Regulation on Safe Containers, Packaging, and Dosing Dispensers for Pharmaceuticals

[Enforcement Date: 8/23/2016] [Ministry of Food and Drug Safety NotificationNo. 2016-88, 8/23/2016, Partial Amendment]

Ministry of Food and Drug Safety (Pharmaceutical Policy Division), 043-719-2641

Chapter 1 General Provisions

Article 1 (Purpose)

The purpose of this Decree is to prescribe the standards for safety containers and packaging of drugs and dosing dispensers such as measuring cups and spoons provided with drugs in order to prevent accidental ingestion of drugs by children and administer drugs including those for pediatric use at the correct dose to children according to dosing and administration instructions, pursuant to the provisions of Articles 38 (1) and 64 of the 『Pharmaceutical Affairs Act』 and Articles 48 subparagraph 4 and 73 (2) of the 『Regulation on the Safety of Pharmaceuticals, etc』.

Article 2 (Definition)

"Drugs for pediatric use" refers to drugs that are administered orally mainly to infants and children under the age of 11 years.

Chapter 2 Safety Containers and Packaging of Pharmaceuticals

Article 3 (Safety Containers and Packaging)

(1) Safety containers and packaging pursuant to the provisions of Article 73 (2) of the 『Regulation on the Safety of Pharmaceuticals, etc』shall be as follows:

1. Disposable Packaging
   Packaging for a single dose according to the approved (notified) measuring and administration (e.g., if the measuring is one packet or two tablets per administration, those packaged with 1 packet or 2 tablets,)
2. Special Packaging [e.g.: packaging designed to be opened by pressing the top or side of the cap and turning (push down and turn caps), packaging where first, the cover film shall be peeled off from

the back before the tablet is forced out (peel and push), packaging that is opened by peeling the seal from the back (peel-open), packaging that is opened by pressing it with a certain force (hard push), packaging that is opened by tearing in a specific direction (tear open), etc.]: A container or package that is designed to be difficult for children under the age of 5 to open within 5 minutes.

(2) The standards for "special packaging" pursuant to the provisions of paragraph (1) 2 follow the 『Safety standards for child-resistant reclosable containers for industrial products』 (Notification by Korean Agency for Technology and Standards of the Ministry of Trade, Industry and Energy)" or 『Child-resistant non-reclosable packaging for pharmaceutical products』 (European Norm14375)", 『child-resistant packaging -requirements and testing procedures for reclosable packages』 (ISO 8317)", "Part 16, Chapter 1700 of the U.S. 『Federal Regulations (16CFR 1700)』 and other equivalent standards. However, a product may be exempt from the standards when using the same packaging type and materials that meet the testing standards.

Chapter 3 Standards and Test Methods for Dosing Dispensers for Pharmaceuticals

Article 4 (General Information)

(1) The dosing dispensers shall be free from any defects such as distortion, cracks, and flaws and the surface shall be smooth with all edges and corners rounded.

(2) The graduations of the dosing dispenser shall be marked corresponding to dosing and administration instructions provided with a drug. The graduations shall be proved to be suitable with the transparency test.

(3) General matters not stipulated in this notification shall comply with the Korean Pharmacopoeia or the official compendium and the standards approved by the Minister of Ministry of Food and Drug Safety pursuant to Annex 1-2 of the 『Regulation on Approvals, Notifications and Reviews for Pharmaceuticals』.

Article 5 (Test Item)

Tests required for a dosing dispenser shall include properties, accuracy of graduations, elution test for heavy metals (only for measuring cups) and transparency test (only when there are graduations). Other tests necessary for quality control (including precision of graduations,) may be added based on valid evidence.

Article 6 (Test Standards)

(1) As for the property, items for identification such as color, shape, material and other features shall be described and be appropriate.

(2) As for the accuracy of graduations, each measured value shall be within ± 5% of the indicated value.

(3) The heavy metal in the eluate shall be lead, which is less than 10 ppm.

(4) When performing a transparency test according to the prescribed test method, the height of the liquid shall be easily identified at eye level, and the volume of the liquid shall be measurable according to the indicated scale.

(5) When setting other tests necessary for quality control, test criteria may be determined according to valid evidence.

Article 7 (Test Method)

(1) The properties shall be observed with the naked eyes.

(2) The accuracy of graduations shall comply with the following:

1. Measuring cup

Take 10 samples and accurately weigh the mass of each empty measuring cup (m1). Place the sample on a horizontal surface and fill it up to the meniscus with distilled water at room temperature, respectively, up to the maximum and minimum graduation lines. Accurately weigh the mass (m2) of the measuring cups filled with distilled water up to each graduation line. The volume of the sample shall be the value obtained by converting the difference of sample's mass (m2-m1) into the volume according to the density conversion table for water in the specific gravity and density test methods of the Korean Pharmacopoeia.

2. Measuring spoon

Place each of the 10 samples on a horizontal surface and fix it using a clamp so that the steel needle is positioned vertically at the center of the recess of the spoon. Make the height of the tip of the needle be 1.7 mm from the edge of the spoon using precision tools such as feeler gauge and add distilled water with a 10 mL burette at room temperature. Then, accurately measure the amount of consumption until the tip of the needle touches the meniscus, and set it as the capacity of the measuring spoon.

(3) The elution test for heavy metals shall be as follows. However, if it is proved that the test results are not affected by the atomic absorption spectrophotometry or inductively coupled plasma analysis, these analytical methods may be used.

Take one sample for each of the eluates 1) to 5) specified in the table below and fill the measuring cups respectively with each eluate to the maximum graduation, and leave it at room temperature for 12±1 hours to use the eluted solution as each elution sample. Add 12 mL of elution sample and 20mL of water, adjust the pH to 3.0-3.5 with ammonia solution or diluted acetic acid, and add water to make

50 mL to use as the test solution. Separately add 12 mL of each eluate, 12 mL of lead standard solution (10 ug/ml), and 8 mL of water and operate in the same manner as for the preparation of the sample solution below to use as each comparison solution. Add 1 drop of sodium sulfide to the test solution and the comparison solution, mix, and leave for 5 minutes. When two tubes are observed from the top or side of the Nessler tube on a white background and the color of the solution is compared, the color of the test solution shall not be darker than the color of the comparison solution.

Type	Composition
Eluate 1)	1.0 mol/L Hydrochloric acid
Eluate 2)	1.0 mol/L Sodium hydroxide solution
Eluate 3)	50 g/L Sodium hypochlorite solution
Eluate 4)	50 g/L Propylene glycol solution
Eluate 5)	Chloroform, Ethanol, Water (1:100:99)

(4) The transparency test shall be conducted as follows:

Take 10 samples and at 200-500 Lux brightness under a 20 W daylight fluorescent lamp located at 1.5 ± 0.1 m vertically above the dosing dispensers, use 1) distilled or deionized water and 2) standard emulsion (Test Method for Plastic Containers for Pharmaceuticals in the Korea Pharmacopoeia) as test solutions. Fill the test solutions 1) and 2) to the closest small graduation line from the center of each dosing dispenser, and observe from eye level with white background.

(5) If there are alternative test methods to the ones specified in Paragraphs (1) to (4) and their accuracy and precision are better than the specified methods, the alternatives may be used. However, if any doubts are raised about the result, the final decision shall be made by the prescribed methods.

Article 8 (Re-review of Regulation)

Pursuant to Article 8 of the 『Framework Act on Administrative Regulations』 and the 『Regulations on the Issuance and Management of Directives and Established Rules』 (Presidential Decree No. 248), the appropriateness of this Decree every three years, counting from January 1, 2014 (referring to the period that ends on December 31 of every third year) shall be reviewed and proper measures including improvements shall be taken.

ADDENDUM <No. 2016 – 88, 8/23/2016>

Article 1 (Enforcement Date)

This notification will take effect on the date of its notification.