention of filled records and documents			
10.5	Is written procedure available for specimen signature?			

10.6	Is written procedures available of all persons authorizing of documents?			
10.7	Is written procedure available for documents standard format and changes thereof?			
10.9	Are all master documents related to manufacturing, quality systems are retained by QA?			
10.10	**Master Production Instructions (Master Production and Control Records)**			
	• Are Master records available which are duly signed and dated for the preparation, review and approval?			
	• Name of product and stage being manufactured and an identifying document reference code, if applicable			
	• Complete list of raw materials and intermediates designated by names or codes sufficiently specific to identify any special quality characteristics			
	• An accurate statement of the quantity or ratio of each raw material or intermediate to be used, including the unit of measure			
	• Variations to quantities should be included where they are justified; • Standard batch size			
10.11	**Batch Production Records (Batch Production and Control Records)**			
	• Are batch records available for each stage and intermediate and product wise?			
	• Are batch records are issued are recorded?			
	• Is written procedure available for issue of batch record?			
	• Is batch are issued with unique identification number?			
	• Is written procedure available for batch numbering system?			
10.12	**Laboratory Control documents and Records**			
	• Are there written specifications and testing procedures available?			
	• Are current versions of the pharmacopoeias available for reference? (Attach list of reference standard books available)			
	• Are working/ reference standards available?			
	• Are working standards qualified before use?			
	• Are working standards stored in designated properly labelled status?			
	• Are log book for the usage of working standard is maintained?			
	• Are equipment usage and cleaning records are maintained?			
	• Are written procedures available of operation and calibration of the instruments?			
	• Are instruments labelled with calibration status label and frequency for the calibration?			
	• Are annual maintenance program is available for the instruments?			
	• Are there instruments which are not covered for the AMC?			

	• Are records of chemicals, reagents and standards used for chemical analysis are subjected to identification test before usage?			
	• Is there sufficient storage space available?			
	• Are there written procedure for the performing analyst validation?			
	• Is written procedure available for the recording of the results?			
	• Is written procedure available for the reporting of analysis results?			
	• Is certificate of analysis is prepared for the all Raw materials, packaging material and finished product?			
10.13	Is written procedure available for out of specification?			
10.14	Is written procedure available for microbiology testing of purified water and raw water?			
10.15	Is written procedure available for analytical method validation? (specify the parameters performed during validation)			
10.16	Is sample inward records are maintained?			
10.17	Are outside testing laboratories used for quality control? **(If yes provide details)**			
11.0	**MATERIALS MANAGEMENT**			
11.1	Is written procedure available describing the receipt, identification, quarantine, storage, handling, sampling, testing, and approval or rejection of materials?			
11.2	Is written procedures available for evaluation of vendors and supplier?			
11.3	Is approved vendor list available in warehouse?			
11.4	**Receipt and Quarantine** Are all received checked while receiving:			
	• For correct labelling (including correlation between the name used by the supplier and the in-house name, if these are different)			
	• container damage			
	• broken seals			
	• evidence of tampering or contamination			
	• Approved vendor			
	• Quantity as mentioned			
	• Storage conditions			
	• For solvents: certificate of cleaning			
11.5	Is solvents if used are stored in tanks:			
	• Checked for cleaning of the storage tank?			
	• Mixing followed with re-sampling for the analysis			
	• Are appropriate safety measures available?			
	• Are solvents dispensed through transfer lines?			
	• Are all transfer lines are identified using colour codes?			

	• Are solvent dispensing is through computer access control for dispensing?			
11.6	Are all the containers of the materials sampled and tested?			
11.7	Is there dedicate areas for the sampling of the raw materials, packing materials.			
11.8	Are there separate areas with appropriate safety provisions for the safety of hazardous and toxic materials?			
11.9	Is there specified sampling area?			
11.10	Is written procedures available for the sampling aids to be used and are calibrated and cleaned and frequency of re-cleaning?			
11.11	Are there areas for storage of materials based on the status?			
11.12	Are materials are stored on the racks/ pellets/?			
11.13	Are materials stored under controlled temperature and relative humidity conditions?			
11.14	Are materials stored for easy to clean, dispense and store?			
11.15	Are material issued based on FIFO/FEFO basis?			
11.16	Are there separate areas for the rejected materials?			
11.17	Are access to rejected material is restricted?			
11.18	Are materials re-evaluated if any physical changes in the materials are identified?			
11.19	Is procedure available for the retest of the materials?			
11.20	Are all materials issued on the authorised request?			
11.21	Are all materials dispensed are labelled with details including: batch no., product, name, quantity, mfg. date, exp. Date, AR No., Dispensed by, checked by?			
11.22	Are calibrated weights and weighing balances are used for the dispensing?			
12.0	**PRODUCTION AND IN-PROCESS CONTROLS**			
12.1	**Production Operations** • Are all raw materials are verified for the weights before addition into the batch?			
	• Are all raw materials verified for the correctness before additions and recorded in the batch production record?			
	• Are all production steps are verified by the supervisor?			
	• Are all intermediate stages are weighed and yield is recorded in the batch records?			
	• Are batch production records followed for the routine production? Any changes to the standard process are recorded?			
	• Are materials to be reprocessed or reworked should be appropriately controlled to prevent unauthorized use?			
	• Are time limits for the operations mentioned in the batch process			

	records and filled?			
	• Are Intermediates held for further processing stored under appropriate conditions to ensure their suitability for use?			
	• Are all intermediate and in-process testing of samples are recorded and traceable?			
	• Are critical In-process controls identified by bold letters in the batch process records?			
	• Is written procedure for the sampling methods are available?			
	• Are there lots made with mixing of batches?			
	• Are Out-Of-Specification batches blended with other batches for the purpose of meeting specifications?			
	• Are blended process tested for meeting the finished product specifications?			
	• Are the holding time study performed for intermediate and ready to dry stages of products?			
	• Are stability testing is performed for the blended batches?			
	• Is cleaning validation is performed?			
12.2	How reprocessed/ reworked batch is assigned batch number?			
12.3	Is recovery of the solvents is done?			
12.4	Are specifications of the fresh and recovered solvents are same?			
12.5	Are finished products tested for the carryover of the impurities?			
12.8	Are the raw data sheets available for the procedure followed and the calculation and observations monitored?			
12.10	Are all the cultures received are stored properly, maintained and traceable for the sub culturing?			
13.0	**STABILITY**			
13.1	Is there written procedures available for the conducting stability of the products?			
13.2	Specify the storage conditions for the stability performed?			
13.3	Are humidity chambers qualified and calibrated on defined frequency?			
13.4	Tests to be performed during the stability? **(specify)**			
13.5	Procedure for assigning shelf life of the products?			
13.6	Are suitability of the finished product packing assessed for the storage?			
13.7	Are stability samples stored till incubation for stability and before analysis?			
13.8	Is forced degradation study is performed? **(define conditions)**			
13.9	Are impurities generated during the study are qualified and identified and validated?			
13.10	Are records of the stability testing are maintained and how long?			

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Note: Y – YES, N – NO, NA – Not Applicable. (If Not Applicable please provides the justification)

Attachments:

S.No.	Description	Y	N	NA
1	Vendor registration form/self-assessment/Evaluation form etc.			
2	Three samples of different batches/lots along with their COA's.			
3	Site Master File.			
4	Specification of RM.			
5	Certificate of Declaration statement (TSE/BSE/GMO etc.)			
6	GMP certificate.			
7	Valid Manufacturing License.			
8	Regulatory accreditations/ certificates (USFDA/MHRA/KFDA/TFDA/EU/TGA/WHO/ISO etc.			
9	Drug master file.			
10	Stability data.			
11	Material safety data sheet.			
12	Product list.			
13	List of Equipment's and Instruments.			

Note : Y – YES, N – NO, NA – Not Applicable. (If Not Applicable please provide the justification)

Questionnaire filled by (vendor):

Name	Designation	Signature	Date

To be filled by .....

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Activity	Designation	Signature	Date
Reviewed By	Executive/Officer/Designee-QA		

Review and Approval: Manager-QA:

Conclusion:_____

_____

_____

Vendor Approved/Reject

Activity	Designation	Signature	Date
Authorization By	Head- Quality Assurance		

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ANNEXURE-III
VENDOR EVALUATION REPORT

Product/Material Name	
Name of Vendor	
Vendor Address	
Audit Date	
Auditors	
Auditees	

S. No.	Audit Observations
1	**Audit Item:** **Non-conformances:**

S. No.	Observations	Category (Critical/Major/Minor)	Remarks

[The Vendor Evaluation Report will be a descriptive report prepared during the site audit of vendor by considering the requirements of ICH Q 7, WHO guideline for manufacturing pharmaceutical Excipients etc. for the following key elements (as applicable)]

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Key elements for Audit	
Quality management	**Storage and Distribution**
Personnel	**Laboratories Controls**
Building and facility	**Validations**
Process Equipments	**Change Control**
Documentation and records	**Rejection and Re use of Material**
Material Management	**Complaints and Recalls**
Production and In Process controls	**Contract manufacturers (including laboratories)**
Packing and Identification labelling of API's / Excipients	**Agents, brokers, traders, distributors, repackers, and relabellers**

CONCLUSION & CERTIFICATION:

M/s _____ is approved for the supply of _____to .....

Audited by/reviewed by: _____ Signature/date: _____

Authorized by: _____ Signature/date: _____

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ANNEXURE-IV

APPROVED VENDOR LIST - (RAW MATERIALS)

Effective date: **Revision No.:**

Category:

S.No.	Name of Item	Specification	Manufacturer Name	Supplier Name	Address

PREPARED BY
DATE:

CHECKED BY
DATE:

STANDARD OPERATING PROCEDURE	
Department: Quality Assurance	**SOP No.:**
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Supersedes: Nil	**Review Date:**
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ANNEXURE-V

APPROVED VENDOR LIST - (PACKAGING MATERIALS)

Effective date: **Revision No.:**

S. No.	Name of Item	Manufacturer Name	Supplier Name	Address

PREPARED BY	**CHECKED BY**
DATE:	**DATE:**

ANNEXURE-VI

VENDOR HISTORY CARD

Vendor Name: .....

Address: .....

.....

Approved for supplies of:.....

Assessment for the year:

S.No.	Particulars	Ratings	Rated By	Remarks
1.	**No. of supplies received in Nos.: _____**			
2.	**Approved**			
3.	**Rejected**			
4.	**Acceptance criteria** **≥ 90%**			
Evaluation **(Quality Score ≥90%)**				
PREPARED BY:			**CHECKED BY:**	
DATE:			**DATE:**	

ANNEXURE-VII
LIST OF DOCUMENTS REQUIRED FOR THE VENDOR EVALUATION OF RM AND PM

S.No.	List of Documents	API	Excipient	Primary Packing Material	Secondary / Tertiary PM
1.	Vendor Registration Form / Self Assessment / Evaluation form etc.				
2.	Three samples of different Batch/ Lots along with their COA's.				
3.	One samples of Batch/ Lot along with their COA's.				
4.	Specification of material./COA				
5.	Certificate of declaration statement (TSE, BSE, GMO, etc.).				
6.	GMP certificate				
7.	Valid Manufacturing license.				
8.	Regulatory accreditations/certificates (USFDA/MHRA/ EU /PMDA/TGA/ KFDA /TFDA /WHO /ISO (whichever applicable etc.).				
9.	DMF Status (For Concerned Market)				
10.	Stability Data / Declaration				
11.	Route of synthesis.				

DECODING PHARMA

QUALITY ASSURANCE DEPARTMENT

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ANNEXURE-VIII
SUMMARY SHEET FOR VENDOR STATUS (APPROVED/REJECTED)

Year:

S.No.	Vendor Name	Material Name	Detail of consignment			Rating	Status
			Total Received	Approved	Rejected		

Prepared by:	**Checked by:**
Designation:	**Designation:**
Sign/date	**Sign/date**
Remark :	

ANNEXURE-IX
VENDOR DEVELOPMENT INTIMATION SLIPS

Purchase:

Material Name **:** …….

Material Status (New/ Existing) **:** …….

Vendor Status (New/ Existing) **:** …….

Material type (RM/PM) **:** ……...

Name And Site Address Of Vendor: **:**……

……

……

If existing ,list the other material supplied by the vendor.

(Attached the copy if required)

Comments/Recommendation : ……

……

Initiated By : Head Purchase / Designee :…….(Sign /Date)

Quality Assurance :

Comments/Recommendation……

Review By : Executive QA / Designee:…….(Sign /Date)

Quality Assurance :

Comments/Recommendation……

……

…… Approved By :

Head QA ::…….(Sign /Date

ANNEXURE-X
AUDITOR QUALIFICATION CERTIFICATE

This is to certified that Mr/Ms._____ of _____

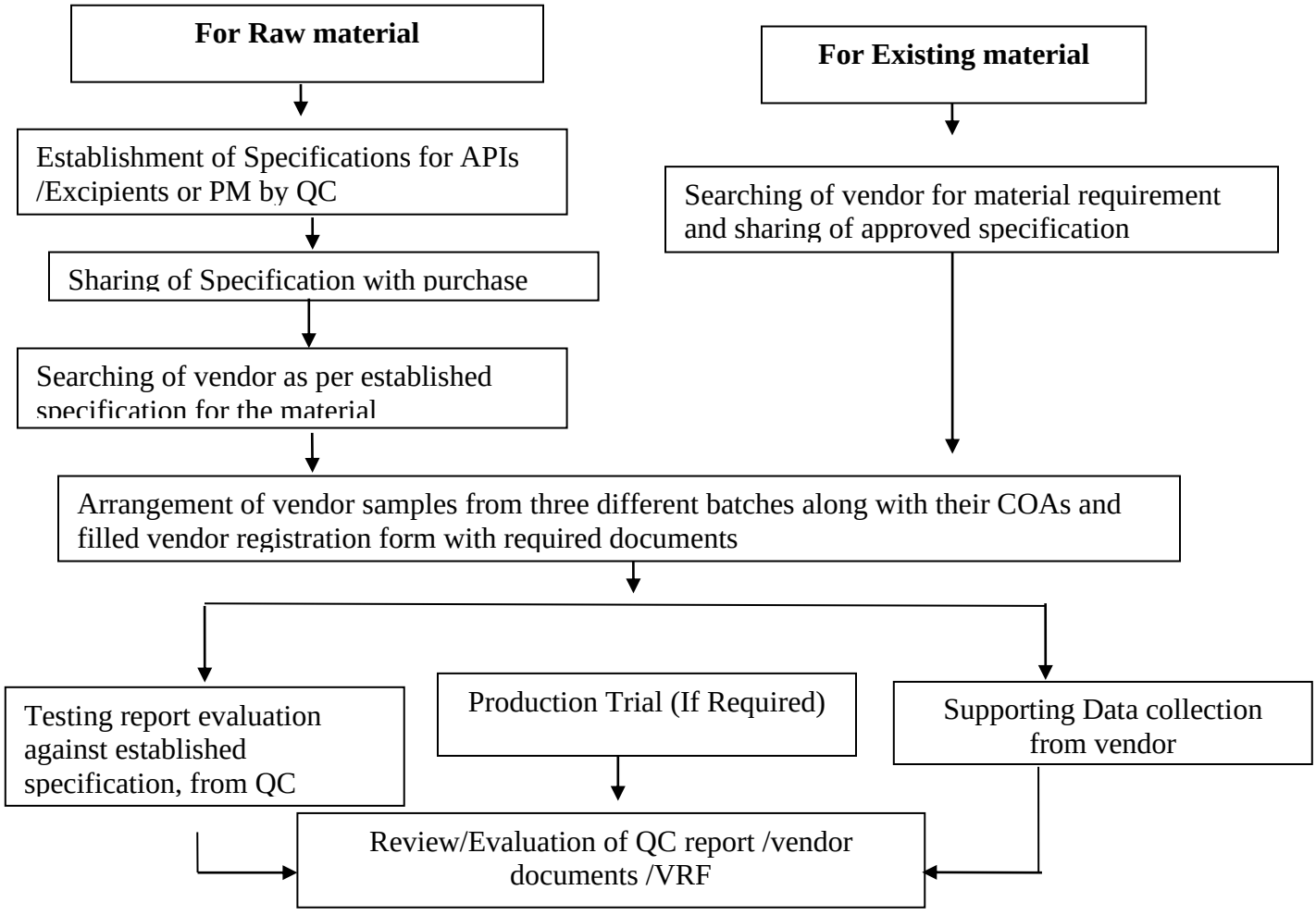
Department/section has certified as "Qualified Auditor "based upon the qualification, experience and skill. He/she is authorized to conduct Vendor Audits to qualify the vendor for the Supply of following material at .....).

Packing Material, Active pharmaceutical Ingredients and excipient etc.

Head-Quality

*Sign/Date*_____

ANNEXURE-XI
FLOW CHART OF VENDOR APPROVAL



DECODING PHARMA

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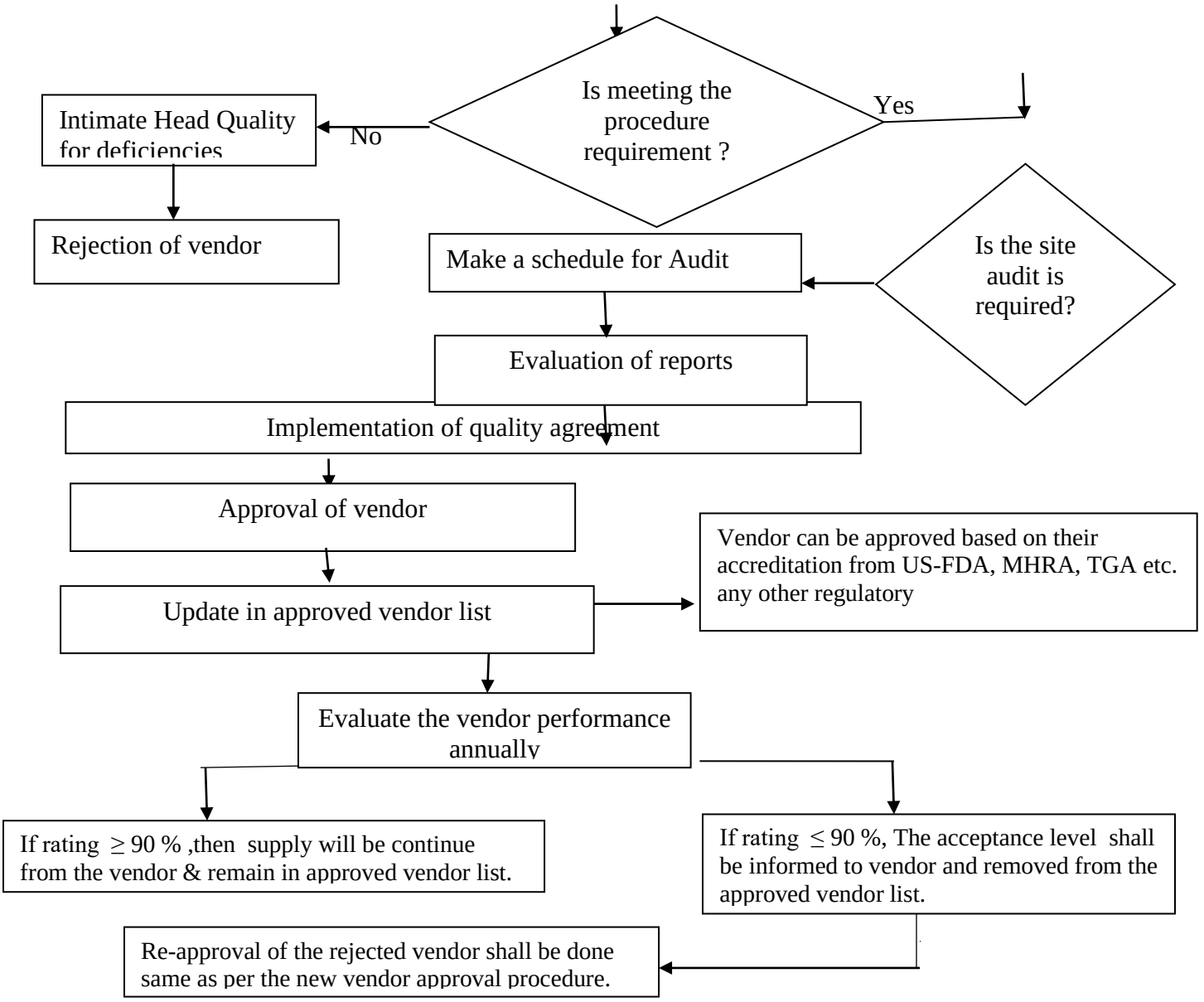

ANNEXURE-XII
PACKING MATERIAL VENDOR REGISTRATION FORM

Name of the Vendor	
Address of the Vendor	
Name/s of partners/directors	
Address of factory	
Telephones Nos. (Office)	
Telephone Nos. (Factory)	
Name of the contact person (Factory)	
Email I.D.	

S. No.	Description	Y	N	NA
1.0	**PACKAGING AND IDENTIFICATION LABELLING**			
1.1	Is there written procedures describing the receipt, identification, quarantine, sampling, examination and/or testing and release, and handling of packaging and labelling materials?			
1.2	Is printed labels issued after authorized issue slip?			
1.3	Is there access control for the issue and store of the packing materials? Is there lock and key system available for the printed labelling material storage?			
1.4	Is records maintained for the issue, uses and destruction of the printed materials?			
1.5	Is separate area available for the storage of rejected printed labels?			
1.6	Are all containers tested as per the specifications?			
2.0	**STORAGE AND DISTRIBUTION**			
2.1	Are there separate areas for the storage of finished products?			
2.2	Is there provision of segregation of the quarantine, under test, sampled and approved materials?			
2.3	Is there a record for the stocks transferred of the finished products by production?			
2.4	Are there records available of the material dispatched?			
2.5	Is there vehicle inspection procedure available while dispatch of goods for cleaning and required transport conditions?			
2.6	Are warehouse secure for the restricted entry?			
2.7	Are there records of general housekeeping of the area?			
2.8	Are there records available of weighing balances?			
2.9	Are weighing balances calibrated on defined frequencies and recorded?			
2.10	Are there separate areas for rejected and recalled goods?			
3.0	**WAREHOUSE**			

3.1	Are receiving procedures adequate?			
3.2	Are materials identified properly as to their contents?			
3.3	Are incoming material checked for following?			
3.3.1	Condition of containers			
3.3.2	Proper labels on containers			
3.3.3	Material received is as per challan.			
3.3.4	Cleanliness of containers/bags.			
3.4.	Are records kept that track the date of receipt, lot number and vendor?			
3.5	Are they having enough space for storage of material?			
3.6	Are materials adequately segregated to avoid mix-up?			
3.7	Are materials properly handled and stored to prevent damage, contamination or loss?			
3.8	Is there an acceptable area/procedure for sampling?			
3.9	Is materials adequately identified as to acceptance or Rejection?			
3.10	Is rejected material adequately controlled?			
3.11	Is there a first-in first-out system for materials?			
3.12	Does the vendor maintain a list of approved sources for materials employed in manufacturing process?			
4.0	**MANUFACTURING**			
4.1	Are the manufacturing procedures written down properly and controlled?			
4.2	Is the product identifiable throughout the manufacturing process?			
4.3	Is the manufacturing environment acceptable to produce quality products?			
4.4	Is there quality check during process of various stages?			
4.5	Are there formal procedures for line clearance before taking up new product?			
4.6	Are the employees in the manufacturing area knowledgeable and quality conscious?			
5.0	**PACKING**			
5.1	Are the shipping containers correctly marked to identify the contents?			
5.2	Are the final shipment checked for correctness and quantity mentioned?			
5.3	Are the facilities used to store or release materials awaiting shipment			

	adequate?			
6.0	**QUALITY ASSURANCE**			
6.1	Record for receipt and issue of material?			
6.2	Is there a system to inform your buyer for any changes of in process/specification?			
6.3	Are there records for testing products maintained?			
6.4	Is there a complaint handling system?			
6.5	List of companies who has audited and approved your facility.			
7.0	**QUALITY CONTROL**			
7.1	Are they have and follow the quality policy of the company?			
7.2	Are they receiving certificate of analysis with inputs?			
7.3	Are they using calibrated instruments for the testing?			
7.4	Are they performing internal quality audits?			
7.5	Laboratory is equipped with required testing facility?			
8.0	**Documentation Control (For primary packing material)**			
8.1	Does the facility have adequate systems to control specifications, test methods and other documents?			
8.2	How long is the retention of the control samples of every batch?			
8.3	Are records maintained that identify the reasons for changes in documents?			
8.4	Are the batch records maintained?			

Note: Y – YES, N – NO, NA – Not Applicable. (If Not Applicable please provide the justification)

Mention List of attachments:

S. No.	Description	Y	N	NA
1	List of Major Customers			
2	Manufacturing Flow Chart			
3	Certificates **(if any please specify)**			
4	List of Manufacturing equipment's.			
5	List of QC instruments			
6	Specification and testing procedure - For PM			
7	Material Food Grade Certificate Of Primary Packing Material.			

8	Drug Master file of Primary Packing Material			
9	IR Spectrogram of Primary Packing Material			

Questionnaire filled by (vendor):

Name	**Designation**	**Signature**	**Date**

To be filled by .....

Activity	**Designation**	**Signature**	**Date**
Reviewed By	Executive/Officer/Designee-QA		

Review and Approval: In-Charge-QA:

Conclusion:_____

_____

_____

_____

Vendor Approved/Reject

Activity	**Designation**	**Signature**	**Date**
Authorization By	Head- Quality Assurance		

ANNEXURE-XIII
VENDOR DISQUALIFICATION/RE-APPROVAL

Date:	
A. VENDOR DETAILS	
Vendor Name and address	
Material Name	
Material Code	
Reason for Disqualification/Re-Approved	
Audit conducted on	
Compliance report received on	
Corrective action plan implemented on	
Whether all observations have been addressed or not?	
Re-approval on	
Requested by	**Name :** **Designation :** **Department :**

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B. HEAD – QA COMMENTS				
Requirement of Vendor Disqualification/Re-approval	Temporary, until further instructions issued		Permanent	
Approved by Head QA	**Sign & Date:**			

ANNEXURE-XIV

DECODING PHARMA

QUALITY ASSURANCE DEPARTMENT

STANDARD OPERATING PROCEDURE	
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VENDOR CAUTION/WARNING LETTER

Date					
A. Vendor Details					
Vendor Name					
Material Name		**Material Code/AR No.**			
Received on		**Received Quantity**			
Batch No.		**AR No.**			
Mfg. Date		**Exp. Date**			
B. Reason for Rejection					
a. Failed in Chemical test	**Test parameter & Result**				
b. Failed in Microbiology test	**Test parameter & Result**				
c. Failed in Physical test	**Observation**				
Rejection Status	**1st Time**		**2nd Time**		**3rd Time**	
	Date		**Date**		**Date**	

DECODING PHARMA

QUALITY ASSURANCE DEPARTMENT

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	Caution letter issued	**Y**	**N**	**Warning letter issued**	**Y**	**N**	**Vendor Black listed**	**Y**	**N**

Prepared by: QA	**Sign& Date:**

C. Conclusion:

Based on the above-mentioned information the consignment is rejected.

As it is …… Rejection, we are issuing ———————— letter and material procurement is stopped until investigation report received from your end. Future supplies shall be depends upon satisfaction of investigations report only.

Specific information / Instructions if any

Approved by:	**Sign & Date**
Head QA	

ANNEXURE-XV

VENDOR AUDIT PLANNER:

S.No.	Vendor Name	Material Name/AR No.	Date of audit	Vendor Approved/ Rejected	Next due Date	Status of Vendor History Card	Remark

Note: i. If vendor site visit not required vendor will be qualified on the behalf of Vendor Qualification Questionnaires.

ii. If Vendor quality score found ≥ 90% in Vendor history card then Vendor can be re-qualified without site visit else audit shall be conducted to re-qualify the Vendor.