C: A marked line.
D: Bath made of glass or plastics.
E: Stirring rod made of glass or stainless steel (3 mm in diameter, the lower end part of it is bent to make a loop, about 18 mm in diameter).
F: Thermometer with an immersion line.
G: Thermometer with an immersion line or a total immersion thermometer.
H: Immersion line

Procedure

Transfer the sample into sample container B up to the marked line C. When the sample is solid, melt the sample by heating to a temperature not higher than 20°C above the expected congealing point, and transfer to B. Fill the glass or plastic bath D with water at a temperature about 5°C below the expected congealing point. When the sample is liquid at room temperature, fill bath D with water at a temperature between 10°C and 15°C lower than the expected congealing point.

Insert the sample container B containing the sample into cylinder A. Adjust the immersion line H of thermometer F to the same level of the meniscus of the sample. After cooling the sample to about 5°C above the expected congealing point, move vertically the stirrer E at the rate of about 60 to 80 strokes per minute, and observe the thermometer readings at 30-second intervals. The temperature falls gradually. Discontinue stirring, when an appreciable amount of crystals has formed and the temperature is constant or has begun to rise. Usually, read the maximum temperature (reading of F), that is constant for a while after a rise of temperature. If no rise of temperature occurs, read the temperature that is constant for a while. The average of not less than four consecutive readings that lie within a range of 0.2°C constitutes the congealing point.

Note: If a state of super cooling is anticipated, rub the inner wall of bath B or put a small fragment of the solid sample into bath B for promoting the congealment, when the temperature approaches near the expected congealing point.

10. Content Uniformity Test

Content Uniformity Test is the test to determine the uniformity of dosage units by assay of individual units as directed in the individual monograph. If no specification for the *Content Uniformity Test* exists in the monograph, use the method in individual *Assay* procedure or an alternative appropriate method. Apply the following test unless otherwise specified in the individual monograph.

Select 30 units, assay the first 10 units individually and calculate the acceptance value. The requirements are met if the acceptance value is less than or equal to 15.0%. When the acceptance value is greater than 15.0%, test the next 20 units. The requirements are met if the final acceptance value of the 30 dosage units does not exceed 15.0% and no unit shows a deviation that exceeds 25.0% of the label claim.

$$\text{Acceptance value} = |M - \bar{X}| + ks$$

M: Label claim (100.0%), unless otherwise specified in the individual monograph.
$\bar{X}$: Mean of individual contents (x_1, $x_2 \cdots x_n$).
x_1, $x_2 \cdots x_n$: Individual contents of the units tested, expressed as a percentage of the label claim.
n: Sample size (number of units in a sample).
k: Acceptability constant, $k = 2.2$ when the sample size is 10, and $k = 1.9$ when the sample size is 30.
s: Standard deviation of the sample.

$$s = \sqrt{\frac{\sum_{i=1}^{n} (x_i - \bar{X})^2}{n - 1}}$$

11. Crude Drugs Test

The Crude Drugs Test is applied to the crude drugs mentioned in the General Rules for Crude Drugs.

Sampling

Unless otherwise specified, sample should be taken by the following methods. If necessary, preserve the samples in tight containers.

(1) When crude drugs to be sampled are small-sized, cut or powdered, 50 to 250 g of sample should be taken after mixing thoroughly.

(2) When crude drugs to be sampled are large-sized, 250 to 500 g of sample should be taken after mixing thoroughly.

(3) When the mass of each single piece of the crude drugs is not less than 100 g, not less than 5 pieces should be taken for a sample, or not less than 500 g of the sample should be taken after cutting to a suitable size and mixing thoroughly.

Foreign matter

Unless otherwise specified, weigh 25 to 500 g of the sample, spread out in a thin layer, and separate the foreign matter by inspecting with the naked eye or with the use of a magnifying glass of 10 magnifications. Weigh, and determine the percentage of foreign matter.

Preparation of the test sample for analysis

Preparations are to be made by mixing the sample well. Powdered drugs should be used as they are, and in the case of unpowdered drugs, unless otherwise specified, grind the sample into powder. If the sample cannot be ground into powder, reduce it as finely as possible, spread it out in a thin layer, and withdraw a typical portion for analysis. If necessary, preserve the test sample in a tight container.

Loss on drying

Unless otherwise specified, transfer 2 to 6 g of the test sample for analysis to a tared weighing bottle, and weigh accurately. Dry at 105°C for 5 hours, allow to cool in a desiccator (silica gel), and weigh accurately. Continue the drying at 105°C, and weigh accurately at 1-hour intervals. When the mass of the sample becomes constant, the loss of mass represents the percentage of loss on drying (%). When the period of time for drying is specified, weigh accurately after drying for the period of time specified, and determine the loss on drying (%).

Total ash

Ignite previously a crucible of platinum, quartz or porcelain between 500°C and 550°C for 1 hour. Cool, and weigh accurately the crucible. Unless otherwise specified, weigh accurately 2 to 4 g of the test sample for analysis in this cruci-