PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

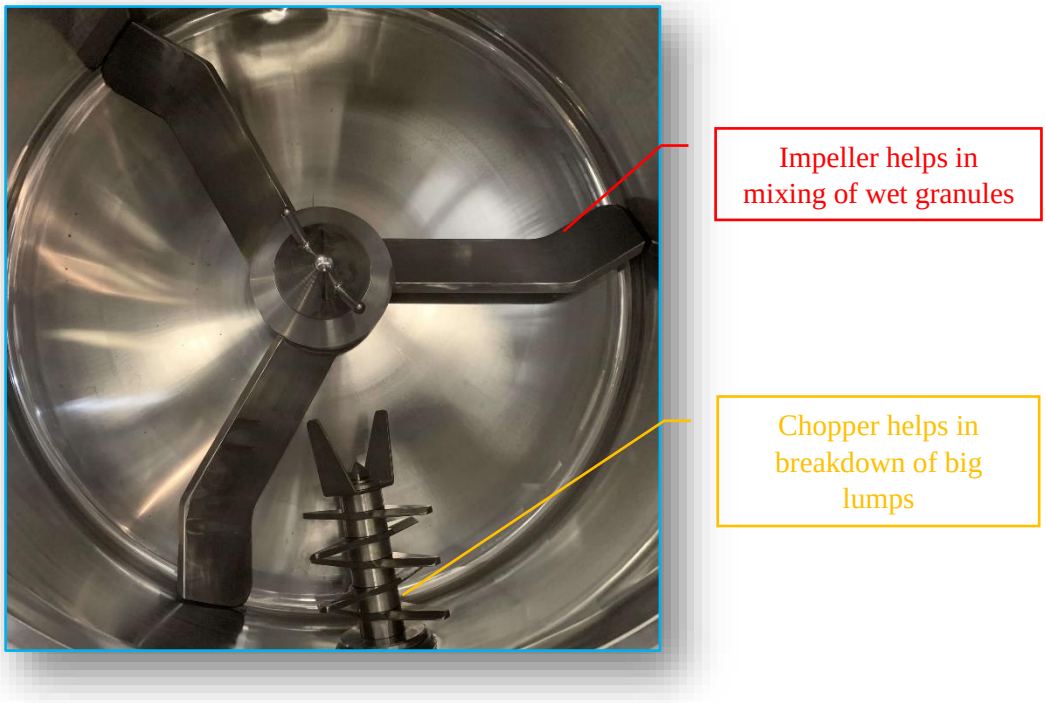
QUALITY RISK ASSESSMENT FOR AMPERE LOAD

Determination of the End Point: Granulation end point is the time when granules with desirable properties are formed. This is required to be determined to ensure smooth tablet compression and obtain desired tablet properties. These pre-compression granule properties include strength, bulk density, particle size distribution, and flow ability.

Wet mixing duration is one of the oldest methods for endpoint determination is based on the duration of the wet mixing step, which follows the binder addition phase.

Power consumption is another popular endpoint determination method which is based on measuring the power consumed by the motor mixer (in amperes). Ampere load on Impeller and Chopper i.e. the current which is used by Impeller and chopper motor to rotate when granules are formed.

Impeller& Chopper in RMG:



RISK IDENTIFICATION	RISK EVALUATION	RISK MITIGATION
Risk related to fluctuation in ampere load or ampere load failure is high, as ampere load is directly proportional to the quality of the granules. Improper granules may result into failure of critical quality parameters like Hardness, Disintegration time, Friability, Blend Uniformity etc.	When going through evaluation of risk related to ampere load fluctuation or failure, we have to go through the basic concept of the ampere load theory, that ampere load is achieved when there is a change in the consistency of the powder mixture which further increases the resistance on the granulator blades, which in turn affects the power consumption of a motor. Measuring Ampere load by using power consumption in regard to impeller method has	As all critical quality parameters and critical quality attributes are within the acceptance criteria, hence no mitigation plan or recommendation required.

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RISK IDENTIFICATION	RISK EVALUATION	RISK MITIGATION
	certain limitations. The readings are affected by various factors such as the formulation, type of equipment, process variables, and wear and tear of the motor, bearing, gearbox, etc. A major drawback of the power consumption measurement is that the load is measured on the motor rather than on the impeller where the actual process is conducted. These measurement readings fluctuate with the time and conditions of the motor regardless of the load. Hence in parallel time consumption during wet granulation also plays major role in ampere load achievement. In this case, time of 03 minutes run has been achieved while ampere load is slightly behind (49.20 ampere) the limit i.e. 50 ampere. All critical quality parameters and attributes are within the limit during the manufacturing process till release of the batch. Trend of results of previous 50 batches reviewed and found in limit. No Out of Specification related to hardness of Paracetamol Tablets observed since the batch manufactured at site.	

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S.No.	Item/Function	Potential Failure Mode	Potential Effect of Failure	Potential Cause/Mechanism of Failure	Current Control	Reference Document No.	S	O	D	RPN (SxOxD)	Recommended Action (If any)	Post Risk Evaluation			
												S	O	D	RPN (SxOxD)
1.	**Ampere Load**	• Ampere Load not achieved • Ampere Load not verified	•Wrong interpretation of Ampere load •Bulk Density not achieved •Improper size distribution •Flow property of granules will be affected •End point not achieved •Reproducible results not achieved •Roping flow motion of granules not achieved •Bumping motion of granules observed	•Binder addition time not as per BMR •Manual binder addition •Raw material supplier not qualified •Formulation not validated •Equipment not qualified •Improper wet mixing time not achieved •Possibility of passing the wet granules between the mixing chamber base and impeller resulting into wrong ampere load interpretation •Traditional method (Banana breaking method	•Tablet hardness during online IPQA verification observed within limit •Tablet hardness verified online by Tantra software •Checked By process is in place •Ampere load verified & noted in BMR during binder addition •Ampere load verified noted in BMR after binder addition •All the critical process variables (speed of impeller, speed of chopper, Ampere load of impeller, Ampere load of chopper, time of wet mixing at each stage) are controlled by PLC i.e. recipe entered during the processing	•BMR •APQR •Qualification planner •Approved vendor list •Process validation report	3	2	1	6 **Severity:** Severity of failure of ampere load is high, as it may affect the product quality **Occurrence:** Possibility of occurrence of wrong interpretation of ampere load is there. **Detectability:** Detection of Ampere load is done by verifying from PLC	Risk probable number calculated is low hence no recommended action required	NA	NA	NA	NA

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S.No.	Item/Function	Potential Failure Mode	Potential Effect of Failure	Potential Cause/Mechanism of Failure	Current Control	Reference Document No.	S	O	D	RPN (SxOxD)	Recommended Action (If any)	Post Risk Evaluation			
												S	O	D	RPN (SxOxD)
			•Critical Quality parameters not achieved •RPM of impeller not achieved •RPM of chopper not achieved	of verification by taking wet granules in fist) used for verifying granules properties • PLC showing ampere load not qualified • Breakdown during processing • Chance of fluctuation in electric current may result into fluctuation in ampere load	•Raw material used from approved vendor •Process validation already done for 03 batches •No any variation in critical quality attributes observed in Annual product quality review •Equipment qualified as per schedule •Trend of last 50 batches manufactured verified for any variation, no any variation observed •PLC validation already done •No any breakdown or power failure observed during the manufacturing process.									

REMARK: No any recommendation required

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CONCLUSION:

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