

ZYDUS LIFESCIENCES LIMITED



Annexure No.	0301-SOP-QA-00122-24	Version No.	9.0, CURRENT
Annexure Title	Batch record review observations sheet		

Product Name				Sheet No.		of	
Batch No.	Stage		Stage Reviewed by (Name and Sign)		Date		

Sr No	Page No. / Format No.	Observation	Error Type#	Responsible Person (Name)	Justification / Explanation and how the error was complies ##	Observation complies by (User Dept.) (Name, Sign &Date)	Compliance Reviewed By: (QA) (Name, sign &Date.)

## Refer SOP No. 0301-SOP-QA-00170 Step No. 24.0 Guidance on How to Correct the Errors,

# Error Type			Sum	# Error Type			Sum	# Error Type			Sum
WEQ	Wrong Equipment Referred or used			WW	Wrong Word used			MC	Miscalculated		
DM	Supporting Documents are missing or not available not attached			WS	Wrong Stamping			ME	Missing Entry		
NFS	Not Following Steps (e.g. steps from BMR/ BPR)			MS	Missing Signature			OW	Overwriting		
OR	Out of Range (Set Parameter Range)			OO	Other Observations			MP	Missing Page		
NL	Writing Not Legible (or numbers cannot differentiate			WN	Wrong Number			GD	GDP Error		
WR	Wrong Recording (for data or date /time)			OE-OK	Original Entry okay			SE	Software Error		
CR	Chronology not Followed/Sequence not in order			WUM	Wrong Unit of Measurement			ID	Inaccurate Data		
OS	Outside Specification and No Justification			WF	Wrong Format Used			WE	Writing Error		
YR	Yield and Reconciliation issue			CE	Calculation Error						