COPY OF MASTER FORMAT

ZYDUS LIFESCIENCES LIMITED

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Dedicated To Life

Annexure No.	**0301-SOP-QA-00122-19**	**Version No.**	**10.0, CURRENT**
Annexure Title	**Batch Manufacturing Record Review Sheet: Production- For OSD**		

Product Name		**Batch No.**	

Instruction:

1. Ensure that the batch review is done at the end of each manufacturing stage.
2. Ensure that a complete Batch record must contain at-least following details and technical information.
3. Write in observation column 'Yes' for complying, 'No' for not complying and 'NA' for not applicable.

Sr No	Check points	Observation Production (Yes/No/NA)			
		Stage 1	Stage 2	Stage 3	Stage 4
1	Check Product details (Batch No, Manufacturing Date and Expiry Date).				
2	Check the correctness of API calculation (based on assay & moisture content).				
3	Check all the dispensed material quantity (Net Weight) are as per BOM and as per API calculation.				
4	Check dispensing label for all dispensed material with complete details and balance ID.				
5	Ensure that the area/equipment was used post line clearance.				
6	**Ensure the Manufacturing process entries done as per instructions and recorded parameters are within the limit.**				
7	**All entries are legible and signed/dated.**				
8	Check the equipment cleaned status labels attached with complete details.				
9	Printout (Audit trail, exceptional report, alarm summary, batch event reports, others) at respective stage reviewed and attached with BMR.				
10	Process critical alarms if any, are reported in annexure and evaluated.				

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Sr No	Check points	Observation Production (Yes/No/NA)			
		Stage 1	Stage 2	Stage 3	Stage 4
11	Check reconciliation for completeness, correctness and within limit.				
12	Ensure that the GMP document/Stability sample tracking sheet is updated by referring the BMR/process history page/Batch record review sheet.				
13	Ensure that the additional annexure/Pages are compiled, checked and verified by production.				
14	Ensure that employee details (Employee. No., Employee. Name, Department Area, specimen signature) of Person involved in Manufacturing activity are available in signature log.				
15	Ensure that Reconciliation of issued Annexures at each stage is done in D2 (zydms).				
	Production: (Sign/Date)	__/__/__	__/__/__	__/__/__	__/__/__

Check point – For submission to QA: Review and release to Compression/Encapsulation /Filling /inspection/Packing stage			
16	Check the CPP parameters Printout is complies at all stages as per SOP: 0301-SOP-QA-00211 and signed.	**Observation (Yes/No/NA)**	
17	In View of compliance to above checkpoints, it is certified that the, Batch is reviewed and submitted to QA for review and release.	**BMR Reviewed by Production: (Sign/Date)**	__/__/__