*Minimum Stability testing reporting requirements (Guidance) for stability reports - Nutritional Supplements (Tablets & Oral Solutions)**																			
Product Number		**Primary packaging**																	
Mfg Date		**Stability protocol ID**						**Expiry date**											
Product		**Batch Number**						**Batch Size**											
Stability initiation/Start date		**Storage condition (Temperature, %RH)**						**API(s)**											
Laboratory test provider								**Commercial or Pilot batch**											
Accredation of test provider																			
Manufacturing site								**Manufacturer/Bidder**											
Physical Parameters			**Results**																
	Phamacopoeial reference e.g. USP/BP/ Ph. Eur. /In-House reference* **	**Phamacopoeial reference Limits**	M0**	M1	M2	M3**	M4	M5	M6**	M9	M12	M18	M24	M30	M36	M48	M60	**Interpretation of results**	
Description																			
Container closure intergrity test (for oral liquids)																			
Friability*																			
Disintegration*																			
Hardness*																			
Dissolution*																			
Average weight																			
Moisture Content (if applicable)																			
Supplier may include additional tests																			
Chemical parameters			**Results**																
	Phamacopoeial reference e.g. USP/BP/ Ph. Eur. /In-House reference* **	**Phamacopoeial reference Limits**	M0**	M1	M2	M3**	M4	M5	M6**	M9	M12	M18	M24		M36	M48	M60	**Interpretation of results**	
Identification Component 1																			
Identifcation Component 2																			
Identification Component 3																			
Quantifcation/Assay Component 1																			
Quantification/Assay Component 2																			
Quantification/Assay Component3																			
Quantification/Assay Component 4																			
Quantification/Assay Component 5																			
Supplier may include more assay of rest component																			
Related Impurities****																			
Microbiological Parameters																			
	Pharmacopea Reference (legally effective version at initiation of study)/In house reference* **	**Phamacopoeial reference Limits**	M0**	M1	M2	M3**	M4	M5	M6**	M9	M12	M18	M24		M36	M48	M60	**Interpretation of results**	
Total Aerobic Microbial count																			
Total yeast/moulds count																			
E.coli																			
Stability Testing Date																			
Discussion of results																			
Conclusion																			

** Stability protocol has to be submitted along with stability reports. In-Use stability should be carried out wherever the applicable (e.g, oral solutions).The manufacturer must/should comply with WHO/ ICH stability guidelines.This template is based on WHO/ICH guidlines and is an example templete for reporting stability studies. It should not replace WHO or ICH guidelines. Manufacturere may choose to include additional testing time points.*

*** Minimum frequency of testing at accelarated conditions*

**** In- House method if used then, the limits for In-House specifications should be more stringent or equivalent to USP/BP/ Ph. Eur pharmacopiea*

***** Related impurities if mentioned in any of the international pharmacopiea they must be used or In- House method*

** https://extranet.who.int/pqweb/sites/default/files/documents/TRS1010_Annex10.pdf*

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