DECODING PHARMA

QUALITY ASSURANCE DEPARTMENT

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

1.0 OBJECTIVE:

1.1 The objective of this SOP is:

1.1.1. To describe a procedure to assess the vendors who can manufacture and supply materials of consistent quality and quantity and at right time.

2.0 RESPONSIBILITY:

2.1 The Head - Quality Assurance or Head – Technical Operations shall be:

2.1.1. Responsible for auditing the vendor for cGMP Compliance periodically in co-ordination with Head – Materials.

2.1.2. Responsible for preparing the vendor audit report and further necessary actions.

3.0 ACCOUNTABILITY

Head – Technical Operations

4.0 PROCEDURE:

4.1 Methodology:

4.1.1 All existing Vendors who have already been approved by Mother Plant and Research & Development shall continue as Approved Vendor.

4.1.1 Head - Materials shall be responsible for initiating the need for New vendors.

4.1.2 All the specifications of materials shall be provided to vendor/supplier by the purchase officer of materials department.

4.1.3 R & D shall analyse 3 batches of pre- purchase samples as per specification

4.1.4 New Vendors shall be assessed for their technical capabilities by Quality Assurance and Head - Materials shall negotiate on commercial aspects viz. delivery schedule, packing, price etc.

4.1.5 The Head Quality Assurance or Head –Technical Operations and Head - Materials shall audit the facility of the concerned vendor and shall record all information given in checklist for ready reference as per Annexure - 1.

4.1.6 Irrespective of any amount of urgency, receipt of duly filled checklist and its review will be emphasized before placing the trial order for new vendor.

4.1.7 The current vendor shall continue to remain approved, on the basis of their past performance, and re-approval which shall be done once in 2 year to continue as approved vendor for API as well as Raw Material.

4.2 Assessment of the pre-purchase samples:

4.2.1 Based on the agreed specification and technical discussion, the vendor shall arrange to forward pre-purchase samples of 3 independent batches to materials department along with their certificates of analysis.

4.2.2 Materials Department shall send the Pre-purchased sample to Research & Development (R & D) along with Certificate of Analysis for complete evaluation.

4.2.3 R & D shall analysis the sample as per specification, if any clarification is needed, then contact the vendor for Standard Test procedure or Working Standard etc.

4.2.4 Sample performance shall be finally evaluated by Head – R & D, based on the COA. In specific situation, such as suitability through stability evaluation or trial, the approval of vendor shall await, till the same is completed.

4.2.5 R & D shall convey the finding to location Quality Assurance Head and Head – Technical Operations on the basis of which Quality Assurance shall plan and carry out vendor audit to confirm the compliance level of cGMP.

4.3 Vendor Audit

4.3.1 Head – Quality Assurance or Head- Technical Operations shall recommend approval of a New Vendor based on their overall technical capabilities and quality management system which shall be assessed by Vendor audit & documented as per the check list as per Annexure - 1.

4.3.2 Head – Technical Operations shall take the decision for approval or rejection of the basis of vendor audit report and data submitted by R & D.

4.3.3 If the vendor is approved, the vendor list shall be updated and the Master Copy shall be remained with Quality Assurance, and Certified copy shall be issued to Warehouse, Materials and R & D.

4.3.4 During annual product review if any adverse observation was detected due to any of the raw materials then the vendor shall be identified and his approval is canceled. The vendor is then enrolled as Black listed Vendor.

4.3.5 Annual Plan for Vendor Audit shall be prepared in advance and inspection shall be done accordingly.

4.3.6 Approved vendor shall be re-evaluated for compliance of cGMP with in 2 year of approval or earlier base on the trend of rejections for a particular vendor.

5.0 REASION FOR REVISION

5.1 Harmonization of format.

6.0 Training:

Trainer	--	Head – Technical Operations
Trainee	--	Departmental Heads – Injection, Orals, Warehouse, Materials
Period	--	One day

7.0 DISTRIBUTION:

Certified Copy No. 1	-	Head of Department Quality control
Certified Copy No. 2	-	Head of Department - Materials
Certified Copy No. 3	-	Head of Department – Purchase
Certified Copy No. 4	-	Head of Department – R & D
Original Copy	-	Quality Assurance

8.0 ANNEXURES:

Annexure – 1 : Vendor Audit Questionnaire.

9.0 REFERENCE:

In-house.

ANNEXURE -1

CHECKLIST OF QUALITY EVALUATION OF THE VENDOR

NAME OF THE VENDOR : ----------

LOCATION OF THE PLANT: ----------

PRODUCTS OFFERED : ----------

A. ORGANISATION

ORGANOGRAM

Plant	Yes/No
QA/QC	Yes/No
CONTACTED PERSON DURING VISIT	
Managing Director/ Technical Director	Yes/No
Site in charge/Plant Manager	Yes/No
QA Manager/ QC Manager	Yes/No
Production/ Packaging Manager	Yes/No
Sales Manager	Yes/No

B. FACILITIES

Plant layout	Acceptable/Not acceptable
Maintenance of the Premises	Acceptable/Not acceptable
General house keeping	Acceptable/Not acceptable
Scope for expansion	Yes/No
Plant Life	0-5, 5-10, > 10Years
Is the Facility dedicated	Yes/No
Is the Manufacturing area is adequately Ventilated	Yes/No

ANNEXURE - 1

Is the separate area for sampling of Raw Material Available	Yes/No
Is the manufacturing/Packing area provided with adequate light	Yes/No
Are area available for Sterility (for sterile Preparations) intermediates and finished products	Yes/No
Are balances and measuring equipment's of the appropriate range available	Yes/No
Are fixed pipe works labeled to indicate the Contents and directive for flow	Yes/No
Is pest and rodent Control program is available	Yes/No

Rating

1	2	3	4	5

(1-Poor, 2-4- Opportunity to Improve, 5- Very good)

C. QUALITY ASSURANCE SYSTEM

Do they have approved specification	Yes/No
Do they have approved STP_s	Yes/No
Do they have approved SOP_s	Yes/No
Do they have stability Programs	Yes/No
Do they have formal training programs For Production and QA	Yes/No
Do they have written schedule for training	Yes/No
Do they have written calibration schedule of the analytical instruments	Yes/No
Do they have quality Assurance system for the supplier	Yes/No
Do they have standard sampling plan	Yes/No

ANNEXURE - 1

Do they have proper storage facility	Yes/No
Do they have proper system to check inputs	Yes/No
Do they receive material with certificate of analysis	Yes/No
Do they posses adequate testing facility	Yes/No
Do they have competent and adequate staff	Yes/No
Is corrective action taken for defect identification	Yes/No
Does an authorized manufacturing formula exist	Yes/No
Are processing instruction provided in details	Yes/No
Is a batch processing record available for each batch processed	Yes/No
Are dates and times are recorded for various stage of operation	Yes/No
Are critical steps are cross verified	Yes/No

Rating

1	2	3	4	5

(1-Poor, 2-4- Opportunity to Improve, 5- Very good)

D. MATERIAL CONTROL

Are Released/Rejected/ Under test materials segregated properly	Yes/No
Is rejected material controlled adequately destruction in case of PMS – printed material	Yes/No
Are Material handled properly to prevent damages	Yes/No
Do they have secured, lockable facilities to control narcotic drugs and labels	Yes/No

ANNEXURE - 1

Are Material properly segregated to prevent mix-ups	Yes/No
Do all the containers have the proper label for product, batch no. Qty, Mfg, Exp, Date etc.	Yes/No
Are receiving procedure adequate	Yes/No
Are adequate facilities available to store the material at their premises	Yes/No
Ware house of Incoming material	Adequate/ Inadequate
Ware house of outgoing material	Adequate/ Inadequate
Insurance facilities	Adequate/ Inadequate
Transport facilities for receiving materials	Adequate/ Inadequate
Transport facilities for dispatching materials	Adequate/ Inadequate

Rating

1	2	3	4	5

(1-Poor, 2-4- Opportunity to Improve, 5- Very good)

E. MANUFACTURING/ PACKAGING

Are manufacturing process adequate to produce quality components (written/ Approved document)	Yes/No
Are line clearance concept adopted at the time of change over of product to prevent batch mix-ups/ Product mix - ups	Yes/No
Do the personnel in manufacturing have the awareness towards the quality	Yes/No
Do production personnel follow the working disciplines as per c GMP requirements (Head gear, Safety goggles, Hand gloves, Nose masks ets.)	Yes/No
Are waste material kept separately in proper container	Yes/No
Are equipment's maintained/calibrated as per schedule	Yes/No

ANNEXURE-1

Are in process checks adequate to ensure consistency in quality Yes/No

Are proper accountability done after completion of the batch Yes/No

Are adequate precaution exercised during packging to prevent mix-ups Yes/No

Are excess coded packaging material (labels/ Cartons etc.) destroyed after completion of the batch Yes/No

Are documentation adequate during manufacturing and packaging to ensure the Quality Yes/No

In handling of material and product performed in accordance with written procedures Yes/No

Are all manufacturing process clearly defined Yes/No

Whether systems exists for process/product/equipment status indication system Yes/No

Are there any checks on yields to ensure that they are not out side acceptable limits Yes/No

Are air locks or air extraction system provided to avoid contamination in necessary Yes/No

RATING

1	2	3	4	5

(1-Poor, 2-4- Opportunity to Improve, 5- Very good)

F. RELIABILITY/ CUSTOMER SATISFACTION

Is there formal system to investigate rejection/ market complaints Yes/No

Is there proper system to report failures Yes/No

Is there formal system to provide feed back to customers Yes/No

ANNEXURE - 1

Is there any list of other customer's available Yes/No

Does vendor complete entire work or take the help of sub - contractor Yes/No

Are they capable to adhere delivery schedule Yes/No

Do they have proper record on feed back on quality of their product from other customers Yes/No

RATING

1	2	3	4	5

(1-Poor, 2-4- Opportunity to Improve, 5- Very good)

G. FINANCIAL RANKING (CREDIBILITY IN MARKET)

What is the approximate value of inventory held Rs. _____

What are the major items for which inventory held Class A____%, B_____%

What is approximate annual turnover of sales Rs. _____.

Study of financial terms:

- Documents against acceptance
- L/c sight or clean credit
- Documents through bank
- Performa Purchase
- Co-acceptance scheme
- Direct suppliers

Is he open if we approach his bankers to check his financial rating Yes/No

What is the last year approximate gross profit Rs._____

Any future plans for expansion/diversification Yes/No

RATING

1	2	3	4	5

(1-Poor, 2-4- Opportunity to Improve, 5- Very good)

ANNEXURE - 1

H. COMMERCIAL OBSERVATIONS

Does he prefer long term contract? Order backed supplies

Does he prefer delivery FOR Sight /Works

Discount structure

Can he supply through DAMAN TAX FREE ZONE

I. RECORDS KEEPING — Adequate/Inadequate

J. COMPUTERISATION — Adequate/Inadequate/Nil

K. SCRAP DISPOSAL PROCEDURE — Adequate/Inadequate

L. LABOUR MANAGEMENT RELATION — Adequate/Inadequate

M. GENERAL OBSERVATIONS

How would you rate the morale of the total Organization	Poor/High/Very high
How would you rate the progressiveness and competence of supplier's management	Poor/High/Very high
How would you rate the technical capability of the vendor	Poor/High/Very high
How would you rate the financial capability of the supplier	Poor/High/Very high
How would you rate the commitment to Quality/ performance of the material from supplier	Poor/High/Very high
How would you rate the commitment to timely delivery of the material from supplier	Poor/High/Very high

RATING

1	2	3	4	5

(1-Poor, 2-4- Opportunity to Improve, 5- Very good)

ANNEXURE - 1

N. CONCLUSION

Remarks :

_____
_____
_____
_____
_____

Date

SIGNATURE :

NAME :

DESIGNATION

SIGNATURE :

NAME :

DESIGNATION