

## PHARMA DEVILS QUALITY ASSURANCE DEPARTMENT

Departmen Item/Proces		Batch	size vs Small Batch Size				Date FME	e: A No.:	
			essment of Standard Batch Siz	e Vs. sn	nall batch size				
<ul> <li>Potential Failur</li> <li>Mode</li> </ul>	e Potential Effect (process/end User) or Consequences	otential Effect S Contributory O Curr process/end Factors M User) or			nt Control easures	D	RPN (SXO XD)		RPN Rank
			Standard Patch siz						
<ul> <li>Approach for Ba Formula record prepared based Quality design parameters. Failure</li> <li>Approach to identified Critica process parame Failure</li> <li>Approach to identified the Critical material Attributes Failur</li> <li>Change of Prod elements that an Dosage form, Pharmacokineti</li> </ul>	each stages • Failure of Quality Target Product Profile. • • • • • • • • • • • • •	4	Standard Batch siz         • . 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> <li>Systematic at to develop the formula by the Establish the Functional relationship with CMA/C CQA</li> <li>Process consound scient development scientific lited prior knowled ICH Q8 R2/ etc.</li> <li>Identification by validation and stability</li> </ul>	he he R&D. he that link PP to htrol and ce ht by erature, edge. /ICH Q9 h of CQA h batche	K A S	24	



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Department : Item/Process/Product: Standard Batch size vs Small Batch Size								Date: FMEA No.:				
	nem/Process/P			FIVIEA	INO.:							
S.	Potential Failure	Potential Effect	sk Asse S	Contributory		Current Control	D	RPN	RPN Rank			
No.	Mode	(process/end User) or Consequences		Factors		Measures		(SXO XD)				
		1		1				1				
	and					Equipment	are					
	Pharmacodynamics					Qualified						
	result may be very.					<ul> <li>Flow of pro</li> </ul>	cess of					
						manufactur	ing					
						controlled b	by BMR					
						Cleaning p	rocess is					
						validated.						
						Environme	nt					
						Monitoring	of					
						Temperatu	re and R	н				
						as per exis	ting SOP					
						<ul> <li>Microbial m</li> </ul>	onitoring					
						of area by s	settle					
						plate metho	od.					

Small Batch size



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S. No.	. Potential Failure Potential Effect S		ssment of Standard Batch Size V Contributory O O Factors		Curre	e Vs. small batch size Current Control D RPN RPN Ra Measures (SXO XD)								
02	<ul> <li>Batch size change from standard batch size to small batch size lead to product Failure</li> <li>Product parameter not matches with register parameters.</li> </ul>	<ul> <li>Product failure at each stage.</li> <li>May impact the performance of the machine.</li> <li>Failure of Quality Target Product Profile.</li> <li>Batch manufacturing process will be change.</li> <li>Process parameter not design hence intended result might be creating problem.</li> </ul>	2	<ul> <li>Product C Quality A Failure</li> <li>Equipmer qualified</li> <li>Product C Process Paramete</li> <li>Product C material A failure</li> <li>Effect on Quality/Sa acy for the</li> <li>Equipmer</li> <li>Flow of pr manufactor</li> <li>Cleaning</li> <li>Environm condition</li> <li>Microbial m of area</li> </ul>	ttributes at are critical rs Failure critical attributes product afety/Effic e patients at rocess ure procedur ent	e	<ul> <li>Flow of proc manufacturi controlled by</li> <li>Preventive maintenance machine dous schedule.</li> <li>Cleaning prevalidated.</li> <li>Cleaning prevalidated.</li> <li>Environmen Monitoring of Temperature as per existi</li> <li>Microbial me of area by s plate metho</li> <li>Cleaning SC available</li> <li>Temperature Humidity SC place.</li> <li>Identification microbial</li> </ul>	ng y BMR e of ne as pe ocess is t of e and RF ng SOP onitoring ettle d. OP e and OP in		12				



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	Department	:	Date:							
	Item/Process/I	Product: Standard		FMEA No.:						
		Ri	sk Asse	Batch Size	e Vs. small bat	ch size				
S. No.	Potential Failure Mode	Potential Effect (process/end User) or Consequences	S	Contributory Factors	0	Current Control Measures		RPN (SXO XD)	RPN Rank	
				<ul> <li>Change of size lead to failure.</li> <li>Product for remains un</li> <li>The chang the reproduand consist the product</li> <li>Use of different of equipment</li> <li>Validation not availab</li> <li>Batch releases shelf life of to be change.</li> <li>Stability stuprotocol to change.</li> <li>Changes of manufactur process</li> </ul>	product mula achanged. es affect ucibility tency of t. erent size ent. Protocol le. ase and product ge. udy be	in p BM No the and the Sar use mai bato Vali and Sta prot ava No mai	atamination So blace. R remains sat changes affect reproducibility d consistency product me equipment ed for the nufacturing of ches. idation protoc d report availa bility product tocol and report at a changes of nufacturing cess	me. ct of ol ole.		

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





	Department	Date:							
	Item/Process/I	Product: Standard I	Batch s	ize vs Small Batc	h Size			FMEA I	No.:
		Ri	sk Asse	ssment of Standard	Batch S	ize Vs. small batch size			
S. No.	Potential Failure Mode	Potential Effect (process/end User) or Consequences	S	Contributory Factors	0	Current Control Measures	D	RPN (SXO XD)	RPN Rank

**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.