PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

FAILURE MODE EFFECT ANALYSIS FOR NEW VENODR INTRODUCED

:

S.No.	Potential Failure Mode	Potential Effect(process/end User) or Consequences	S	Contributory Factors	O	Current Control Measures	D	RPN (SXOXD)	RPN Rank
1	**Alteration in physicochemical properties of API**	Impact on the in-process attributes of ……. tablets	2	Alteration in physical characteristics may impact on the BD, TD, PSD which can lead alteration in compressibility index, so physical properties such as hardness, thickness, DT and friability.	**3**	As proposed material is received from approved vendor Physical attributes are checked during in-process checks by production as well as IPQA personnel as per frequency mentioned in batch document, , and process validation will also be carried out for assessment of change.	**2**	**12**	**Minor**
		Impact on release profile of said product	2	Variation in physical and chemical properties may impact on assay and dissolution of said product.	**2**	Next stage of processing will only be carried out after getting QC release of previous stage	**1**	**4**	**Minor**
		Impact on stability	3	Variation in physical and chemical properties may impact on long term stability	**2**	Stability studies will be carried out as per respective stability protocol.	**2**	**12**	**Minor**
2	**Item code will not be reflected in batch record & BOM sheet of ERP**	It my became difficult for getting root cause analysis of alteration in any quality attribute	3	BMR & MFR	**2**	Information for new item code will be incorporated in BMR, MFR and BOM present in ERP for said product.	**1**	**6**	**Minor**
		ERP will not be providing the provision for dispensing of ---------- with new item code.	3	BOM sheet in ERP	**3**	New item code will incorporated as additional item code.	**2**	**18**	**Minor**
						Overall RPN	**52**		

FAILURE MODE EFFECT ANALYSIS FOR NEW VENODR INTRODUCED

S- Severity, O- Occurrence rating, D-Detection rating, RPN Risk Priority Number

Compiled by (QA) Sign/Date	Approved By (HOD) Sign/Date	Authorised By (Head QA) Sign/Date