



PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

Department : Production

Item/Process/Product :

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

Date:

FMEA No.:

S.No	Potential Failure Mode	Potential Effect (process/end User) or Consequences	S	Contributory Factors	O	Current Control Measures	D	RPN (SXO XD)	RPN Rank
1	Difference in feeding mechanism	Die fill weight may change on change of feeding mechanism	2	35 station: Gravity feeder 45 station: Force feeder May lead to weight variation	2	Validation activity shall be performed to control the performance.	1	4	Validation to be conducted to check the robustness of the process.
2	Difference in tooling of compression machine	Different tooling lead to pressure change on rollers.	1	May lead to hardness and weight variation	2	Validation activity shall be performed for satisfactory parameters	2	4	
3	Number of compression machine station is different.	Impact of productivity.	2	Number of tablets/hr. would be change.	3	Machine speed(Turret)RPM) shall be validated for consistent results	1	6	
4	Change in machine	Physical parameters may not comply with the specification	3	Hardness , thickness Variation may observed, - which can lead directly change in disintegration time	2	All parameters shall be monitored carefully during initial setting of validation batches after that BMR Shall be revised accordingly.	1	6	
							Overall RPN	20	