



PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

Department :
Item/Process/Product: Standard Batch size vs Small Batch Size

Date:
FMEA No.:

Risk Assessment of Standard Batch Size Vs. small batch size

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
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Standard Batch size

01	<ul style="list-style-type: none"> Approach for Batch Formula record prepared based on Quality design parameters. Failure Approach to identified Critical process parameter Failure Approach to identified the Critical material Attributes Failure Change of Product elements that are Dosage form, Pharmacokinetic 	<ul style="list-style-type: none"> Product failure at each stages Failure of Quality Target Product Profile. 	4	<ul style="list-style-type: none"> Product Critical Quality Attributes Failure Product Critical Process. Parameters Failure Product Critical material Attributes failure. Effect on product Quality/Safety/Efficacy for the patients Equipment Flow of process manufacture Cleaning procedure Environment condition Microbial monitoring of area 	3	<ul style="list-style-type: none"> Systematic approach to develop the formula by the R&D. Establish the Functional relationship that link with CMA/CPP to CQA Process control and sound science development by scientific literature, prior knowledge. ICH Q8 R2/ICH Q9 etc. Identification of CQA by validation batches and stability batches. 	2	24	
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	and Pharmacodynamics result may be very.					<ul style="list-style-type: none"> • Equipment are Qualified • Flow of process of manufacturing controlled by BMR • Cleaning process is validated. • Environment Monitoring of Temperature and RH as per existing SOP. • Microbial monitoring of area by settle plate method. 			
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Small Batch size



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02	<ul style="list-style-type: none"> Batch size change from standard batch size to small batch size lead to product Failure Product parameter not matches with register parameters. 	<ul style="list-style-type: none"> Product failure at each stage. May impact the performance of the machine. Failure of Quality Target Product Profile. Batch manufacturing process will be change. Process parameter not design hence intended result might be creating problem. 	2	<ul style="list-style-type: none"> Product Critical Quality Attributes Failure Equipment are qualified Product Critical Process Parameters Failure Product Critical material Attributes failure Effect on product Quality/Safety/Efficacy for the patients Equipment Flow of process manufacture Cleaning procedure Environment condition Microbial monitoring of area 	3	<ul style="list-style-type: none"> Flow of process of manufacturing controlled by BMR Preventive maintenance of machine done as per schedule. Cleaning process is validated. Environment Monitoring of Temperature and RH as per existing SOP Microbial monitoring of area by settle plate method. Cleaning SOP available Temperature and Humidity SOP in place. Identification of microbial 	2	12	



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				<ul style="list-style-type: none"> Change of batches size lead to product failure. Product formula remains unchanged. The changes affect the reproducibility and consistency of the product. Use of different size of equipment. Validation Protocol not available. Batch release and shelf life of product to be change. Stability study protocol to be change. Changes of manufacturing process 		<ul style="list-style-type: none"> contamination SOP in place. BMR remains same. No changes affect the reproducibility and consistency of the product Same equipment used for the manufacturing of batches. Validation protocol and report available. Stability product protocol and report available. No changes of manufacturing process 			

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



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Conclusion: Risk assessment has been performed to identify the potential failure mode at site which may impact the product quality.

All identified potential risk has been calculated for their risk label.

Risk label are minor hence change of batch size from standard to small batch size not impact the product quality.