PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

QUALITY RISK ASSESSMENT & MITIGATION PLAN

FAILURE MODE EFFECT ANALYSIS FOR DIFFERENT API VENDOR'S USED IN COMMERCIAL BATCHES

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

FAILURE MODE EFFECT ANALYSIS FOR DIFFERENT API VENDOR'S USED IN COMMERCIAL BATCHES

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

QUALITY RISK ASSESSMENT & MITIGATION PLAN

FAILURE MODE EFFECT ANALYSIS FOR DIFFERENT API VENDOR'S USED IN COMMERCIAL BATCHES

Reference Document No.:	Risk Assessment No.:

1. **OBJECTIVE:** To provide the documented evidence that there is low level of risk in case of "Different API vendors used in commercial batches".

2. **SCOPE:** The scope of this document is limited to manufacturing areas at facility.

3. **RESPONSIBILITY:**

DEPARTMENT	RESPONSIBILITY
Quality Assurance	• Preparation, Review, and Compilation of FMEA • Post Approval of FMEA
Warehouse	• Review of FMEA
Production	• Review of FMEA

4. **REASON FOR RISK ANALYSIS:**
   To mitigate & monitor the risk associated with the "Different API vendors used in commercial batches".

5. **SITE OF STUDY:**

6. **RISK COMMUNICATION & TRAINING:**
   - The Risk analysis team shall be authorized by the Head-QA or his/her designee.
   - Quality Risk Management Team shall be cross functional team comprised of expert from different areas.
   - Training shall be imparted to the concerned team.

QUALITY RISK ASSESSMENT & MITIGATION PLAN

FAILURE MODE EFFECT ANALYSIS FOR DIFFERENT API VENDOR'S USED IN COMMERCIAL BATCHES

Reference Document No.:	Risk Assessment No.:

7. RISK IDENTIFICATION, EVALUATION & MITIGATION:

Failure Modes, Effects Analysis (FMEA) is the methodology designed to identify potential failure modes for a product or process, to assess the risk associated with those failure modes, to rank the issues in terms of importance and to identify and carry out corrective actions to address the most serious concerns.

RISK IDENTIFICATION	RISK EVALUATION	RISK MITIGATION
There is a risk of usage of different vendors in commercial batches which may further result into failure of finished product.	After risk identification, it has been evaluated that risk of using different vendor API in commercial batches is high and there is a chance of product failure if not well monitored &mitigated timely.	• Approved vendor list is in place. • Material received as per procedure. • Standard Testing Procedure is in place. • Critical Quality parameters & attributes are verified. • Finish product complies as per specification. • Comparison study of both vendors available.

QUALITY RISK ASSESSMENT & MITIGATION PLAN

FAILURE MODE EFFECT ANALYSIS FOR DIFFERENT API VENDOR'S USED IN COMMERCIAL BATCHES

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

8. RISK ASSESSMENT TOOL:

In the following section a table is produced for the risk analysis using FMEA tool. The significance or instruction for each column is described in the following paragraph.

Column 1	Serial number of Risk Analysis item.
Column 2	Item/Function: Identify the process step or component associated with the risk.
Column 3	Potential Failure Mode: Identify the type of risk associated with the process or component.
Column 4	Potential Cause
Column 5	Effect of Potential Failure/Cause: Verify that whether risk have GMP impact.
Column 6	Risk Mitigation: Write the risk mitigation strategy as considered in design.
Column 7	References
Column 8/9/10/11	Severity/Occurrence/Detection/Risk level/Risk Acceptance: Risk Priority Number to be calculated by taking Severity, Occurrence & Detection of potential failure into consideration.
Column 12	Recommended action: Recommended actions should be given for controlling failure occurrence.
Column13/14/15/16	Severity/Occurrence/Detection/Risk level/Risk Acceptance: After recommendation implementations, Risk Priority Number to be calculated by taking Severity, Occurrence & Detection of potential failure into consideration.

Table 1: Instruction for each column given above

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

QUALITY RISK ASSESSMENT & MITIGATION PLAN

FAILURE MODE EFFECT ANALYSIS FOR DIFFERENT API VENDOR'S USED IN COMMERCIAL BATCHES

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

Name of Facility/Equipment/Utility/System/Activity/Procedure/UnitOperation**:** Different API vendors used in commercial batches	**Quality Risk Assessment Date**:

S.No.	Item/Function	Potential Failure Mode (Failure Mode)	Potential Effect of Failure	Potential Cause/ Mechanism of Failure	Current Control	Reference Document No.	S	O	D	RPN (SxOxD)	Recommended Actions (if any)	Post Risk Evaluation			
												S	O	D	RPN (SxOxD)
1.	Different API vendors used in Process commercial batches	• Process validation process not available.	• Inadequate critical parameters & manufacturing process controls. • Product failure. • Market complaint	• Written procedure (SOP) is not available.	• SOP is in place	SOP No.: "Process Validation"	3	2	1	6	NA	**NA**	**NA**	**NA**	NA
		• Unapproved vendor		• Approved vendor list not available at site • Approved Vendor procedure is not in place	• Approved vendor list is in place and all 03 vendors are approved as per approved vendors list. • Approved vendor procedure is in place. • Procedure for "Receipt of Raw materials in warehouse is in place. • Procedure is available for verification of raw material like batch information, vendor name, material grade etc during preparation of GRN.	SOP No.: "Vendor Qualification" SOP No.: "Receipt of Raw material in Warehouse"	3	1	1	3	NA	**NA**	**NA**	**NA**	NA

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

QUALITY RISK ASSESSMENT & MITIGATION PLAN

FAILURE MODE EFFECT ANALYSIS FOR DIFFERENT API VENDOR'S USED IN COMMERCIAL BATCHES

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

S.No.	Item/Function	Potential Failure Mode (Failure Mode)	Potential Effect of Failure	Potential Cause/ Mechanism of Failure	Current Control	Reference Document No.	S	O	D	RPN (SxOxD)	Recommended Actions (if any)	Post Risk Evaluation			
												S	O	D	RPN (SxOxD)
		• Raw material not complies with specification • Finish product & in process parameters not complies with specification • Vendor not freeze for the particular API		• Procedure of Testing for raw material is not in place • Finish product testing procedure is not in place • Both vendors have different specification	• Procedure of Testing for raw material is in place and used in batches after complete testing. • All critical quality attributes and process parameters are well within limit. • Finish product compiles with specification. • Comparison have been performed of both the vendors' material specifications and concluded that both vendors' specifications are same and material complies as per specifications.	STS and STP Finish COA Comparison data sheet	3	1	1	3	NA	NA	NA	NA	NA

Table 2: The above table shows Potential failure mode, effect of potential failure along with Risk Probable Number, Risk Mitigation & Recommended Actions.

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

QUALITY RISK ASSESSMENT & MITIGATION PLAN

FAILURE MODE EFFECT ANALYSIS FOR DIFFERENT API VENDOR'S USED IN COMMERCIAL BATCHES

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

Assessment of Severity, Occurrence and Detection:

Severity Effect	Likelihood Occurrence	Likelihood of Detection	Rating
No Effect	Unlikely	Always Detected	1
Moderate Effect	Possible	Might Detect Failure	2
Serious Effect	Almost Certain (Every time)	Lack of Detection Control	3

Evaluation of RPN:

RPN Rating	Category
12 to 27	High
7 to 11	Medium
Up to 6	Low

S.No.	Recommended Action	Responsible Person	Target Date of Completion
1.	NA	NA	NA

CAPA (Required/Not Required): Not Required

If required, mention CAPA No.: ……..

Quality Risk Management Team			Reviewed By Head Operations (Sign & Date)	Approved By Head QA (Sign & Date)
Name	**Department**	**Sign & Date**		

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

QUALITY RISK ASSESSMENT & MITIGATION PLAN

FAILURE MODE EFFECT ANALYSIS FOR DIFFERENT API VENDOR'S USED IN COMMERCIAL BATCHES

Reference Document No.:	Risk Assessment No.:

Verification of Recommended Action:

……..
……..
……..
……..

Remarks (if any):

……..
……..
……..
……..
……..
……..

Verified By
Operating Person QA
(Sign & Date)

Approved By
Head QA
(Sign & Date)

QUALITY RISK ASSESSMENT & MITIGATION PLAN

FAILURE MODE EFFECT ANALYSIS FOR DIFFERENT API VENDOR'S USED IN COMMERCIAL BATCHES

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

9. REFERENCES:

- Reference SOP of Risk Assessment
- https://ispe.org/pharmaceutical-engineering/ispeak/osd-gowning-procedures-knowledge-brief.

10. DOCUMENTS TO BE ATTACHED:

Not Applicable

11. DEVIATION FROM PRE DEFINED SPECIFICATION, IF ANY:

……
……
……

12. CHANGE CONTROL, IF ANY:

……
……
……
……
……

13. ABBREVIATIONS:

FMEA	:	Failure Mode Effect Analysis
RPN	:	Risk Priority Number
CAPA	:	Corrective action preventive action
SOP	:	Standard Operating Procedure
QRM	:	Quality Risk Management
QA	:	Quality Assurance

QUALITY RISK ASSESSMENT & MITIGATION PLAN

FAILURE MODE EFFECT ANALYSIS FOR DIFFERENT API VENDOR'S USED IN COMMERCIAL BATCHES

Reference Document No.:	Risk Assessment No.:

14. FMEA APPROVAL:

PREPARED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OPERATING PERSON (QUALITY ASSURANCE)			

REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OPERATING MANAGER (QUALITY ASSURANCE)			
OPERATING MANAGER (WAREHOUSE)			
OPERATING MANAGER (PRODUCTION)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			