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<b>TITLE: VENDOR MANAGEMENT SYSTEM</b>				

## 1.0 PURPOSE:

To provide a procedure for qualifying and managing the vendors involved in supply of raw materials and packing materials.

## 2.0 SCOPE:

This procedure is applicable to all vendors who supply the raw materials, packing materials for Discovery Laboratories Pvt. Ltd.

## 3.0 RESPONSIBILITY:

- 3.1 It is the responsibility of the Quality Assurance departments to qualify the vendors of raw materials and to prepare a list of Key Starting Materials for each product.
- 3.2 It is the responsibility of R&D to conduct use test and submit the report to Quality Assurance if required.
- 3.3 It is the responsibility of ware house department to receive the samples as per the procedure.
- 3.4 It is the responsibility of quality control department to analyze the samples and submit the results to quality assurance.

## 4.0 DEFINITIONS:


- 4.1 **KSM:** A raw material, intermediate, that is used in producing of an intermediate incorporated as a significant structural fragment into the structure of desired entity.
- 4.2 **General Raw material:** A general term used to denote starting materials, reagents, and solvents intended for use in the production of intermediates or APIs.

## 5.0 PROCEDURE:

### 5.1 New vendor procedure for KSM:


- 5.1.1 Purchase department shall identify vendors for each material based on the ability of vendor to comply with the specifications as per Discovery Specification.
- 5.1.2 The Purchase shall send Vendor Questionnaire forms as per current version QA016-FM060 to vendor.

	<b>Prepared by</b>	<b>Reviewed by</b>	<b>Approved by</b>
Sign & Date			
Name	R.Pallavi	T.Ramya	K.V.Nagendra Kumar
Department	Quality Assurance	Quality Assurance	Quality Assurance

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- 5.1.3 Purchase shall get all the vendor qualification documents along with samples from the vendor, preferably 3 samples.
- 5.1.4 Purchase shall send the samples to Quality Assurance along with vendor qualification documents.
- 5.1.5 QA Shall review all relevant documents related to entire vendor qualification.
- 5.1.6 VSL (Vendor Support Lab) representative shall be responsible to analyse vendor samples and use test sample and report the same.
- 5.1.7 QC (Quality Control) representative shall be responsible to provide testing support during vendor qualification process as defined.
- 5.1.8 PDL (Process Development Lab) representative shall be responsible to conduct use test as defined.
- 5.1.9 In case, it is not possible to obtain samples from three different batches (applicable to Hazardous materials only), then certificate of analysis shall be obtained from three different batches by Purchase, for review by Quality Assurance. Based on review, Quality Assurance shall give clearance to Purchase for trial supply. The quality data along shall be reviewed by QA before giving further clearance.
- 5.1.10 If direct commercial batches are received from non approved vendor ware house department will intimate to Quality Assurance through IOC.
- 5.1.11 Quality Assurance department shall intimate to Quality Control for sampling and analysis. After completion of analysis QA shall establish the Quality Equivalence report in between new vendor and existing vendor. Upon satisfactory of the Quality Equivalence, QA shall give the clearance for commercial consumption.
- 5.1.12 Quality Assurance shall record the details of the Raw Material, Manufacturer Name, Date of Samples receipt & the details of the documents receipt in the New Vendor Evaluation Record.

	<b>Prepared by</b>	<b>Reviewed by</b>	<b>Approved by</b>
Sign & Date			
Name	R.Pallavi	T.Ramya	K.V.Nagendra Kumar
Department	Quality Assurance	Quality Assurance	Quality Assurance

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5.1.13 QA shall ensure that the synthetic scheme of KSM from new vendor shall be equivalent to the existing vendor scheme. Where the new vendor synthetic scheme differs from existing then QA shall review the synthetic scheme of the starting material and check whether the current specification and MOA can control all the impurities/potential impurities of the new vendor material either at starting material or subsequent stages. In case the existing controls are inadequate new MOA / additional test shall be developed to control all the potential impurities at appropriate stages.

5.1.14 Quality Assurance shall send samples to QC after review of the vendor qualification documents.

5.1.15 Purchase shall place the trial order with a specific requirement to supply from different batches for starting materials on the vendor for the material on obtaining clearance from Quality Assurance.

5.1.16 On receipt of the trial supplies at warehouse from new vendor, ware house shall inform to Quality Assurance/ Production/ Quality Control before inward entry.

5.1.17 Production shall raise the change control form for Consumption. QA shall mention the stages at which equivalence should be shown based on new vendor scheme.

5.1.18 First In First out (FIFO) is not applicable for issue of raw materials during vendor qualification.


5.1.19 After completion of three batches execution with new vendor material, production shall compile a report and submit to Quality Assurance.

5.1.20 Based on the review of Quality Assurance shall qualify/ disqualify the vendor and intimate to Purchase.

5.1.21 Raise the Change control form and update Approved vendor list whenever required.

5.1.22 Approved vendor list shall be maintained for Raw material i.e. General, packing and Key starting material.

	<b>Prepared by</b>	<b>Reviewed by</b>	<b>Approved by</b>
Sign & Date			
Name	R.Pallavi	T.Ramya	K.V.Nagendra Kumar
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5.1.23 If the same raw material (from an already approved vendor) has to be used for different product, the requirements of raw material w.r.t specific process of product shall be reviewed by Quality Assurance before giving clearance.

5.1.24 “Vendor under Evaluation” status shall be displayed for trial consignments.

5.1.25 Based on one year supply & Quality data retrospective qualification shall performed for KSM for which initial qualification is not performed.

5.1.26 New vendor samples numbering system is follows:

NVE/XXX/YYNNN

NVE : New Vendor Evaluation

XXX : RM code

YY : Year code i.e.’18’

NNN : Serial number will starts with “001”

5.1.27 Analytical numbering shall be follows:

NVE/YYNNN

NVE : New vendor evaluation

YY : Year i.e.’18’

NNN : Serial number in particular year


## 5.2 Vendor Qualification for General raw materials & Packing materials.

5.2.1 Purchase department should provide filled vendor qualification questionnaire for general raw materials current version (QA016-FM137) & Packing material current version (QA016-FM138) to QA before shipment of any material.

5.2.2 After received VQ documents QA department shall verify the documents, give clearance to purchase for procurement.

5.2.3 The approved vendor list should be updated and this should be communicated to purchase and ware house departments.

	<b>Prepared by</b>	<b>Reviewed by</b>	<b>Approved by</b>
Sign & Date			
Name	R.Pallavi	T.Ramya	K.V.Nagendra Kumar
Department	Quality Assurance	Quality Assurance	Quality Assurance

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5.2.4 Based on the one year supply & Quality data retrospective qualification shall Performed for General raw materials and Packing materials for which initial qualification is not performed.

5.2.5 Primary packing materials re qualification audit shall be performed once in 3 years±3months.

### 5.3 Vendor Audit:

5.3.1 The approved vendors for KSM shall be audited once in every three years or when ever required.

5.3.2 Purchase department shall coordinate with QA and attend the vendor audit with customer.

5.3.3 Quality Assurance shall co-ordinate vendor audit activity.

5.3.4 The audit team shall visit the facility of the vendor and carry out an audit of all the relevant departments in accordance with the audit checklist.

5.3.5 The vendor shall give the corrective and preventive action for the non-conforming issues and such reports can be closed based on satisfactory review during re-visit or satisfactory response from vendor.

5.3.6 In case any raw material is supplied through customers (CMU) mode, follow as below:

5.3.7 Samples are not required.

5.3.8 Based on raw material COA, enter the manufacturer details in new vendor evaluation and no need to conduct full study analysis at QC (any material).


5.3.9 Request customer to share the Vendor qualification documents.

5.3.10 Follow customer instructions in case of any observed.

5.3.11 Overseas manufacturers shall be qualified based on Vendor Questionnaire and TSE/ BSE declaration. Vendor audits shall be performed on need basis.

### 5.4 De-listing Procedure:

	<b>Prepared by</b>	<b>Reviewed by</b>	<b>Approved by</b>
Sign & Date			
Name	R.Pallavi	T.Ramya	K.V.Nagendra Kumar
Department	Quality Assurance	Quality Assurance	Quality Assurance


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- 5.4.1 Quality Assurance Department shall compile a report on vendor analysis on a yearly basis.
- 5.4.2 If the annual vendor analysis data shows that more than 10% of the batches are rejected when there are minimum 30 supplies or above then such vendors shall be removed from Approved Vendors List.
- 5.4.3 If the Raw materials not procured from approved vendor for last 3 years, then remove this vendor from Approved Vendor List and add in Block vendor List.
- 5.4.4 In case re-supply to be required from the Block listed vendor shall re-qualify the same vendor as per procedure.
- 5.4.5 In case material is to be procured from non-qualified vendors, the vendor shall be re-qualified based on proper justification report.

## 6.0 FORMATS/ ANNEXURE(S):

- 6.1 Approved Vendor list : QA016-FM013
- 6.2 Free samples inward register : QA016-FM059
- 6.3 Vendor Questionnaire for KSM : QA016-FM060
- 6.4 Vendor Audit check list : QA016-FM061
- 6.5 Vendor Evaluation record for the year : QA016-FM062
- 6.6 New Vendor Evaluation record : QA016-FM063
- 6.7 Statement on residual solvents : QA016-FM065
- 6.8 Supplier Document Checklist for Key starting materials/  
Critical materials : QA016-FM066
- 6.9 Supplier Document Checklist for other materials : QA016-FM067
- 6.10 GMP Statement : QA016-FM068
- 6.11 Letter of undertaking : QA016-FM069
- 6.12 TSE/BSE declaration/ (Template) : QA016-FM070
- 6.13 Vendor Questionnaire for General raw Materials. : QA016-FM137

	<b>Prepared by</b>	<b>Reviewed by</b>	<b>Approved by</b>
Sign & Date			
Name	R.Pallavi	T.Ramya	K.V.Nagendra Kumar
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6.14 Vendor Questionnaire for packing Materials.

: QA016-FM138

6.15 Block vendor list


: QA016-FM173

## 7.0 CHANGE HISTORY:

Revision No.	Effective Date	Details of Revision	Ref CCF No.
00	01.06.2007	New SOP is introduced	--
01	01.07.2009	SOP format changed and reviewed for more clarity	--
02	01.07.2012	Separate approved vendor list format has been revised to include the manufacturer address for more clarity	--
03	01.01.2013	SOP was revised with more clarity	--
04	15.06.2014	Sub contractor assessment& Transportation Agency/Transporter Removed	--
05	02.11.2015	General raw materials& packing materials procedure included.	--
06	21.03.2016	Revised as per current format & More clarity.	--
07	01.03.2018	1. SOP format changed make to inline with SOP-QA-001-05. 2. De-listing procedure is incorporated 3. Block vendor list format incorporated 4. All together procedure has been rephrased for better clarity.	CCF/GEN/18006
08		Primary packing materials re qualification audit shall be performed once in 3years ±3months.	CCF/GEN/22003

	Prepared by	Reviewed by	Approved by
Sign & Date			
Name	R.Pallavi	T.Ramya	K.V.Nagendra Kumar
Department	Quality Assurance	Quality Assurance	Quality Assurance

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	<b>Prepared by</b>	<b>Reviewed by</b>	<b>Approved by</b>
Sign & Date			
Name	R.Pallavi	T.Ramya	K.V.Nagendra Kumar
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