MINISTRY OF HEALTH OF THE RUSSIAN FEDERATION

GENERAL PHARMACOPOEIA MONOGRAPH

Weight loss on drying **GPM**.1.2.1.0010.15

Replaces the State Pharmacopoeia of the Russian Federation XI Monograph

The present General Pharmacopoeia Monograph describes the method used to determine weight loss on drying for medicinal products and immunobiologicals. The term «Weight loss on drying» means the weight loss due to hygroscopic moisture and volatile substances determined in a substance after it is dried to a constant weight or for the period of time specified in the Pharmacopoeia Monograph or in the Normative Document.

The “weight loss on drying” test is performed using the methods described below or other validated methods specified in the Pharmacopoeia Monograph or in the Normative Document. The obtained result is expressed as a per cent mass fraction.

The drying procedure

The accurately measured weight of the tested substance specified in the Pharmacopoeia Monograph or in the Normative Document is placed in a weighing cup dried beforehand to a constant weight and weighed in the test conditions. The sample is dried, with the weighing cup cover off, to a constant weight or for the period of time specified in the Pharmacopoeia Monograph or in the Normative Document.

Method 1. Unless otherwise specified, the sample is dried for 2 hours in a baker within the temperature interval specified in the Pharmacopoeia Monograph

or in the Normative Document. After that, the open weighing cup with its cover is placed in an exsiccator to cool down for 50 minutes, after which it is closed with the cover and weighed. Subsequent weighing procedures are performed once an hour during the subsequent weighing, until a constant weight is achieved. Unless otherwise directed, the sample is dried to a constant weight in the temperature range of 100 to 105 ºC.

Method 2. Drying is performed in an exsiccator over phosphorus (V) oxide using one of the following methods:

– at atmospheric pressure and room temperature;

– in a vacuum, at room temperature or the temperature specified in the Pharmacopoeia Monograph or in the Normative Document;

– in «deep vacuum»: at a pressure not exceeding 0.1 kPa, at the temperature specified in the Pharmacopoeia Monograph or in the Normative Document.

Other conditions may be used, provided that they are specified in the Pharmacopoeia Monograph or in the Normative Document.

The weight loss on drying test procedure for immunobiological medicinal products

Measuring cups with a height of 35 mm and a diameter of 25 mm are used for this test. An accurately measured weight of 0.15 to 0.20 g of the tested sample is placed in a measuring cup and dried with the cover open at 60 ± 1 °C and a residual pressure not exceeding 0.667 kPa (5 mm Hg), over a period of 3 hours. The open weighing cup with its cover is placed in an exsiccator to cool down for 40 minutes, after which it is closed with the cover and weighed.

The weight loss on drying (X) is calculated as a percentage according to the following equation:

$$X = \frac{m_2 - m_3}{m_2 - m_1} \times 100\% \ ,$$

where: m_1 is the weight of the measuring cup brought to a constant weight (g);

m_2 is the weight of the measuring cup containing the tested sample before drying (g);

m_3 is the weight of the measuring cup containing the tested sample after drying (g).