PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

QUALITY RISK ASSESSMENT & MITIGATION PLAN

FAILURE MODE EFFECT ANALYSIS FOR BALANCE VERIFICATION

Reference Document No.: | **Risk Assessment No.:** …….

Name of Procedure: Balance verification | **Quality Risk Assessment Date:…….**

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)	Recomm--ended Actions (if any)	Post Risk Evaluation			
												S	O	D	RPN SxOxD
1.	Balance verification.	• Wrong quantity taken during RM sampling stage. • Wrong quantity dispense during RM dispensing stage. • Wrong quantity taken during PM sampling stage. • Wrong quantity dispense during PM dispensing stage. • Wrong weight entry in BMR after dry milling stage of manufacturing. • Wrong weight entry in BMR after blending stage of manufacturing.	• Actual weight different from quantity of raw material in system. • Actual weight different from quantity of packing material in system. • Wrong yield calculation in manufacturing. • Wrong yield calculation in packing • Batch failure.	• Balance out of calibration. • Balance verification not performed. • Balance location change and use without calibration.	➢ **Verification electronic weighing balances:** • First check the spirit level and record the observation, adjust the level, if not leveled. • Daily weight verification shall be done at 3 level minimum/ Maximum and middle of working range. • Place the calibrated weight as defined in respective Annexure at canter position of pan / Platform and wait for stabilization. • Record the weight on the respective annexure. • Replace the weight with one by one another weight and record the observation. • After corrective action again verify the balance and allow using if it comply the specification. • **Frequency**: At-least once in a only working day. ➢ **Calibration electronic weighing balances:** • Check the level of the Balance with the help of Spirit Level. Adjust the level, if not levelled. • Calibrate the Balance using Standard Weights as per respective annexure of their capacity.	SOP	3	2	3	18	Low Risk category	4	1	3	9

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		• Wrong weight entry in BMR after compression stage of manufacturing. • Wrong weight entry in BMR after capsule filling stage of manufacturing. • Wrong weight entry in BMR after coating stage of manufacturing. • Wrong inprocess performed.			• Place the Standard Weights one by one in the canter of the pan of the Balance and note down the reading in the **"Balance Calibration Record"** as per Respective annexure. • **Calibration Frequency:** First working day of every month before use. ±3 days and any maintenance work and after relocation of balance.									
					➢ **Verification weighing balances:** • **Verification Frequency:** once in a working day before use and immediately after maintenance work. • Verify the weighing Balance using 100.0 kg of Standard Weights certified by Weights and Measures Department. • Place the Standard Weights in the center of the Platform of the Balance and record the observations in **(Annexure – I).** ➢ **Calibration weighing balances:** • **Calibration Frequency:** First working day of every month ±3 days, before use. • Following parameters to be checked while performing Calibration • Accuracy	SOP	3	2	3	18	Low Risk category	4	1	3	9

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												S	O	D	RPN SxOxD
					• Linearity • Precision • Corner Load Test **Note:** • If Balance is not calibrated on or before due date, stop using the Balance till satisfactory Calibration is done. • If balance is moved from one area to another area then such relocation is required to be initiated through a change control procedure than complete calibration/verification shall be done. • Whereas in case of movement of electronic balance within the same area i.e. cleaning the table top or due to some reason, balance shall be checked for level and recalibration/ verification shall be performed after its internal calibration (where ever such internal calibration is provided) process is shall be perform prior to its operation & recorded in log book.									

Where: S=Severity; O=Occurrence Probability; D=Detection:, Risk category up to 25 is low risk, 26-50 is medium risk, 51 -125 high risk.
Remarks (if any):- The entire above failure mode and their severity, Occurrence, Detectability rating done & found risk is Low

Conclusion:- On the basis of above risk assessment the balance verification leads to low risk, all evaluated risk during assessment of all concern department like warehouse, manufacturing area, packing area, department which can be lower down after follow above mentioned SOP's Operation, Cleaning, Verification and Calibration of Electronic Weighing Balances (SOP no. ……..) and Operation, Cleaning, Verification and Calibration of weighing Balance (SOP no. ……..).

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Reference Document No.:	Risk Assessment No.: …….

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

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

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: Balance verification

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Reference Document No.:	Risk Assessment No.: …….

Verification of Recommended Action: NIL

Remarks (if any): NA

Verified By
Officer/Executive QA
(Sign & Date)

Approved By
Head QA
(Sign & Date)