

Annex 2

Stability study template for Nutritional Products¹

Formulation ID		Ingredients														
Stability protocol ID		Mfg. date	BB Date													
Product		Batch Nr.	Batch Size													
Composition of primary packaging		Storage condition (Temperature, %RH)	Start date													
Major changes (raw material, packaging material, production equipment)																
Laboratory test provider																
Accreditation of test provider																
Manufacturing Site																
Physical and organoleptic parameters***		Accredited test method (Y/N)	Test Method	Results**												
				M0 (40 C)	M0 (30 C)	M3 (40 C)	M3 (30 C)	M6 (40 C)	M6 (30 C)	M12 (40 C)	M12 (30 C)	M18 (40 C)	M18 (30 C)	M25 (40 C)	M25 (30 C)	
Appearance (include picture for each point) ²	Internal physical and organoleptic evaluation and acceptance criteria			x	x	x	x	x	x	x	x	x	x	x	x	
Taste and flavor				x	x	x	x	x	x	x	x	x	x	x	x	
Odour				x	x	x	x	x	x	x	x	x	x	x	x	
Mouthfeel (texture)				x	x	x	x	x	x	x	x	x	x	x	x	
Homogeneity (texture, taste and odour)				x	x	x	x	x	x	x	x	x	x	x	x	
Oil separation				x	x	x	x	x	x	x	x	x	x	x	x	
Primary packaging integrity (include picture of each time point) ²				x	x	x	x	x	x	x	x	x	x	x	x	
Printing quality including date and batch marking				x	x	x	x	x	x	x	x	x	x	x	x	
Chemical parameters		UNICEF Specification at shelf life period (RUTF)*	Accredited test method (Y/N)	Test Method	M0 (40 C)	M0 (30 C)	M3 (40 C)	M3 (30 C)	M6 (40 C)	M6 (30 C)	M12 (40 C)	M12 (30 C)	M18 (40 C)	M18 (30 C)	M25 (40 C)	M25 (30 C)
		Min	Max													
Water activity (aw)			0.6													
Peroxide value (mEq/kg)																
n-3 fatty acid content (g/100 g)		0.58	1.53													
n-6 fatty acid content (g/100 g)		1.7	4.3													
Vitamins																
#Vitamin A (Retinol Equivalent) (mg/100g)		0.8	1.6													
Vitamin E (Tocopherol) (mg/100g)		>20														
#Vitamin C (Ascorbic Acid) (mg/100 g)		>50														
Vitamin B1 (Thiamin) (mg/100g)		>0.5														
Vitamin D3 (Cholecalciferol) (mcg/100g)		15	22													
Vitamin K1 (Phytonadione)(mcg/100g)		15	30													
Vitamin B2 (Riboflavin)(mg/100g)		>1.6														
Vitamin B6 (Pyridoxine) (mg/100g)		>0.6														
Vitamin B3(Niacin)(mg/100g)		>5														
Vitamin B12 (Cyanocobalamin)(mcg/100g)		>1.6														
Vitamin B7(Biotin) (mcg/100g)		>60														
Vitamin B9 (Folic Acid)(mcg/100g)		>200														
Vitamin B5 (Pantothenic acid)(mg/100g)		>3														
Microbiological Parameters		Results**														
TPC (CFU/g)																
Conclusion																
¹ This stability template is derived from the interagency stability requirement and should not be considered as an alternate to suppliers stability protocol and a complete report. Suppliers may use this template as an example to submit a summary of stability study protocol.																
² Manufacture may test the packaging integrity with suitable validated method. The picture of each time point for appearance and packaging integrity can be included in separate table.																
**Manufacturers may choose to include additional testing time points. Manufacturers may present trends of nutrients in their report for each deviation and discuss and justify the obtained results.																
* The analytical parameters included are for RUTF. The parameters will be changed when the product for stability study is changed. Eg for BEP LNS-PLW, Super cereal, HEB, LNS-SQ, LNS-MQ, RUSF and alternative RUTF																
X indicated shell represents reporting points for corresponding time points in real time and accelerated conditions.																
*** This is minimum requirements for physical and organoleptic test, for detail please look Annex I.																
# The vitamins to be tested in each time point of stability studies																

