



Palestinian Flour Fortification Formula

Nutrient	Fortificant compound	Min. Addition Lev. (mg/kg)	Average Addition Level (mg/kg)	Maximum Tolerance Level (mg/kg)
Folate	folic acid	1.0	1.5	2.5
Fe	ferrous sulfate dried	25.0	34.4	60
B-12	Vitamin B12 0.1% WS	0.0025	0.0040	N.A
B-1	Thiamin Mononitrate	2.0	2.9	N.A
B-2	Riboflavin	2.5	3.6	N.A
B-6	Pyridoxin	2.5	3.6	N.A
Niacin	Niacinamide	25.0	35.0	N.A
Zn	zinc oxide	15.0	20.6	40
Vit. A	Vit. A Palm. CWS-250	1.00	1.5	2.5
Vit. D	Vit. D3, 100 CWS/A	0.015	0.023	0.050
Filling material (CaCO ₃): 250 - forficants				

Palestinian Premix Specifications

Parameters	Range
General Specifications	
Nutrient Content	The same as Palestinian Premix formula ¹
Particle size	100% NMT 250 microns, pass through mesh number 60
Fillers and other additives	Calcium Carbonate (QS), NMT 2% of (colloidal silicon dioxide or any other suitable glidant like lactose)
Humidity	NMT 6.0%
Bulk Density	NLT 0.5 g/ml
Packaging material	Laminated aluminum
General appearance	Creamy to Yellowish orange
Color	No color addition
Odor	Vitamins odor

Safety Parameters	
Parameters	Range
Physical	As mentioned above
Chemical	Heavy metals for raw materials
Microbiological	TAC (NMT 3000 CFU/g). Mold & Yeast (NMT 100 CFU/g). E. Coli, Salmonella & Staph. Aureus (Absent).
Labeling	
Name	Premix powder for flour fortification
Manufacturer	Should be mentioned
Address	Should be mentioned
Lot #	Should be mentioned
Production date	Should be mentioned as (month / year)
Exp. Date	Six months from production date
Additives	Should be mentioned
Weight	Should be mentioned
Instructions for use: (dilution)	Should be mentioned on label
Storage condition	In a dry place at room temperatures
Composition	Should be mentioned
Colored fortification logo	Should be printed
Methods	
Sampling	Same as drug
Sample size	Same as drug
Reference sample	Same as drug
Physical methods	According to CPHL SOPs
Chemical methods	According to CPHL SOPs
Microbiological	Assay for Vit B12

¹ Palestinian Premix Formula

Micronutrients	Unit / Kg Premix	Conc. of Micronutrient	Applied Material
Vitamin A	IU	20,000,000	Vit. A Palm. CWS-250
Vitamin D	IU	3,600,000	Vit. D3, 100 CWS/A
Thiamine (vitamin B1 Base)	mg	11,600	Thiamine Mononitrate
Riboflavine (vitamin B2)	mg	14,500	Riboflavine
Pyridoxine (vitamin B6)	mg	14,500	Pyridoxin
Niacinamide	mg	140,000	Niacinamide
Folic acid (anhydrous vitamin B9)	mg	6,100	Folic acid
Vitamin B12	µg	16,500	Vitamin B12 0.1% WS
Zinc	mg	80,400	Zinc oxide
Iron	mg	136,000	Ferrous sulfate dried
Calcium	mg	57,078	Filling material (CaCO ₃): 250 - fortificants

Mixing Rate: 250 g premix / Metric Ton Flour.

**Registration Requirement of
Fortificants for Wheat Flour (Premix)**

The Importer or Premix Agent should registrate the Premix before using or marketing. The following documents should be presented to the Drug Control and Registration Department in Ministry of Health:

1. Master formula including all the materials used in the formulation & their quantities (w/w or %).
2. The specification of all active raw materials used in the master formula, & their references.
3. Original certificate of analysis of all active materials used in the master formula.
4. The physical, chemical & biological specification of the manufactured product (Premix).
5. Method of analysis of the manufactured product (Premix).
6. Certificate of analysis of the manufactured product (Premix).
7. Specification of the label & the packaging material & empty samples.
8. Samples sufficient for 3 analyses.
9. Analysis fees.
10. Registration fees.

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