

MINIMUM REQUIRED SAMPLES FOR LABORATORY ANALYSIS

BFAD MEMORANDUM CIRCULAR NO. 20, S. 1994, September 07, 1994

Read online (full-text search, related cases, audio case brief): <https://batas.org/library/e9f51189d143/>

For the information and guidance of all concerned, hereunder is the list of the minimum required samples for laboratory analysis.

1. Pharmaceutical Products (Applicable only for product registration and deliveries)

1.1 Physico-Chemical Analysis (including Microbiological Test)

1.1.1 Tablet/Capsule

- 1 commercial presentation-100 tablets or capsules

1.1.2 Liquid/Suspension - 60 ml - 10 bottles

Solution - 120 ml - 6 bottles

1.1.3 Ointment/Cream - less than 5 gm. - 6 tubes/bots.

- 5 to 10 gm. - 3 tubes/bots.

- 3.5 gm or 15 gm- tubes/bots.

- 15 to 30 gm. - 1 tube/bots.

1.1.4 Granule for Suspension - 30 mL - 10 bottles

60 mL - 6 bottles

1.1.5 Powder/Bulk Material - 500 g

1.1.6 Aerosol - 3 commercial presentations

1.1.7 Suppositories - 25 pcs.

1.1.8 Injectables - less than 2 mL - 12 ampules

- 5 mL to 10 mL - 3 vials

- 20 mL to 100 mL - 1 vial

1.2 Sterility Test

1.2.1 Liquid Preparations:

1 mL or less - 15 vials or ampules

2 mL - 5 mL - 12 vials or ampules

10 mL - 20 mL - 10 vials or ampules

25 mL - 50 mL - 6 bottles

100 mL - 1000 mL - 6 bottles

1.2.2 Solid Preparation:

Less than 50 mg - 18 vials

50 mg or more but

less than 200 mg - 14 vials

200 mg or more - 12 vials

Ointments - 12 pcs.

1.2.3 Medical Devices (including leachability test)

Sutures - 16 pcs.

Surgical Blades - 16 pcs.

Needles - 17 pcs.

I.V. Catheters - 19 pcs.

Scalp Vein Sets/Butterfly - 19 pcs.

Transfusion Sets - 11 pcs.

Infusion Sets - 11 pcs.

Syringes 10 mL-50 mL - 19 pcs.

5 mL-5 mL - 27 pcs.

Oxygen Cannula - 10 pcs.

Stomach Tube - 10 pcs.

Foley Ballon Catheter - 10 pcs.

Gloves - 11 packs

Contact Lens & Implant - 4 pcs. *

Gauze & Surgical Dressings - 8 pcs. *

Dialyzing device/tubings - 9 pcs.

Drainage Tubings - 10 pcs.

Endotracheal Tube - 10 pcs.

Feeding Tube - 11 pcs.

Oxygen Catheter - 10 pcs.

Oxygen Mask - 10 pcs.

Peritoneal Dialysis

Administration Set - 11 pcs.

Rectal Catheter - 10 pcs.

Rectal Tubes - 10 pcs.

Duodenal Tubes - 10 pcs.

Urine Collecting Bag - 8 pcs.

Suction Catheter - 8 pcs.

* Sterility test only

1.3 Leachability Test

1.3.2 Containers for Pharmaceutical Preparations

Plabottles/IV Infusion bags - 4 pcs.

Polyampoules - 12 pcs.

Ophthalmic containers - 12 pcs.

Vials - 12 pcs.

Nebulizer/Rotahalers/Diskhalers - 2 pcs.

Plastic Containers for Suspension/Syrups

10 mL - 8 pcs.

30-60 mL - 6 pcs.

greater than 60mL - 4 pcs.

1.4 Pyrogen Test

1.4.1 Solution for correcting water, electrolytes, acid base and caloric disturbances: ex: parenterals, electrolytes or IV additive solutions, etc.

Volume of Product

Amount to be Submitted

5 mL

48 pcs.

10 mL

24 pcs.

50 mL

5 pcs.

100 mL

4 pcs.

250 mL

2 pcs.

500 mL

2 pcs.

1000 mL

2 pcs.

1.4.2 Liquid preparations e.g. antibiotics, antineoplastics, vitamins, sedatives, tranquilizers, dissociative agents, anesthetics, analgesics, etc.

1 mL or less 15 vials or ampules

2 mL to 5 mL 10 vials or ampules

10 mL or more 5 vials or ampules

1.4.3 Sterile powder for injection to be reconstituted

Less than 50 mg 10 vials or ampules

50 mg or more but less than 200 mg 8 vials or ampules

200 mg or more 5 vials or ampules

1.5 Primary Skin Irritation Test

2 pcs.

commercial presentation

1.6 Muscle Irritation Test (I.M. Adm. Drug)

3 pcs.

- do -

1.7 Implantation Test

3 pcs.

- do -

1.8 Primary Eye Irritation Test

2 pcs.

- do -

1.9. Insulin Assay

3 pcs.

- do -

1.10 Hemolytic Test

3 pcs.

- do -

1.11 Micronucleus Test

3 pcs.

- do -

1.12 Safety Test

3 pcs.

- do -

1.13 Histamine Test

3 pcs.

- do -

1.14 Skin Sensitization Test

3 pcs.

- do -

1.15 Iron Dextran Injection Test

3 pcs.

- do -

1.16 Other Biological Test - Refer to Animal House Section LSD

2. Food/Food Products

2.1 Physio-Chemical Analysis (Including Microbiological Test [whenever applicable])

Alcoholic Beverages 750 mL - 1

Baking Powder 350 g - 2

Bagoong (Shrimp & Fish) 370 g - 3

Sauce/Catsup 370 g - 3

Barquillos 350 g - 2

Beer 320 mL - 3

Biscuits, Cookies, Snack Foods

2 packs of not less than 250 g per pack

Bread - do -

Canned Fish (Sardines, Mackerel, Tuna)

6 cans x 155 g or 4 cans x 370 g

Canned and Frozen Foods

2 packs of not less than 250 g per pack

Candy/Confectionary Products 2 x 250 g

Cheese, Butter, Margarine 2 x 370 g

Chocolate/Cacao Products 2 x 350 g

Corned Beef, Meat Loaf 2 x 370 g

Dried Fruits 2 x 500 g

Fats and Oils

2 container of not less than 250 mL per container

Flavor, Essences, Food Color 2 x 200 mL

Flour, Bake mixes 2 x 500 g

Fish sauce, Soy sauce, Vinegar 2 x 750 mL

Food Supplement (Tablet, Capsule)

50 pcs. (1 bot. in original pack with at least 50 pcs)

Fruit juices & Beverages

4 packs of not less than 200 mL/g per pack

Frozen meat, Ham, Bacon, Sausages, etc.

2 packs of not less than 250 g per pack

Fruit preserves 4 x 340 g

Ice cream 2 x half gallon

Instant soup/noodles 10 x 85 g

Milk powder/Infant formula evaporated, condensed

2 samples of not less than 250 g/sample

Oats/Cereals 2 x 500 g

Spices/seasoning 4 x 100 g

Nut & nut products 2 x 500 g

Noodles, pasta, Macaroni 2 x 350 g

Pickles 2 x 250 g

Tea 2 x 250 g

Ready to mix dessert 10 x 85 g

Coffee 2 x 200 g

Mineral/Bottled Water 5 x 750 mL

Cereal-based chips, curls, Pretzels 2 x 250 g

Nutritive Sweeteners 2 x 250 g

Non-Nutritive Sweeteners 2 x 100 g

Food Dressings and Spreads 2 x 500 g

Note: pack means in original commercial pack

3. Cosmetics Products

3.1 Physico-Chemical Analysis

3.1.1 Skin Care Products

Deodorants/antiperspirant 100 mL

Feminine Deodorant 100 mL

Lotions/Moisturizers 100 mL

Cleansing creams/Lotions 100 mL

Astringents 200 mL

Depilatories 100 mL/g

Skin Lighteners 100 mL

Skin fresheners 100 mL

Foot powder 100 g

Suntan/Sunscreen 100 mL/g

Shaving cream 100 mL

3.1.2 Hair Care Products

3.1.2.1 Noncoloring

Hair Conditioners/Rinses 200 mL

Hair Spray 100 mL

Hair Straightener 100 mL/g

Shampoos 200 mL

Permanent Wave Lotion and Neutralizers 100 mL @

Tonics 100 mL

Dressings, other grooming aids 100 mL/g

Wave Set 100 mL

3.1.2.2 Hair Coloring Preparations

Hair Dyes, Shampoo-ins and Hair Rinse 100 mL

Hair Lighteners, bleaches 100 mL

3.1.3 Make-up and Beauty Care

Blushers 1 commercial presentation

Lipsticks - do -

Foundations - do -

Pressed powder - do -

Eye area make-up

Eyebrow pencil 2 commercial presentation

Eyeline - do -

Eyeshadow 20 g

Eye Lotion 20 g

Eye make-up remover 20 g

Mascara 20 g

3.1.4 Baby Products

Shampoos 100 mL/g

Lotions, Colognes - do -

Oils/Creams - do -

Powder - do -

3.1.5 Fragrance Preparations

Colognes/Toilet Water 100 mL

Powder (Dusting, Talcum) 100 g

Perfume 1 commercial presentation

3.1.6 Others

3.1.6.1 Manicuring Preparations

Cuticle remover 100 mL

Nail Polish & Enamel 30 mL

Nail Polish Remover 100 mL

3.1.6.2 Oral Hygiene

Dentrifices 100 mL

Mouthwashes/Breath Fresheners 100 mL

3.2 Microbiological Test - for selected cosmetic preparations

3.2.1 Additional samples of not less than 50 g in separate commercial presentation

NOTE: In cases where there is a need for a retest, additional samples will be requested.

4. Household Hazardous Substances

4.1.1 Category I Petroleum Distillates

Cigarette Lighter fluid 100 mL

Solvent Points, Lacquer, Thinner, Mineral Spirits 100 mL

Paints, Lacquers, varnishes 100 mL

Adhesives

2 commercial presentation each (tubes) 50 mL/g

4.1.2 Category II Polishes and Waxes

Furniture Polish 100 mL/g each

Shoe polish - do -

Floor polish - do -

4.1.3 Category III Cleanser and Detergent

Bleaches 200 mL

Cleansers 100 mL

Detergent/soap 200 g/mL

Fabric softener 100 mL

Fabric cleaner 200 mL

Glass cleaner 200 mL

Toilet bowl cleaner 200 mL

Alkali cleaners 200 mL

4.1.4 Category IV Do it Yourself and Hobby Items

Glues 100 mL/g

4.1.5 Category V

Room freshener 100 mL

Deodorant Cake 20 g

4.1.6 Disinfectant

Phenolic compounds/Quarternary Ammonium Compounds 200 mL

5. Food Chemicals, direct and indirect 250 g

6. Boiler water additives 250 g
7. Printing Inks/Paints 50 g
8. Protective Coatings/Prints coated on metal or glass size 1" x 3", 10 pcs.
9. Diagnostic Reagents 1 set
10. Plastic Food Packaging Containers 6 pcs. 12" x 12"
11. Food/Food Products (Pesticide Residue Analysis) 250 g

This Memorandum Circular shall take effect immediately.

Adopted: 07 Sept. 1994

(SGD.) QUINTIN L. KINTANAR, M.D., PH.D.
Director - CESO I

ABOUT BATAS.ORG

Study smarter at BATAS.org

The Philippine bar review and law-school companion built around how your brain actually remembers.

The complete Philippine law library - free for everyone.

More than 100,000 Supreme Court decisions, Republic Acts, and executive issuances - full-text searchable, browsable by category and year, and always free. No paywall, no login. This PDF came from it.

Audio case-brief lectures.

Any decision becomes a podcast-style lecture - facts, issues, ruling, and doctrine - with read-along highlighting and a hands-free presentation mode. Study while commuting, working out, or resting your eyes.

Bar review built on the science of memory.

Complete, sequenced courses for all eight bar subjects, narrated like podcasts and reinforced with retrieval practice and spaced review - the study techniques with the strongest evidence behind them.

The full law-school curriculum.

One subscription unlocks the entire J.D. curriculum - every subject, every lesson, with your progress tracked down to the paragraph so you can pick up exactly where you left off, on any device.

Mock exams that tell you where you stand.

Timed multiple-choice exams graded instantly, with per-subject score breakdowns and focus suggestions that point you at your weakest topics first.

A study planner that keeps you on pace.

Set your schedule and BATAS tells you every day whether you are on track for bar day - and exactly which lesson to take next.

Start free at <https://batas.org>

The law library is free forever - and your first lesson is one click away.

The text of this document is an official public record and remains in the public domain. Formatting, presentation, and compilation © 2026 batas.org.

Downloaded free from the batas.org Law Library. Share it freely - the library is free for every law student, bar reviewee, and practitioner.