

**DEPARTMENT OF HEALTH
PHARMACEUTICAL SERVICE
PHARMACEUTICALS REGISTRATION
SECTION**

**Guidelines on the Testing of
Pharmaceutical Products containing Vitamins, Minerals, etc.**

A. Identification tests and assay tests are required for products containing the following ingredients:

Vitamins:

1. Vitamin A and its derivatives: all strengths.
2. Vitamins B₁, B₂, B₃ (nicotinamide), B₅ (pantothenic acid), B₆, and their derivatives: when contained in products at greater than 0.2mg per unit dosage.
3. Vitamin B₉ (folic acid): when contained in products at greater than 0.1mg per unit dosage.
4. Vitamin B₁₂ and its derivatives: when contained in products at greater than 0.01mg per unit dosage.
5. Vitamin C and its derivatives: when contained in products at greater than 0.2mg per unit dosage.
6. Vitamin D and its derivatives: all strengths.
7. Vitamin E and its derivatives: all strengths (except for products containing mixed tocopherols or optically pure forms such as d-alpha tocopherol, please refer to Part B for such products).
8. Vitamin H (biotin): all strengths.
9. Vitamin K and its derivatives: all strengths.

Minerals:

10. Mineral salts: when contained in products at greater than 1mg per unit dosage.

Others:

11. Glucosamine and its derivatives: all strengths.
12. Chondroitin and its derivatives: all strengths.

B. Identification tests only are required for products containing the following ingredients:

Vitamins:

1. Vitamin B₁, B₂, B₃ (nicotinamide), B₅ (pantothenic acid), B₆, and their derivatives: when contained in products at equal to or less than 0.2mg per unit dosage.
2. Vitamin B₉ (folic acid): when contained in products at equal to or less than 0.1mg per unit dosage.
3. Vitamin B₁₂ and its derivatives: when contained in products at equal to or less than 0.01mg per unit dosage.
4. Vitamin C and its derivatives: when contained in products at equal to or less than 0.2mg per unit dosage.
5. Vitamin E and its derivatives (for preparations containing mixed tocopherols or optically pure forms such as d-alpha tocopherol) : all strengths.

Minerals:

6. Mineral salts: when contained in products at equal to or less than 1mg per unit dosage.

Others:

7. Amino acids
8. Choline and its derivatives
9. Lecithin: when contained in products at equal to or more than 1000mg per unit dosage. Test for the presence of choline and phosphorous only.
10. Products containing more than or equal to 1000mg pure fish oil per unit dosage, test for the presence of eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA) for labelled content of more than or equal to 180mg and 120mg respectively.

C. Identification tests and assay tests are NOT required for the following ingredients (for such ingredients, control by input is required):

1. Animal extracts (e.g. liver concentrate).
2. Fish oil with label content containing less than 1000mg pure fish oil per unit dosage and other fatty acids.
3. Herbal materials and extracts (e.g. garlic, ginkgo biloba, ginger, ginseng, kava, rosehip, St. John's Wort).
4. Microorganisms (e.g. dried yeast, Lactobacillus acidophilus, Lactobacillus rhamnosus).
5. Lecithin: when contained in products at less than 1000mg per unit dosage.
6. Phospholipids other than lecithin (e.g. phosphatidylcholine, phosphatidylethanolamine, phosphatidylserine).
7. Inositol and cysteine.