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Food and Drug Administration




Updates on the Microbiological Standards of the Food and Pharmaceutical Industries in the Philippines


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- FDA Circular 2013-010
"Revised Guidelines for the Assessment of Microbiological Quality of Processed Food"
 - tabulated list of reference criteria for certain processed food
 - Made effective on 27 February 2013

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- **Revision history of The Guidelines of the Microbiological Quality of Processed Foods**
 - B.C No. 01-As 2004 - Issued on 4 February 2004
 - B.C No. 7s 2001 - Issued on 22 June 2001

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- Methods and cited specifications in FDA Circular 2013-010 were taken from internationally recognized references such as:
 - FDA Bacteriological Analytical Manual published by AOAC
 - Compendium of Analytical Methods of the Canadian Health Protection Branch
 - Compendium of Methods for the Microbiological Examination of Foods compiled by the American Public Health Association (APHA)

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- Specifications and Standards for Foods, Food Additives, etc. Japan External Trade Organization
- Microorganisms in Foods by the International Commission on Microbiological Specifications for Foods (ICMSF)
- Codex Alimentarius Commission Guidelines
- International Standards Organization (ISO) Microbiological Methods
- Australia New Zealand Food Authority (ANZFA)

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- FDA Circular No. 2013-010 is divided into 14 food categories:
 1. Milk and Dairy Products
 2. Fats, Oils and Fat Emulsions
 3. Edible Ices, Including Sherbet and Sorbet
 4. Confectioneries
 5. Fruits and Vegetables, Nuts and Seeds
 6. Egg and Egg Products



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7. Cereals and Cereal Products
8. Bakery Products
9. Ready to Eat Savouries
10. Meat and Meat Products
11. Fish and Fish Products
12. Spices, Soups, Sauces, Salads and Protein Products
13. Beverages
14. Food for Infants and Young Children



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[FDA Circular 2013-010.pdf](#)
[FDA Circular 2013-010-A.pdf](#)

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- For Food products not found in the **FDA Circular 2013-010**, issuances from **Bureau of Product Standards** of the **Department of Trade and Industry** specifically the **Philippine National Standards** are used.

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- For Drug and Pharmaceutical Products, methods and reference criteria are referred from the **United States Pharmacopeia**.
- Certain specific drug products are tested according to specified parameters stated in the monograph.
- Products without official monographs will fall under the following categories:
 - Non-sterile Products
 - Dietary Supplements

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Parameters	Non-sterile Products
Total Aerobic Microbial Count (TAMC)	250 cfu/g
Total Yeast and Molds Count (TYMC)	50 cfu/g
Bile-tolerant Gram-Negative bacteria	Negative
<i>Escherichia coli</i>	Negative
<i>Salmonella</i>	Negative
<i>Pseudomonas aeruginosa</i>	Negative
<i>Staphylococcus aureus</i>	Negative
Clostridia	Negative
<i>Candida albicans</i>	Negative

Table 1. Microbiological limits for Non-sterile Products.

Material	Recommended Microbial Limit Requirements (cfu/g or mL)
Dried or Powdered Botanicals	Total Aerobic Microbial Count NMT 10 ⁷
	Total Combined Yeast & Mold Count NMT 10 ⁶
	Absence of <i>Salmonella</i> spp. B. F. coli in 10 g
	Absence of <i>Shigella</i> spp. B. F. coli in 10 g

Material	Recommended Microbial Limit Requirements (cfu/g or mL)
Other raw materials and dietary supplement ingredients	Total Aerobic Microbial Count NMT 10 ⁷
	Total Combined Yeast & Mold Count NMT 10 ⁶
	Absence of <i>E. coli</i> in 10 g
	Total Aerobic Microbial Count NMT 10 ⁶
Nonsterile supplements with synthetic or highly refined ingredients	Total Aerobic Microbial Count NMT 10 ⁷
	Absence of <i>E. coli</i> in 10 g

Table 2. Microbial Limits for Botanical Ingredients and Products



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• Herbal products are evaluated based on the specifications stipulated in the following:

- Administrative Order No. 184 s.2004: **Guidelines on the Registration of Traditionally-Used Herbal Products***
- Administrative Order No. 172 s.2004: **Guidelines on the Registration of Herbal Products***

* Both A.O shows identical microbiological specifications for raw materials and finished product.

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3.9 Microbial limits
Test to detect and quantify the following microbial contaminants shall be conducted: aerobic bacteria, Sacchromycoetes and Hypomycoetes

3.9.1 For untreated plant material harvested under acceptable hygienic conditions intended for further processing:

Organisms	Unit	Limits
Escherichia coli	cfu/g	Negative
Moulds propagules	cfu/g	Maximum 10 ⁴
Staphylococcus	cfu/g	Negative

3.9.2 Plant materials that will undergo pre-treatment (e.g. with boiling water as used for herbal teas and infusions) or if the material is to be used for topical dosage form:

Organisms	Unit	Limits
Aerobic bacteria	cfu/g	Maximum 10 ⁴
Yeasts and moulds	cfu/g	Maximum 10 ⁴
Escherichia coli	cfu/g	Negative
Salmonellae	cfu/g	Negative
Staphylococcus	cfu/g	Negative
Other Enterobacteria	cfu/g	Maximum 10 ⁴

3.9.3 Plant materials to be used in drugs for internal use:

Organisms	Unit	Limits
Aerobic bacteria	cfu/g	Maximum 10 ³
Yeasts and moulds	cfu/g	Maximum 10 ³
Escherichia coli	cfu/g	Negative
Salmonellae	cfu/g	Negative
Staphylococcus	cfu/g	Negative
Other Enterobacteria	cfu/g	Maximum 10 ³

Table 3. Microbial limits for raw materials according to AO No. 184 s 2004.

the following tests and standards shall be utilized in determining the quality of the finished product:

1. Moisture Content –not more than 10%
2. pH
3. Microbial Limits

4.3.1 For Solid Products

Organisms	Unit	Limits
Aerobic bacteria	cfu/g	Maximum 10 ⁴
Yeasts and moulds	cfu/g	Maximum 10 ²
Escherichia coli	cfu/g	Negative
Salmonellae	cfu/g	Negative
Staphylococcus	cfu/g	Negative
Other Enterobacteria	cfu/g	Maximum 10 ²

4.3.2 For Liquid Products

Organisms	Unit	Limits
Aerobic bacteria	cfu/g	Maximum 10 ²
Yeasts and moulds	cfu/g	Maximum 10 ²
Escherichia coli	cfu/g	Negative
Salmonellae	cfu/g	Negative
Staphylococcus	cfu/g	Negative
Other Enterobacteria	cfu/g	Maximum 10 ²

Table 4. Microbial limits for finished products according to AO No. 184 s. 2004



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Criteria for Acceptance of Samples for Microbiological Analyses

- o Sufficient number of samples
- o Proper storage/transport condition
- o Absence of foreign object, insect or rodent
- o Unspoiled samples
- o Accurately and completely filled-up Request of Analysis

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MINIMUM SAMPLE REQUIREMENTS

1. Samples for Conformity Assessment:
 - monitoring purposes
 1. water bottled - 5 units with same lot identification code not < 350 mL/bot.
 2. snack foods, etc. - should follow required # of samples for micro specs (FDA Circular No. 2013-010-27 Feb.2013)
 3. Samples collected from bulk - collect from 5 diff. containers (not < 200 g)
 4. Drugs - solid form (capsules, tablets) - 20 g
- liquid - 2 bottles in commercial presentation

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MINIMUM SAMPLE REQUIREMENTS

2. Samples for Sanitation Purposes - 2 units commercial presentation
3. Samples for investigation purposes - 2 units commercial presentation
4. Samples for Commercial Sterility - 6 units (commercial presentation) not < 100 g

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