

# Microbial Quality Control in Food and Pharmaceutical Industries (SEC – A - 1)

## BIS Standards for Common Foods (Unit - 4)

## IS 11536 : 2007 PROCESSED-CEREAL BASED COMPLEMENTARY FOODS SPECIFICATION

- Processed-cereal based complementary foods are mainly intended to accustom the infant's digestive tract to solid foods.
- Nutritionally, this category of foods serves as an important source of calories to meet the energy requirements due to increased physical activity of infant.
- Beginning with the introduction of cereals after four months of age, the intake is slowly increased so that by 8 months of age and onwards nearly half of the total intake is from milk and remaining from cereals and a variety of other foods.
- With such a feeding practice, milk almost completely meets the protein requirements, while cereals and/or other foods meet the energy and satiety requirements of the infant.

- This Indian Standard (Second Revision) was adopted by the Bureau of Indian Standards, after the draft finalized by the Food grains, Starches and Ready-to-Eat Foods Sectional Committee had been approved by the Food and Agriculture Division Council.
- In this revision, recommendatory list of sources of vitamin compounds and minerals salts, list of permitted Food Additives have been included and the chemical and microbiological requirements updated.
- ‘Infant food’ means any food being marketed or otherwise represented as a complement to mother’s milk to meet the growing nutritional needs of the infant after the age of six months.

- At present mainly two types of infant foods are being marketed in our country, namely, milk-cereal based complementary foods and processed cereal-based complementary foods.
- This standard covers the requirements for processed-cereal based complementary foods
- While formulating this standard, due consideration has been given to the relevant rules prescribed by the Government of India, namely Rule 37-A, 37-B, 49(19) and items under Appendix B of *PFA Rules, 1955; Infant Milk Substitutes, Feeding Bottles and Infant Foods (Regulation of Production, Supply and Distribution) Act, 1992 and Rules 1993; Rule 5 and 'Third Schedule' of the Standards of Weights and Measures (Packaged Commodities) Rules, 1971.*

- This standard prescribes the requirements, methods of test and sampling for processed-cereal based complementary foods intended to supplement the diet of infants after the age of six months and upto the age of two years.
- Processed-cereal based complementary food, commonly called as weaning food or supplementary food means foods based on cereals and/or legumes (pulses), soyabean, millets, nuts and edible oilseeds, processed to low moisture content and so fragmented as to permit dilution with water, milk or other suitable medium.
- Processed-cereal based complementary foods are obtained from variety of cereals, pulses, soyabean, millets, nuts and edible oilseeds after processing.

- **Routine tests** are carried out on each lot to check essential requirements which are likely to vary during production
- **Type tests** are carried out to prove conformity to the requirements of this standard. These are intended to approve the formulation & quality of the product at least in the beginning of marketing or certification or both
- These tests are conducted periodically to supplement the routine tests or whenever the basic formula or method is changed
- The processed-cereal based complementary food should be in the form of powder, small granules or flakes, free from lumps and should be uniform in appearance.
- The processed-cereal based complementary food should be free from preservatives, added colour and flavour.

- It should contain milled cereal and legumes combined not less than 75%.
- Where the product is intended to be mixed with water before consumption, the minimum content of protein should not be less than 15% on a dry weight basis and the quality of the protein should not be less than 70% of that of casein.
- The sodium content of the product should not exceed 100 mg/100 g of the ready-to-eat product.
- Hydrogenated fats containing trans-fatty acids should not be added to the products.

The product may contain food additives –

<i>Food Additives</i>	<i>Maximum Level in 100 g of the Product on a Dry Weight Basis</i>
<b>Emulsifiers:</b>	
Lecithin	1.5 g
Mono and Diglycerides	1.5 g
<b>pH-Adjusting Agents:</b>	
Sodium hydrogen carbonate	Limited by good manufacturing practice and within the limits for sodium
Potassium hydrogen carbonate	} Limited by good manufacturing practice
Calcium carbonate	
L (+) Lactic acid	1.5 g
Citric acid	2.5 g
<b>Antioxidants:</b>	
Mixed tocopherols concentrate	} 300 mg/kg fat, singly or in combination
Alpha-tocopherol	
L-Ascorbyl palmitate	200 mg/kg fat
L-Ascorbic acid and its sodium and potassium salts	50 mg, expressed as ascorbic acid and within the limits for sodium

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*Food Additives*

*Maximum Level in  
100 g of the Product  
on a Dry Weight Basis*

**Enzymes:**

Malt carbohydrates

Limited by good  
manufacturing  
practice

**Leavening Agents:**

Ammonium carbonate  
Ammonium hydrogen  
carbonate

} Limited by good  
manufacturing practice

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- **Quality of Ingredients:** All ingredients, including optional ingredients, should be clean, safe, suitable and of good quality.
- It may also contain following ingredients: protein concentrates, essential L - amino acids, iodized salt; milk and milk products; eggs; edible vegetable oils and fats, fruits and vegetables; various carbohydrates such as sucrose, dextrose, dextrin, maltose dextrin, lactose and carbohydrate rich foods like honey, corn syrup, malt and potatoes.
- The vitamins and minerals used should be of food grade. The source of vitamin compounds and mineral salts may be used from the following list:-

- Minerals:
- Calcium (Ca) — Calcium carbonate, calcium phosphate tribasic, calcium sulphate
- Phosphorous (P) — Calcium phosphate tribasic, phosphoric acid
- Chloride — Sodium chloride, hydrochloric acid
- Iron (Fe) — Hydrogen reduced iron, electrolytic iron
- Sodium (Na) — Sodium chloride and
- Zinc (Zn) — Zinc acetate, zinc chloride, zinc oxide, zinc sulphate.

- Vitamins
- Vitamin A — Retinyl acetate, retinyl palmitate, retinyl propionate
- Provitamin A — Beta-carotene
- Vitamin D — Vitamin D<sub>2</sub> — Ergocalciferol
- Vitamin D<sub>3</sub> — Cholecalciferol, cholecalciferol- cholesterol
- Vitamin E — d-alpha- tocopherol, dl-alpha- tocopherol, d-alpha- tocopheryl acetate, d- alpha-tocopheryl acetate, d-alpha-tocopheryl succinate, d-alpha-tocopheryl succinate
- Thiamin (Vitamin B<sub>1</sub>) — Thiamin chloride hydrochloride, thiamin mononitrate
- Riboflavin (Vitamin B<sub>2</sub>) — Riboflavin, riboflavin 5' — phosphate sodium
- Niacin — Nicotinamide, nicotinic acid
- Vitamin B<sub>6</sub> — Pyridoxine hydrochloride
- Biotin (Vitamin H) — d-biotin
- Folacin — Folic acid
- Pantothenic acid — Calcium pantothenate, pantothenol
- Vitamin B<sub>12</sub> — Cyanocobalamin, hydroxy- cobalamin
- Vitamin K — Phytylmenaquinone
- Vitamin C — Ascorbic acid, sodium ascorbate, calcium ascorbate, ascorbyl-6-palmitate
- Choline — Choline bitartrate, choline chloride
- Inositol and Selenium — Sodium selenite

- **Hygienic Conditions**
- The material should be manufactured and packed under hygienic conditions
- **Flavour and Odour**
- The flavour and odour of the processed-cereal based weaning food in the powder form or when reconstituted with water should be fresh and sweet.
- It should not have a rancid taste or off flavour or a musty odour.
- **Bacteriological Specifications:**
  - a) Bacterial count – bacterial colony count/ gm of the product should not be more than 10,000 when determined according to the prescribed method
  - b) Coliform count – should be absent per 0.1 gm of the product when tested according to the prescribed method

- c) *Escherichia coli* - should be absent per 0.1 gm of the product when tested according to the prescribed method
- d) *Staphylococcus aureus* - should be absent per 0.1 gm of the product when tested according to the prescribed method
- e) *Salmonella* & *Shigella* - should be absent per 25 gm of the product when tested according to the prescribed method
- f) Yeast & Mould Count - should be absent per 0.1 gm of the product when tested according to the prescribed method
- The aflatoxins content in the product when tested in accordance with the prescribed method should not exceed 0.03 mg/kg.

- The processed-cereal based complementary food should also comply with the following requirements given in the Table -

Sl. No.	Characteristics	Requirement
1.	Moisture, % by mass, <i>Max</i>	4.0
2.	Total Protein, % by mass, <i>Min</i>	15.0
3.	Total carbohydrates, % by mass, <i>Min</i>	55.0
4.	Total ash, % by mass, <i>Max</i>	5.0
5.	Ash insoluble in dilute hydrochloric acid, % by mass, <i>Max</i>	0.1
6.	Iron, mg/100 g, <i>Min</i>	5.0
7.	Vitamin A (as retinol), µg/100 g, <i>Min</i>	350.0
8.	Vitamin C, mg/100g, <i>Min</i>	25.0
9.	Added Vitamin D (expressed as chole- calciferol or Ergocalciferol), µg/100 g, <i>Min</i>	5.0
10.	Thiamine (as hydrochloride), mg/100 g, <i>Min</i>	0.5

Sl. No.	Characteristics	Requirement
11.	Riboflavin, mg/100 g, <i>Min</i>	0.3
12.	Niacin, mg/100 g, <i>Min</i>	3.0
13.	Folic Acid, µg/100 g, <i>Min</i>	20.0
14.	Crude fibre (on dry basis), % by mass, <i>Max</i>	1.0
15.	Zinc, mg/100 g, <i>Min</i> <i>Max</i>	2.5 5.0
16.	Heavy metals: a) Lead, mg/ kg, <i>Max</i> b) Copper, mg/ kg, <i>Min</i> <i>Max</i> c) Arsenic, mg/ kg, <i>Max</i> d) Tin, mg/ kg, <i>Max</i> e) Cadmium, mg/ kg, <i>Max</i>	0.2 2.8 15 0.05 5.0 0.1

- **Additional Requirements for ECO-Mark :**

The manufacturers should produce the consent clearance as per provisions of *Water (PCP) Act, 1974*, *Water (PCP) Cess Act, 1977* and *Air (PCP) Act, 1981* along with the authorization if required under *Environment (Protection) Act, 1986* & the Rules made there under to the BIS

- The product should also be in accordance with the *Prevention of Food Adulteration Act, 1954* & the Rules made there under
- Additionally, *FPO (Fruit Product Order), 1955* framed under *Essential commodities Act, 1966*, *Standards of Weights and Measures Act, 1977* and 1985 requirements wherever applicable, has to be complied with

- The product/packaging may also display in brief the criteria based on which the product has been labelled environment friendly
- The material used for product packing should be recyclable or biodegradable
- The date of manufacture & date of expiry should be declared on the product package by the manufacturer
- The product should be microbiologically safe when tested & should be free from bacterial and fungal toxins
- The pesticide residues, if any, should not exceed the limit as prescribed in *PFA Act*, 1954 & the Rules made thereunder

- The product package or leaflet accompanying it may display instruction of proper use, storage and transport (including refrigeration temperature compliance) so as to maximize the product performance, safety and minimize wastage
- The material used inside the metal cap of the product should conform to the relevant Indian Standards of food grade plastics as permitted under the *Prevention of Food Adulteration Act, 1954* & the Rules made thereunder
- Caps & closures should not be treated as labels
- If fruit juice/pulp is added, then its percentage should be mentioned on the product package
- No synthetic food colour and artificial sweetener should be added or used in the product

- **PACKING AND MARKING**

- Packing:-

- The processed-cereal based complementary foods should be packed in sealed, clean and sound containers or in a flexible pack made from film or combination of any of the substrates - board paper, polyethylene, polyester, metallized films or aluminium foil so as to protect it from deterioration.
- In case plastic material is used for flexible packaging, only food grade plastic should be used
- The product should be packed in quantities as stipulated under *Standards of Weights and Measures (Packaged Commodities) Rules, 1977* as well as in accordance with requirements under *Prevention of Food Adulteration Act, 1954* and *Rules, 1955*

Marking: The container should bear the following information -

- a) **Name of the material, and brand name, if any;**
- b) **Name and address of the manufacturer;**
- c) **Batch or Code number;**
- d) **Month and year of manufacturing or packing;**
- e) **Net mass (*see* 6.1.1);**
- f) **Date before which the contents should be consumed be indicated by marking the words 'Use before..... (month and year)';**
- g) ***Composition* — Indicating the approximate composition of nutrients per 100 g of the product as well as the energy value in joules;**
- j) **Feed chart and directions for use; and**
- k) **Any other requirements as stipulated under *PFA Rules, 1955, Infant Milk Substitutes, Feeding Bottles and Infant Foods Act, 1992 and Rules 1993; and Standards of Weights and Measures (Packaged Commodities) Rules, 1977.***

- Composition — Indicating the approximate composition of nutrients per 100g of the product as well as the energy value in joules
- Feed chart and directions for use and
- Any other requirements as stipulated under *PFA Rules, 1955, Infant Milk Substitutes, Feeding Bottles and Infant Foods Act, 1992 and Rules 1993, and Standards of Weights and Measures (Packaged Commodities) Rules, 1977.*