PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

QUALITY RISK ASSESSMENT & MITIGATION PLAN

FAILURE MODE EFFECT ANALYSIS FOR VENDOR APPROVAL & EVALUATION

Reference Document No.:	**Risk Assessment No.:**

RISK ASSESSMENT

FOR

VENDOR APPROVAL AND EVALUATION

QUALITY RISK ASSESSMENT & MITIGATION PLAN

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1.0 PRE APPROVAL:

The Author's signature indicates that the document has been prepared in accordance with existing cGMP standards and adequately reflects the tasks and deliverables necessary for Risk Assessment of Process / System / Equipment / Instrument.

Prepared by/ Function	Designation	Signature	Date

The reviewer's signature indicates that, this document has been reviewed and it accurately and completely reflects the tasks and deliverables necessary for risk assessment of the Process / System/Equipment/Instrument and that the documentation and information included compiles with applicable regulatory/departmental requirements and current Good Manufacturing Practices.

Reviewed By/ Function	Designation	Signature	Date
Department Head (Initiating Department)			
Regulatory Affairs			
Quality Assurance			

The approver's signature indicates that the documentation and information contained herein complies with applicable regulatory/departmental requirements and current Good Manufacturing Practices.

Approved By / Function	Designation	Signature	Date
Quality Assurance			

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2.0 OVERVIEW:

2.1 Objective

The objective of the risk assessment is to identify different risks involved in the procedure of vendor approval and evaluation and to evaluate the impact of the risk on the quality product / patient, propose the corrective action and preventive action to mitigate / reduce the level of risk.

2.2 Scope

The scope of the risk assessment is restricted to vendor approval and evaluation.

3.0 REASON FOR RISK ASSESSMENT

The risk assessment shall be performed for following reason (√)

- New / Modification of Product / Process/ System / Equipment / Instrument

  Vendor Approval and Evaluation

- Inclusion of additional parameters in Risk assessment
- Others (Specify)

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4.0 TEAM MEMBERS:

Following team members have been involved in the brain storming session of the risk management of this activity.

Date: _____ **Time: _____** **Venue: _____**

Sr. No.	Name	Designation	Signature
1.			
2.			
3.			
4.			
5.			
6.			
7.			
8.			
9.			
10.			

The details of the discussion of the risk management of the activity, including the process flow of the activity, identification of the risks involved in the activity and corrective action and preventive action of the risk involved in the activity shall be recorded in section 5, 7 & 8.

After implementation of CAPA, the risk shall be recalculated and ensured to be at the acceptable level (Low).

Prepared By : _____ **Date : _____**

Reviewed By : _____ **Date : _____**

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5.0 ACTIVITY: (PROCESS / SYSTEM / EQUIPMENT / INSTRUMENT):

Specify the activities wherein the risk assessment is required. (Tick the appropriate box)

Process	☐
System	☑
Equipment / Instrument	☐
Others: _____	☐

Description:

This Risk assessment is prepared to identify different risks involved in vendor approval and evaluation procedure and to evaluate the impact of the risk on the quality of product.
SOP Vendor Approval and Evaluation is available for approval and evaluation of vendors.

Procedure covers the details related to following

1. **Qualification of vendors used for the R & D batches**
2. **Qualification of vendors for the commercial batches**
3. **Introduction of new vendors**
4. **Vendor Audit Checklist**
5. **Approved Manufacturer (Material Part Number {MPN functionality})**
6. **Exclusion of vendor**
7. **Periodic Evaluation of Vendor**

The qualification of vendors for commercial batches is based on the filled questionnaire, vendor audit (if applicable), analytical reports and stability data of the R&D batches.

The vendor is included in the vendor list for commercial manufacturing, if the evaluation is satisfactory. Periodic evaluation of vendor's performance is done as per procedure. The vendor shall be disqualified based on criteria's given in SOP. The information on exclusion of vendor shall be recorded by QA and Approved Manufacturer List shall be updated (BLOCKED) in SAP.

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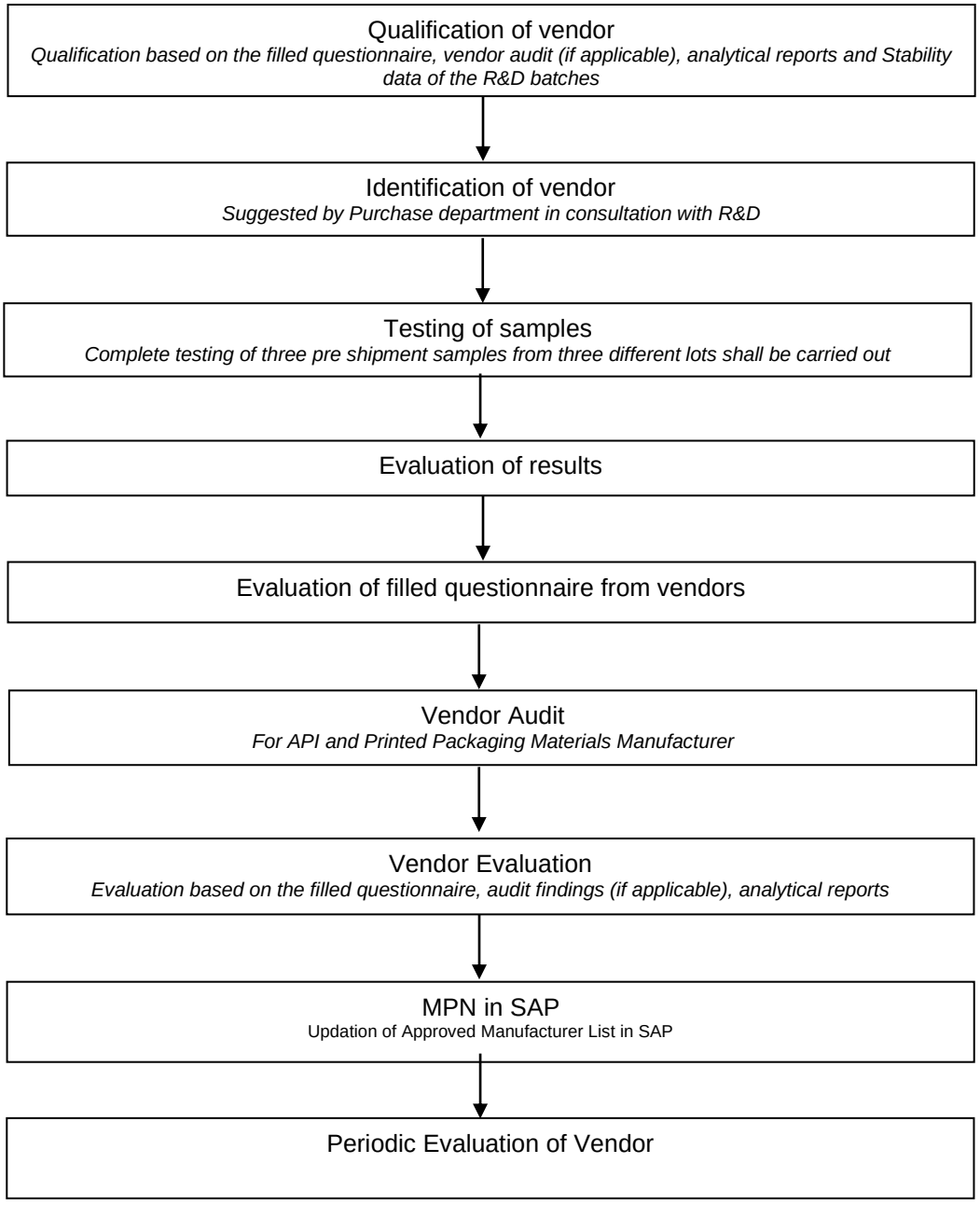
Process Flow:



6.0 DEFINITIONS AND METHODOLOGY:

6.1 Severity of impact:

Identify the severity of impact of the risk on the quality of the product/service. Categorize the severity of impact of risk as Fundamental / High / Moderate / Minor / Insignificant as defined below and put score against each risk at section 7.0.

Category	Description	Score
Fundamental	Very significant and catastrophic impact	5
High	Significant losses and inefficiencies, necessitating timely adressal	4
Moderate	Loss of operating capability, deterioration of efficiency, management intervention required	3
Minor	Impact on operations and efficiency, but not pervasive	2
Insignificant	Limited or no impact on operations and quality of operational efficiency	1

6.2 Occurrence:

Identify the probability of occurrence of risk based on the occurrence frequency and put score against each risk at step 7.0.

Category	Probability of Occurrence	Description	Score
Almost certain	> 90 %	Is expected to occur in most circumstances	5
Likely	60-89 %	Will probably occur in most circumstances	4
Possible	25-59 %	Will probably occur at some time	3
Unlikely	10-24 %	Could occur at some time	2
Rare	< 10 %	May occur in exceptional circumstances	1

6.3 Detection:

Identify the level of detection of risk and give rating as below,

Category	Description	Score
Not aware/ No Control exists	Insufficient information to adequately assess and rate the control	5
Non existent / Very Little chance of detection	No procedural system in place, no risk reduction process procedure in place.	4
Not effective / Likely to be detected	Mitigation plans or risk reduction process & procedures though in place but do not ensure adequate control over risk occurrence / impact as the risk still exists over its acceptance level.	3
Effective / very likely to be detected	Approved Mitigation plans or risk reduction procedures, Checklists are laid down for early detection & immediate corrective actions are taken.	2
Very Effective / 100 % likelihood of detection	Mitigation plans or risk reduction process & procedures involve stringent approval and reporting norms with responsibility duly mapped to various management levels, minimizing possibility of occurrence / optimizing protection in the case of occurrence of the same at very early stage, controlling and reducing the risk.	1

Risk Ranking: Calculate the total score for the particular risk by multiplying the scores of Severity of impact, Occurrence and Detection

Categorize the risk as Low risk, Medium risk or high risk, as follow

RISK LEVEL	OBTAINED SCORE
HIGH RISK	125 to 64
MEDIUM RISK	Below 64 to 27
LOW RISK	Below 27

Upon evaluation of the risk, elaborate the methodology for notification of the risk, responsibility for the handling of risk and Corrective action, Preventive action (CAPA) plan for the identified risk.

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Note: In addition to RPN No. calculation.

a. If any parameter is having severity as 'Fundamental or High' (i.e. 4 or 5 scale number) then final risk level should be decided as 'High' irrespective of RPN number.

b. If any parameter is having severity as 'Moderate' (i.e. 3 scale number) then final risk level should be decided as at least 'Medium' unless and otherwise the risk is classified as High with RPN greater than 64.

- Criteria 'a' & 'b' are applicable at the stage of identification of risk whereas after mitigation control the final risk level should be confirmed on the basis of RPN number only irrespective of individual severity scale.

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7.0 IDENTIFICATION OF RISK INVOLVED:

Sr. No.	Description of Risk	Risk Involved	Severity of the impact (S)	Occurrence (O)	Detection (D)	Risk Priority No. (S x O x D)	Risk Category	Remarks
1	Vendor approval status is not clear	Receipt and usage of material from unapproved manufacturer	4	2	1	8	High	Risk is classified as high as score of severity of impact is 4
2	SOP of Vendor approval and evaluation not followed during routine operation	Receipt and usage of material from unapproved manufacturer	4	2	1	8	High	Risk is classified as high as score of severity of impact is 4
3	Periodic evaluation of Vendor not done	Compliance status of vendor shall not be known	3	2	2	12	Medium	Risk is classified as medium as score of severity of impact is 3
4	Use of blocks, plates, cylinders, stereos, silk screens and other items related to old art works by vendor.	Possibility of use of items with old artwork.	4	2	1	8	High	Risk is classified as high as score of severity of impact is 4
5	Any changes related to manufacturing process of material not communicated by vendor	Possibility of impact on specification. Impact on quality of material and product. Rejection of material at site.	4	2	2	16	High	Risk is classified as high as score of severity of impact is 4

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Sr. No.	Description of Risk	Risk Involved	Severity of the impact (S)	Occurrence (O)	Detection (D)	Risk Priority No. (S x O x D)	Risk Category	Remarks
6	Changes in the material specification by the vendor without prior intimation	Impact on quality of material and product. Rejection of material at site.	4	2	2	16	High	Risk is classified as high as score of severity of impact is 4
7	Blockage of disqualified vendor in the system (SAP) is not done.	Receipt of material from disqualified vendor.	4	2	1	8	High	Risk is classified as high as score of severity of impact is 4

Prepared By : _____ **Date** : _____

Reviewed By : _____ **Date** : _____

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8.0 NOTIFICATION AND CAPA:

8.1 NOTIFICATION AND CAPA OF HIGH RISK:

Risk	Risk Involved	Total Score	Incidence Notification	Corrective action	Preventive action	Responsibility	Remarks
Vendor approval status is not clear	Material receipt from unapproved vendor / Manufacturer. Usage of material from unapproved manufacturer.	8	QA, QC Warehouse, Purchase, Production	As per SOP of Vendor and Evaluation, every manufacturer API, Excipient and Packing Material is approved before receipt of material. After approval and evaluation of vendor as per SOP Vendor and Evaluation, name of manufacturer is added in approved manufacturer list through MPN functionality.	As per MPN functionality mentioned in the SOP of Vendor and Evaluation, Purchase order for specified material can only be created, after inclusion of manufacturer in approved manufacturer list. As per SOP of Receipt and Storage of Raw Material, warehouse personnel has to verify the every consignment against the approved manufacturer list for verification of manufacturer name and address. As per of Sampling of Raw Materials sampling personnel has to verify the vendor COA against the approved manufacturer list before	QA, QC Warehouse, Purchase, Production	-

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Risk	Risk Involved	Total Score	Incidence Notification	Corrective action	Preventive action	Responsibility	Remarks
					sampling of materials.		
SOP of Vendor approval and evaluation not followed during routine operation	Receipt and usage of material from unapproved manufacturer	8	QA, QC Warehouse, Purchase, Production	Relevant personnel's involved in approval of manufacturer are trained on the SOP of Vendor Approval and Evaluation. Personnel involved in receipt of material are trained on the SOP of Receipt and Storage of Raw Materials Personnel's involved in sampling and testing of material are trained on the SOP Sampling of Raw Materials	As per MPN functionality mentioned in the SOP of Vendor and Evaluation, Purchase order for specified material can only be created, after inclusion of manufacturer in approved manufacturer list. Access for MPN creation i.e. addition of material in approved manufacturer list in SAP is restricted to authorized and trained Quality Assurance personnel's only.	QA, QC Warehouse, Purchase, Production	-
Use of blocks, plates, cylinders, stereos, silk screens and other items related to old art works by	Possibility of receipt and use of items with old artwork	8	Purchase, Warehouse, QC, Production, QA	As per procedure of Vendor Approval and Evaluation, printed packing material manufacturers are checked for procedure of handling blocks, plates, cylinders, stereos, silk screens and other items.	Purchase department shall inform vendor for destruction of blocks, plates, cylinders, stereos, silk screens and other items related to old art works and also take declaration from vendor that the same has been destroyed and keep the record.	Purchase, Warehouse, QC, Production, QA	-

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Risk	Risk Involved	Total Score	Incidence Notification	Corrective action	Preventive action	Responsibility	Remarks
printed packaging material vendors.				Vendor shall be communicated about the blocks, plates, cylinders, stereos, silk screens and other items related to old art works and to discontinue the same. Controlled copy of artwork along with its process file (soft copy) shall be issued to Purchase Department for issuance to respective vendors. Vendor shall follow the same. Procedure for control of Artworks and Printed Packaging Components is in place as per SOP for "Preparation, review & approval of artworks for all printed packaging material".	This is being followed as per SOP for "Preparation, review & approval of artworks for all printed packaging material". Old art works printed packing material available in warehouse are destroyed before implementation of new art work.		

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Risk	Risk Involved	Total Score	Incidence Notification	Corrective action	Preventive action	Responsibility	Remarks
Any changes related to manufacturing process of material not communicated by vendor	Possibility of impact on specification. Impact on quality of material and product. Rejection of material at site.	16	QA, Purchase	A commitment shall be taken from each vendor to provide the periodic updates of any changes and updates to the manufacturing process, material specifications and manufacturing area or site. The declarations will be sought from the Vendor periodically and prior to / upon any changes for the manufacturing process, material specification or manufacturing area or site. This is being followed as per SOP for “Vendor approval and evaluation”..	Periodic evaluation and qualification of all vendors are done as a part of SOP “Vendor approval and evaluation”..	QA, Purchase	-
Changes in the material specification by the vendor without prior intimation.	Impact on quality of material and product. Rejection of material at site.	16	QC QA Production	A commitment shall be taken from each vendor to provide the periodic updates of any changes and updates to the manufacturing process, material specifications and manufacturing area or site. The	Periodic evaluation and qualification of all vendors are done as a part of SOP “Vendor approval and evaluation”..	QC QA Production	-

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Reference Document No.: | **Risk Assessment No.:**

Risk	Risk Involved	Total Score	Incidence Notification	Corrective action	Preventive action	Responsibility	Remarks
				declarations will be sought from the Vendor periodically and prior to / upon any changes for the manufacturing process, material specification or manufacturing area or site. This is being followed as per SOP for "Vendor approval and evaluation"..			
Blockage of disqualified vendor in the system (SAP) is not done.	Receipt of material from disqualified vendor. Use of material for manufacturing of product.	8	QA Warehouse QC Production Purchase	Disqualified vendor in the system shall be blocked. This is being done by QA.	Updation of Approved manufacturer list in SAP is done by QA as per SOP for "Vendor approval and evaluation".	QA	-

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8.2 NOTIFICATION AND CAPA OF MEDIUM RISK*:*

Risk	Risk Involved	Total Score	Incidence Notification	Corrective action	Preventive action	Responsibility	Remarks
Periodic evaluation of Vendor not done	Compliance status of vendor shall not be known	12	Quality Assurance	As per SOP Vendor Approval and Evaluation periodic evaluation of vendors are done at periodic frequency.	Personnel's involved in the approval of vendors are trained on the SOP Vendor Approval and Evaluation.	Quality Assurance	-

Prepared By : _____ **Date** : _____

Reviewed By : _____ **Date** : _____

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8.2 NOTIFICATION AND CAPA OF MEDIUM RISK:

Risk	Risk Involved	Total Score	Incidence Notification	Corrective action	Preventive action	Responsibility	Remarks

Prepared By : _____ **Date** : _____

Reviewed By : _____ **Date** : _____

8.3 NOTIFICATION AND CAPA OF LOW RISK :

Risk	Risk Involved	Total Score	Incidence Notification	Corrective action	Preventive action	Responsibility	Remarks

Prepared By : _____ **Date** : _____

Reviewed By : _____ **Date** : _____

8.4 MITIGATION CONYROL& RE-EVALUATION OF IDENTIFIED RISKS AFTER IMPLEMEMNTATION OF CAPA:

S.No.	Description of Risk	Mitigation Control Reference Documents	Severity of the impact (S)	Occurrence (O)	Detection (D)	Risk Priority No. (S x O x D)	Risk Category	Verified By (Sign & Date)
1	Vendor approval status is not clear	Every manufacturer of API, Excipient and Packing Material is approved before receipt of material. After approval and evaluation of vendor as per SOP Vendor and Evaluation, name of manufacturer is added in approved manufacturer list through MPN functionality Personnel's are trained on following SOP's • SOP of Vendor and Evaluation • SOP of Receipt and Storage of Raw Material • Sampling of Raw Materials	4	2	1	8	Low	

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S.No.	Description of Risk	Mitigation Control Reference Documents	Severity of the impact (S)	Occurrence (O)	Detection (D)	Risk Priority No. (S x O x D)	Risk Category	Verified By (Sign & Date)
2	SOP of Vendor approval and evaluation not followed during routine operation	Relevant personnel's involved in approval of manufacturer are trained on the SOP of Vendor Approval and Evaluation. Personnel involved in receipt of material are trained on the SOP of Receipt and Storage of Raw Materials Personnel's involved in sampling and testing of material are trained on the SOP Sampling of Raw Materials	4	2	1	8	Low	

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S.No.	Description of Risk	Mitigation Control Reference Documents	Severity of the impact (S)	Occurrence (O)	Detection (D)	Risk Priority No. (S x O x D)	Risk Category	Verified By (Sign & Date)
3	Use of blocks, plates, cylinders, stereos, silk screens and other items related to old art works by printed packaging material vendors.	Vendor shall be communicated about the blocks, plates, cylinders, stereos, silk screens and other items related to old art works and to discontinue the same. Controlled copy of artwork along with its process file (soft copy) shall be issued to Purchase Department for issuance to respective vendors. Vendor shall follow the same. Relevant personnel's are trained on the • SOP of Vendor Approval and Evaluation. • SOP for "Preparation, review & approval of artworks for all printed packaging material".	4	2	1	8	Low	

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S.No.	Description of Risk	Mitigation Control Reference Documents	Severity of the impact (S)	Occurrence (O)	Detection (D)	Risk Priority No. (S x O x D)	Risk Category	Verified By (Sign & Date)
4	Any changes related to manufacturing process of material not communicated by vendor	A commitment being taken from each vendor to provide the periodic updates of any changes and updates to the manufacturing process, material specifications and manufacturing area or site. Periodic evaluation and qualification of all vendors are done as a part of SOP “Vendor approval and evaluation”..	4	2	2	16	Low	
5	Changes in the material specification by the vendor without prior intimation.	A commitment being taken from each vendor to provide the periodic updates of any changes and updates to the manufacturing process, material specifications and manufacturing area or site.	4	2	2	16	Low	
6	Blockage of disqualified vendor in the system (SAP) is not done.	Updation of Approved manufacturer list in SAP is done by QA as per SOP for “Vendor approval and evaluation”.	4	2	1	8	Low	

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S.No.	Description of Risk	Mitigation Control Reference Documents	Severity of the impact (S)	Occurrence (O)	Detection (D)	Risk Priority No. (S x O x D)	Risk Category	Verified By (Sign & Date)
7	Periodic evaluation of Vendor not done	Personnel's involved in the approval of vendors are trained on the SOP Vendor Approval and Evaluation.	3	2	2	12	Low	

9.0 TRAINING AND EVALUATION RECORD:

Date :	Timing : From _____ to_____
Venue :	Name of Trainer :
Title : Risk Assessment	Method of training:

S. No.	Name of Employee	Employee Code	Evaluation Details	
			Signature of Trainee	Remarks

Signature of Trainer (Sign/Date): _____

Comments:

_____

_____

_____

Verified By: _____ Date : _____

10.0 SUMMARY AND CONCLUSION:

10.1 Evaluation of Data:

Risk analysis conducted to identify different risks involved in vendor approval and evaluation. Seven risks identified for system 'Vendor evaluation and approval'. Six high risks and one medium risk identified.

Following data and relevant current procedures related to 'vendor approval and evaluation' evaluated

1. SOP of Vendor and Evaluation
2. SOP of Receipt and Storage of Raw Material
3. Sampling of Raw Materials
4. SOP for "Preparation, review & approval of artworks for all printed packaging material"
5. Training records of personnel involved in vendor approval and evaluation activity .

Based on evaluation of data, control measures to avoid the risk found adequate and in place.

10.2 Mitigation Plan:

Current control measures to avoid the risk found adequate and in place. After evaluation of current control measures, identified risks now categorized as low risk

10.3 Evaluation of Risk Involved after Mitigation Control:

Not Applicable

10.4 Summary:

Risk assessment is performed to identify different risks involved in vendor approval and evaluation and to evaluate the impact of the risk on the quality of product.

Risks involved in the system were identified and categorized. Identified risks were allotted scores for parameters like severity of impact, occurrence of risk and probability of detection. Each risk has been categorized as High, Medium and Low risk as follows:

High Risk:

Six High Risks are identified for system 'Vendor approval and evaluation'.

1. Vendor approval status is not clear
2. SOP of Vendor approval and evaluation not followed during routine operation
3. Use of blocks, plates, cylinders, stereos, silk screens and other items related to old art works by printed packaging material vendors

4. Any changes related to manufacturing process of material not communicated by vendor.
5. Changes in the material specification by the vendor without prior intimation.
6. Blockage of disqualified vendor in the system (SAP) is not done.

Medium Risk:

One Medium Risk is identified for system 'Vendor approval and evaluation'

1. Periodic evaluation of Vendor not done

Each of the above risk has been evaluated and corrective and preventive action put in place. Current control measures to avoid the risk found adequate and in place. Training has been imparted to the concerned personnel for risk management.

10.5: Conclusion:

Risk involved in 'vendor approval and evaluation' evaluated and found that current control measures are adequate and in place to avoid the risk.

Identification, Categorization, Corrective and Preventive action (CAPA) & Training of risks listed above has provided guidelines to manage vendor approval and evaluation activity efficiently, effectively and safely as per the cGMP requirements.

Prepared By : _____ **Date** : _____

Reviewed By : _____ **Date** : _____

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11.0 REFERENCE DOCUMENTS:

S.No.	Title

Reviewed By : _____ Date : _____

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12.0 ABBREVIATION:

S.No.	Abbreviation	Description

Reviewed By : _____ Date : _____

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13.0 ATTACHMENTS:

S.No.	Description

Reviewed By : _____ Date : _____

14.0 COMPLIANCE VERIFICATION:

S.No..	DESCRIPTION	COMPLIANCE (Y/N)	VERIFIED BY

Reviewed By : _____ Date : _____

15.0 POST APPROVAL:

This is hereby certified by the following functionaries, that the risk assessment of the activity in the department stands qualified for its intended purpose.

The reviewer's signature indicates that, this document has been reviewed and it accurately and completely reflects the tasks and deliverable necessary for risk management and all associated equipment/instruments and systems and that the documentation and information included complies with applicable regulatory / departmental requirements and current Good Manufacturing Practices.

Reviewed By/ Function	Designation	Signature	Date
Department Head (Initiating Department)			
Regulatory Affairs			
Quality Assurance			

The approver's signature indicates that the documentation and information contained herein complies with applicable regulatory/departmental requirements and current Good Manufacturing Practices.

Approved By/ Function	Designation	Signature	Date
Quality Assurance			