DECODING PHARMA

QUALITY ASSURANCE DEPARTMENT

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

1 **Purpose:** The purpose of this SOP is to provide a guideline for Evaluation and Qualification of Vendor supplying Raw Material & Packing material.

2 **Scope:** This SOP is applicable for Qualification of the Vendors supplying/manufacturing API , Excipients & Packing materials for the products being manufactured at ……..

3 **References, Attachments & Annexure :**

3.1 **References:**

3.1.1 SOP "Sampling procedure of raw materials"

3.2 **Attachment :**

3.2.1 **Attachment** : Nil

3.2.2 **Annexure** :

3.2.2.1 Annexure-1 : Vendor information form (CC format)

3.2.2.2 Annexure-2 : Vendor survey form (API) (CC format)

3.2.2.3 Annexure-3 : Vendor survey form (Excipient) (CC format)

3.2.2.4 Annexure-4 : BSE/ TSE Questionnaire (CC format)

3.2.2.5 Annexure-5 : Flow chart for Vendor Qualification in Case of new Product

3.2.2.6 Annexure-6 : Flow chart for Vendor Qualification in case of existing product

3.2.2.7 Annexure-7 : Flow chart for Handling the consignment(s) from new vendor at plant and updation of Approved vendor list

3.2.2.8 Annexure-8 : Flow chart for Handling rejected consignment from the approved vendor

3.2.2.9 Annexure-9 : Flow chart for Discontinuation/De- registration of Vendor

3.2.2.10 Annexure -10: Approved Vendor List.

4 **Responsibilities:**

4.1 **Commercial Department:**

4.1.1 To Identify vendor and arrange Evaluation sample.

4.1.2 To co-ordinate for vendors manufacturing site audit.

4.1.3 To generate vendor code in ERP system.

4.1.4 To arrange for Technical documents from the vendor.

4.1.5 Discontinuation/De- registration of Vendor.

4.2 **Corporate Compliance:**

4.2.1 To ensure availability of vendor Technical documents.

4.2.2 Review and approval of vendor technical documents for adequacy and forward to concern location QA.

4.2.3 Conduct vendor site audit and ensure compliance.

4.2.4 To ensure availability of vendor Technical Agreement for Raw Material & packing materials.

4.2.5 Maintain and update the master data bank for documents, vendor site wise/material-wise.

4.2.6 Discontinuation/De- registration of Vendor.

4.3 **Warehouse:**

4.3.1 To intimate QC and QA department in case of new vendor consignment

4.4 **Quality Assurance:**

4.4.1 To update the "Approved Vendor List" as and when required.

4.4.2 To update Site Item Master in ERP system for Introduction of New Vendor/Material.

4.5 **Quality Control:**

4.5.1 To intimate CC regarding Introduction of new material/vendor.

4.5.2 To analyze Evaluation samples.

4.5.3 To monitor analytical data of each consignment of material and inform to CC, FDD and Commercial Department .

4.6 **Head Quality:**

4.6.1 To monitor the system as per SOP.

4.6.2 To ensure updations of "Approved Vendor List"

5 Distribution :

5.1 Quality Assurance

5.2 Warehouse

5.3 Quality Control

6 Abbreviation & Definition of terms:

6.1 Abbreviation :

6.1.1 ERP : Enterprise Resource Planning.

6.1.2 API : Active Pharmaceutical Ingredient.

6.1.3 FDD : Formulation development department.

6.1.4 ADD : Analytical development department.

6.1.5 CC : Corporate Compliance.

6.1.6 CQA : Corporate Quality Assurance.

6.1.7 R & D : Research and Development.

6.1.8 MPS : Master Product Specification.

6.1.9 VIF : Vendor Information Form.

6.1.10 VSF : Vendor Survey Form.

6.1.11 BSE : Bovine Spongiform Encephalopathy.

6.1.12 TSE : Transmissible Spongiform Encephalopathy.

6.1.13 MSDS : Material Safety Data Sheet.

6.1.14 RS : Residual Solvent.

6.1.15 GIM : Goods inward memo.

6.1.16 GMP : Good Manufacturing Practice.

6.1.17 QA : Quality Assurance

6.1.18 QC : Quality Control

6.2 Definition of terms

6.2.1 **Vendor :** A manufacturer of any raw material which is for the use of manufacturing of drug product is called as a vendor.

6.2.2 **Vendor Audit:** An evaluation of vendor's manufacturing site, for product of interest, for the understanding and application of the GMP practices prevailing in the pharmaceutical industries is called as vendor audit

6.2.3 **Technical documents :** Technical documents in SOP refers to VIF,VSF,BSE/TSE Certificate ,MSDS, RS,GMP Certificate & Stability Data but not limited to these documents.

7 Procedure:

7.1 Identification of vendor, evaluation of sample :

7.1.1 **In Case of new Product** :

7.1.1.1 Formulation development department (FDD) shall identify the vendor and inform to Commercial department.

7.1.1.2 Commercial department shall send vendor information form (Annexure – 1) to the vendor.

This form contains check points regarding vendor's manufacturing facility-capacity, analytical facility and availability of required quality material.

7.1.1.3 Commercial department shall generate a code number for the vendor in the ERP system, which enables to raise requisition for the evaluation sample from the vendor.

7.1.1.4 Commercial department shall collect the evaluation sample(s) along with the certificate of analysis and vendor information form filled from the vendor.

7.1.1.5 Commercial department shall forward the samples to Head formulation development department at respective R & D and send filled Vendor Information form to CC.

7.1.1.6 FDD shall evaluate the sample with respect to it's quality and usability in the proposed formulation.

Note: FDD/ADD shall communicate to the vendor for any clarification, if require, through Commercial department.

7.1.1.7 FDD shall convey it's decision, regarding suitability of the material to Commercial dept. and shall send MPS to plant.

7.1.1.8 CC shall evaluate the vendor information form.

7.1.1.9 If found satisfactory, Commercial department shall order the vendor for the required quantity of material. Simultaneously, commercial department shall arrange for technical documents from the vendor.

7.1.1.10 On receipt of the technical documents from the vendor, commercial department shall forward the same to CC.

7.1.1.11 CC shall review the vendor technical documents for its suitability and adequacy.

7.1.1.12 CC shall send a duly signed and reviewed copy of technical documents to the location .

7.1.2 **In case of existing product :**

7.1.2.1 Commercial department shall identify new vendor.

7.1.2.2 Follow the procedure as per 7.1.1.2 and 7.1.1.4 .

7.1.2.3 Commercial department shall forward the minimum 3 samples of different lot no. to Head Quality and send filled Vendor Information form to CC.

7.1.2.4 QC shall analyze the sample(s) as per the specification.

7.1.2.5 QC shall compare the results against the certificate of analysis of the vendor and evaluate the material quality.

7.1.2.6 QC shall send report to Quality Head.

7.1.2.7 If found satisfactory, Head Quality shall inform to Commercial Department ,CC & FDD

7.1.2.8 Follow the procedure as per 7.1.1.8 and 7.1.1.12 .

7.2 **Handling the consignment(s) from new vendor at plant :**

7.2.1 On receiving of consignment from new vendor, warehouse shall intimate Quality assurance department & Quality control department. QA will enter vendor detail in ERP system.

7.2.2 After updation in ERP system, Warehouse shall receive the consignment and prepare good inward memo (GIM) as per the prevailing SOP(s) and intimate Quality control department through GIM

7.2.3 QC shall collect samples as per prevailing SOP on “Raw material sampling”.

7.2.4 While sampling, quality control/Warehouse shall check integrity of containers, manufacturers’ seal and correspondence between the delivery note and the label. QC shall ensure that results are within the specification.

7.2.5 On receipt of result of analysis, QA shall comply all document. On finding satisfactory, QA shall issued updated version of “Approved Vendor List” and retrieve earlier version.

7.2.6 Vendor list shall be updated on half yearly basis and as and when required.

7.3 **Handling rejected consignment from the approved vendor:**

7.3.1 In case of rejected consignment from the approved vendor, Head quality shall send a “rejection note” to commercial department and to CC. Commercial department shall inform the vendor regarding rejection of consignment.

7.3.2 In case of two consecutive rejections of consignments, the vendor shall be kept under observation.
Head Quality shall evaluate the results and decide on further course of action.

7.3.3 If require, Head Quality shall intimate CC to schedule for vendor’s site audit, to evaluate vendor's understanding of the GMP requirements, Quality assurance systems and manufacturing condition and control on process.

7.3.4 CC shall issue an audit report to the vendor and shall get compliance report, through commercial department.

7.3.5 On satisfactory compliance, CC shall intimate plant Quality Head regarding outcome of the audit. At Plant, QC shall continue evaluation of consignment(s) till three approved consignments are received.

7.4 **Discontinuation / De- registration of Vendor:**

7.4.1 Following reason for Discontinuation / De- registration of Vendor that may include but not limited to :

7.4.1.1 Criticality of Rejections.

7.4.1.2 If the consignment are repeatedly received in bad condition.

7.4.1.3 Critical Non-conformance observed during Surveillance audits.

7.4.1.4 If the Vendor is suspended by Regulatory Authority.
7.4.1.5 In case the item code is made “Obsolete” by ……..
7.4.1.6 If the material is not procured from the Vendor for the last “THREE” years.
7.4.1.7 If the vendor violets the Commercial Agreement.
7.4.1.8 If the Vendor stops the manufacturing of the Product / Change in the Name of the Manufacture / Change in Manufacturing Site.
7.4.1.9 If repeated complaints are raised against the Vendor for various issues.

7.4.2 Head quality shall send details for Discontinuation / De- registration of Vendor to CC.
7.4.3 CC shall evaluate the Vendor De- registration Proposal and forward the same to Head Purchase.
7.4.4 Head commercial to do impact assessment of Vendor De- registration on the procurement of material and business.

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Annexure – 1

SOP No: …….
[Vendor Information form (CC Format)]
Attached Separately

Annexure -2
SOP No: …….
[Vendor survey form API (CC format)]
Attached separately

Annexure- 3
SOP No: …….
[Vendor survey form Excipients (CC format)]
Attached Separately

Annexure - 4
SOP No: …….
[BSE/TSE Questionnaire(CC format)]
Attached Separately

SOP No: ……..

Annexure-5

Flow chart for Vendor Qualification In Case of new Product

FDD shall identify the vendor & inform to commercial department.

↓

Commercial department shall send VIF to the Vendor.

↓

Commercial department shall generate a code number for the vendor in ERP system which enables to raise requisition for the evaluation sample from the vendor.

↓

Commercial department shall collect the evaluation sample(s) along with the COA and VIF filled from the vendor.

↓

Commercial department shall forward the samples to FDD & VIF to CC.

↓

FDD shall evaluate the sample

↓

FDD shall convey it's decision, regarding suitability of the material to Commercial dept. and shall send MPS to plant.

↳

CC shall evaluate the VIF& If found satisfactory them Inform to Commercial department

↓

Commercial department shall order the Materials with Technical documents From the Vendor.

↓

Commercial department shall forward the Technical documents to CC.

↓

CC shall review the Technical documents send a duly signed and reviewed copy to Location.

SOP No: ……..

Annexure-6

Flow chart for Vendor Qualification In case of existing product

Commercial department shall identify the vendor.

↓

Commercial department shall send VIF to the Vendor.

↓

Commercial department shall generate a code number for the vendor in ERP system which enables to raise requisition for the evaluation sample from the vendor.

↓

Commercial department shall collect the evaluation sample(s) along with the COA and VIF filled from the vendor.

↓

Commercial department shall forward the minimum 3 samples of different lot no. to Head Quality & VIF to CC.

↓

QC shall evaluate the sample & Send report to Head Quality.

↓

Head Quality. shall convey it's decision, regarding suitability of the material to Commercial dept. , CC & FDD

CC shall evaluate the VIF& If found satisfactory. then Inform to Commercial department

↓

Commercial department shall order the Materials with Technical documents From the Vendor.

↓

Commercial department shall forward the Technical documents to CC.

↓

CC shall review the Technical documents send a duly signed and reviewed copy to Location.

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Annexure-7

Flow chart for Handling the consignment(s) from new vendor at plant:

On receiving of consignment from new vendor, warehouse shall intimate QA & QC Department, QA will enter vendor detail in ERP system.

⬇

Warehouse shall prepare GIM & intimate QC department through GIM.

⬇

QC shall collect samples as per SOP of "Sampling procedure of raw materials" (SOP No: ……)

⬇

While sampling, QC/Warehouse shall check integrity of containers, manufacturers' seal and correspondence between the delivery note and the label. QC shall ensure that results are within the specification.

⬇

On receipt of results of analysis, QA shall comply all documents.
On finding satisfactory, QA shall issue updated version of the "Approved Vendor" and retrieve earlier version.

⬇

Vendor list shall be updated on half yearly basis and as and when required.

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Annexure-8

Flow chart for Handling rejected consignment from the approved vendor

Head quality shall send a “rejection note” to commercial department and to CC. Commercial department shall inform the vendor regarding rejection of consignment.

⬇

In case of two consecutive rejections of consignments, the vendor shall be kept under observation.

⬇

Head quality shall evaluate the results and decide on further course of action

⬇

If require, Head Quality shall intimate CC to schedule for vendor’s site audit, to evaluate vendor's understanding of the GMP requirements, quality assurance systems and manufacturing condition and control on process.

⬇

CC shall issue an audit report to the vendor and shall get compliance report, through commercial department.

⬇

On satisfactory compliance, CC shall intimate plant Quality Head regarding out come of the audit. At Plant, QC to continue evaluation of consignment(s) keeping the vendor “Under Observation” till three approved consignments are received.

Annexure-9

SOP No: ……. Flow chart for Discontinuation / De-registration of Vendor

Head quality shall send details for Discontinuation / De-registration of Vendor to CC.

⬇

CC shall evaluate the Vendor De-registration Proposal and forward the same to Head Purchase.

⬇

Head commercial to do impact assessment of Vendor De-registration on the procurement of material and business.

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SOP No: …….. **Approved Vendor List**

Annexure –10 (Raw materials/Packing materials)

S.No.	Item Code	Item Description	Manufacturer Code	Manufacturer Name	Manufacturer Address	Remarks

Prepared By	Checked By	Approved By

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8 **History:**

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Implementations :			