PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

RISK ASSESSMENT FOR SIMILAR LOOKING PRODUCT

S.No.	Item/ Function	Potential Failure Mode (Failure Mode)	Potential Effect of Failure	Potential Cause/ Mechanism of Failure	Current Control	Reference document No.	S	O	D	Risk Priority Number (SxOxD)	Recomme -nded Actions (if any)	Post Risk Evaluation			
												S	O	D	RPN SxOx D
1.	Similar looking product	Batch mix-up	Product failure	Batch mix-up in quarantine at batch submission or retrieve after granulation stage	• Officer / Executive Production shall receive the batch containers from the respective section / department & check the containers / bags status Labels, number of containers / bags, individual weight of container / bag and match with the respective BPCR. • Keep the containers / bags of a batch on the rack or on a SS pellet / cage trolley and tie a rope to all the containers of Batch. • Keep the BPCR of the respective batch along with the containers. • In process Granules shall be stored in designated Quarantine Area as per Status. • Enter the Issuance details in **"Inprocess Granule Area Log Quarantine log"**. • Officer / Executive QA shall verify the entries of Quarantine Log, Physical Condition of Containers and Quantity **Quarantine Area Log Quarantine log"**. • Officer / Executive QA shall verify the entries of Quarantine Log, Physical Condition of Containers and Quantity. • There is well defining procedure for line clearance in manufacturing area for avoid miss-up.	SOP no. SOP no.	4	2	3	24	Low Risk category	4	1	3	12
				Batch mix-up in quarantine at batch submission or retrieve after compression stage	• Officer / Executive Production shall receive the batch containers from the respective section / department & check the containers / bags status Labels, number of containers / bags, individual weight of container / bag and match with the respective BPCR. • Keep the containers / bags of a batch on the rack or on a SS pellet / cage trolley and tie a rope to all the containers of Batch. • Keep the BPCR of the respective batch along with the containers. • In process uncoated tablets shall be stored in designated Quarantine Area as per Status.	SOP no.	4	2	3	24	Low Risk category	4	1	3	12

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												S	O	D	RPN SxOx D
					• Enter the Issuance details in **"Inprocess Tablet Quarantine Area Log Quarantine log"**. • Officer / Executive QA shall verify the entries of Quarantine Log, Physical Condition of Containers and Quantity **Quarantine Area Log Quarantine log"**. • Officer / Executive QA shall verify the entries of Quarantine Log, Physical Condition of Containers and Quantity. • There is well defining procedure for line clearance in manufacturing area for avoid miss-up.	SOP no.									
				Batch mix-up in quarantine at batch submission or retrieve after capsule filling stage	• Officer / Executive Production shall receive the batch containers from the respective section / department & check the containers / bags status Labels, number of containers / bags, individual weight of container / bag and match with the respective BPCR. • Keep the containers / bags of a batch on the rack or on a SS pellet / cage trolley and tie a rope to all the containers of Batch. • Keep the BPCR of the respective batch along with the containers**.** • In process Capsules shall be stored in designated Quarantine Area as per Status. • Enter the Issuance details in **"Inprocess Capsule Quarantine Area Log Quarantine log"**. • Officer / Executive QA shall verify the entries of Quarantine Log, Physical Condition of Containers and Quantity **Quarantine Area Log Quarantine log"**. • Officer / Executive QA shall verify the entries of Quarantine Log, Physical Condition of Containers and Quantity. • There is well defining procedure for line clearance in manufacturing area for avoid miss-up.	SOP no. .	4	2	3	24	Low Risk category y	4	1	3	12
				Batch mix-up in quarantine at batch submission or retrieve after	• Officer / Executive Production shall receive the batch containers from the respective section / department & check the containers / bags status Labels, number of containers / bags, individual	SOP no.	4	2	3	24	Low Risk category	4	1	3	12

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S.No.	Item/ Function	Potential Failure Mode (Failure Mode)	Potential Effect of Failure	Potential Cause/ Mechanism of Failure	Current Control	Reference document No.	S	O	D	Risk Priority Number (SxOxD)	Recommended Actions (if any)	Post Risk Evaluation			
												S	O	D	RPN SxOxD
				coating stage	weight of container / bag and match with the respective BPCR. • Keep the containers / bags of a batch on the rack or on a SS pellet / cage trolley and tie a rope to all the containers of Batch. • Keep the BPCR of the respective batch along with the containers**.** • In process uncoated tablets shall be stored in designated Quarantine Area as per Status. • Enter the Issuance details in **"Inprocess Tablet Quarantine Area Log Quarantine log"**. • Officer / Executive QA shall verify the entries of Quarantine Log, Physical Condition of Containers and Quantity **Quarantine Area Log Quarantine log"**. Officer / Executive QA shall verify the entries of Quarantine Log, Physical Condition of Containers and Quantity. • There is well defining procedure for line clearance in manufacturing area for avoid miss-up.	SOP no.									
				Mix-ups of tablets/ capsules/ bottles/ sachets/ strips/blister /Alu-alu pack/cartons/labels & overprinting during adjacent to each other.	• During compression machine to assure that similar looking products are not running on adjacent line to avoid any chances contamination, specially the tablet samples/containers should not in any case come out without any status label. • **Storage:** Containers of similar looking tablets/ capsules products and /or having similar name should not be stored nearby/ adjacent to each other. • During coating machine to assure that similar looking products are not running on adjacent line to avoid any chance contamination, specially the tablet samples/containers should not in any case come out without any status label. • Similarly look alike/ similar name product shall not be inspected/ primary packed on adjacent lines. • Similar look alike labels/ cartons/ foils/ leaflets having similar name shall not be stored adjacent to each other, belt empty or filled with product.	SOP no.	4	2	3	24	Low Risk category	4	1	3	12

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												S	O	D	RPN SxOx D
					• Similar look alike labels/ cartons shall not be over coded on adjacent over coding lines. • Similar looking product's strips/ blisters/cartons/ labels/ shippers shall not be packed on adjacent secondary packing lines. • Two different batches of same product shall also not be packed on adjacent lines. • Annexure- III "Intimation For Physical Verification of Intermediate Product Before Packing". • There is well defining procedure for line clearance in manufacturing area for avoid miss-up.	SOP no.									

Remarks (if any):- Similar looking product risk assessment leads to low risk, which can be lower down after follow SOP **{**Title: Receipt, Storage and Issuance of Raw /Primary Packing Material Staging Area, In Process Granules/Tablets(Core/Coated /Finished)/Capsules/Dry Powder In Quarantine Area**},** SOP (Title : Production Process and Control) and SOP (Title : line clearance).

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

CAPA (Required / Not Required):
If required, mention CAPA No.: NA

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RISK ASSESSMENT FOR SIMILAR LOOKING PRODUCT

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 Procedure: Similar looking product

Verification of Recommended Action: NA

Remarks (if any): NA

Verified By
Officer/Executive QA
(Sign & Date)

Approved By
Head QA
(Sign & Date)