PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

FAILURE MODE EFFECT ANALYSIS FOR MANUFACTURING PROCESS OF RANIPHIR INJECTION

S. No.	Item / Function	Potential Failure Mode	Potential Effect of Failure (Effect)	Potential Cause/ Mechanism of Failure	Current Control	Reference	Risk with Current control Measure				Recommended Actions (if any)	Risk after control measure			RPN (S*O*D)
							S	O	D	Risk Priority Number (S*O*D)		S	O	D	
1.	**Batch size of Raniphir Injection 2 ml**	Standard Batch size of Raniphir Injection were differ in BMR (115 Lit.) and Process validation (100 Lit.)	Dispense quantity of material can be deviate from required quantity. Product can be fail in assay potency	➢ Required quantity of raw material (Active & Excipients) not dispense as per standard batch size. ➢ Analysis result can be out of limit. ➢ Typological error in Batch Manufacturing	➢ Manufactured batch size of **Raniphir Injection** was 100 Liters. But in BMR BOM sheet required quantity of material as per Standard batch size was 115 Liters. ➢ Dispense quantity of material in both document (BMR BOM & PVR BOM) was same. ➢ Material dispensed after the calculation for active and excipients quantity as per the standard batch size 100 liter. ➢ Before the dispensing, calculation for required quantity of Raw material (Active & Excipients) done by warehouse, checked by Production officer and verified by QA In-charge. ➢ COA of analysis report	Batch manufacturing record Process validation protocol and report Certificate of analysis	4	2	3	24	NA	NA	NA	NA	NA

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							S	O	D	Risk Priority Number (S*O*D)		S	O	D	
				record ignored during review.	verified and observed within acceptance criteria. ➢ Wrong standard batch size was mentioned in BOM sheet of Batch Manufacturing record due to typological error but correct batch size of Raniphir Injection 100 Lit. was followed during Dispensing and manufacturing.	Batch manufacturing record Process validation protocol and report									

Note: Action shall be taken if Risk Priority Number is more than 64.

Where: S=Severity; O=Occurrence Probability; D=Detection

Remarks (if any):

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

QUALITY RISK ASSESSEMENT AND MITIGATION SUMMARY REPORT

Name of Facility / Equipment / Utility / System / Activity / Procedure / Unit Operation:	Manufacturing Process

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

Verification of Action Plan:

All the above agreed actions completed, Not Completed.

(*incase any recommendations Not completed, to be tracked through CAPA System)

Remarks (if any):

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Verified By
QA
Sign & Date

Approved By
Head QA
Sign & Date