
Weight loss on drying

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This General monograph is designed to determine the weight loss on drying in medicines and immunobiological medicinal products. “Weight loss on drying” term is defined as the loss in weight due to hygroscopic moisture and volatile matter, which is determined in the substance during drying to the constant weight, or within the time specified in the Pharmacopoeial Monograph or in the Normative Documentation.

The determination of weight loss on drying is carried out by the following methods or other validated methods specified in the Pharmacopoeial Monograph or in the Normative Documentation. The result is expressed as a weight fraction in percent.

Methodology of drying

An accurately weighed quantity of the test substance specified in the Pharmacopoeial Monograph or in the Normative Documentation, is placed in a weighing bottle prior dried to the constant weight and weighed under test conditions. The sample is dried in a weighing bottle with an open cap to the constant weight or for the time specified in the Pharmacopoeial Monograph or in the Normative Documentation, by one of the following ways.

Method 1. Unless otherwise specified, the sample is dried for 2 hours in an oven within the temperature interval specified in the Pharmacopoeial Monograph or in the Normative Documentation. Then an open weighing bottle with the cup is placed in a desiccator to cool for 50 minutes, then it is covered with the cup and weighed. In subsequent cases, the weighing is carried out after each hour of further drying until the constant weight achievement. In the absence of other instructions, the sample is dried to the constant weight at temperature of 100 to 105°C.

Method 2. The drying is carried out in a desiccator over phosphorus (V) oxide by one of the following methods:

- at atmospheric pressure and room temperature;
- in vacuum, at room temperature or the temperature specified in the Pharmacopoeial Monograph or in the Normative Documentation;
- under “deep vacuum”: at pressure of not more than 0.1 kPa, at the temperature specified in the Pharmacopoeial Monograph or in the Normative Documentation.

It is possible to use other conditions specified in the Pharmacopoeial Monograph or in the Normative Documentation.

The method of weight loss on drying determination in immunobiological medicinal products

For analysis, the weighing bottles with height of 35 mm and diameter of 25 mm are used. An accurately weighed quantity of 0.15-0.20 g of the test sample is placed in a weighing bottle and dried with an open cap at temperature of $(60 \pm 1)^\circ\text{C}$ and residual pressure of not more than 0,667 kPa (5 mm Hg) for 3 h. An open weighing bottle with the cup is placed in a desiccator to cool for 40 minutes then it is covered with the cup and weighed.

The weight loss on drying (X) in percent is calculated by the formula:

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

where: m_1 is the mass of a weighing bottle brought to the constant mass, g;

m_2 is the mass of a weighing bottle with the test sample before drying, g;

m_3 is the mass of a weighing bottle with the test sample after drying, g.