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Tests in the New Ph. Eur. Monograph on Cannabis Flower

by Sabine Paris, PhD

The monograph on Cannabis flower (3028) has been published in Ph. Eur. Supplement 11.5 in January 2024, with an implementation date of 1 July 2024. All member states of the European Pharmacopoeia are required to replace their national monographs with this new Ph. Eur. Monograph.

Existing national monographs have been used in the preparation of this new monograph, e. g. the monographs of Germany, Denmark, the Netherlands and Switzerland.

The Ph. Eur. monograph on Cannabis flower covers the herbal drug used as a raw material for the production of extracts, or prescribed as is, to be taken by patients by inhalation or oral administration (i.e. prescribed to patients as a medicinal product).

The European Directorate for the Quality of Medicines and HealthCare (EDQM) presented key points and background information in a webinar on 14 December 2023.

This feature summarises the necessary tests required by the monograph.

Tests Cannabis Monograph (3028)	Maximum	Comment/Background Information
Total CBN: sum of cannabinol (CBN), and cannabinolic acid (CBNA) expressed as CBN	1.0 %	Contents of more than 1.0 % of CBN indicate significant degradation of the herbal drug. Liquid chromatography (UV detection) with an octadecylsilyl silica gel column is the method of choice.
Foreign Matter	2.0 %	Seeds and leaves longer than 10 mm are considered foreign matter.
Loss on Drying	12.0 %	It is necessary to perform this test at low temperature (40 °C) and under 'medium vacuum' to minimise evaporation of non-water volatiles (e.g. essential oil/terpenes).
Arsenic	0.2 ppm	If the herbal drug is not used as a medicinal product, the same limits as in the general monograph Herbal Drugs (1433) apply. Otherwise, the listed limits derived from
Cadmium	1.0 ppm	
Lead	5.0 ppm	

Tests Cannabis Monograph (3028)	Maximum	Comment/Background Information
Mercury	0.1 ppm	ICH Q3D for Class I elements based on the permissible daily inhalation exposure apply.

Figure 1 Test of Ph. Eur. Cannabis flower monograph

A specification for **moulds** is not included in the monograph but this is covered in the general chapter on foreign matter (2.8.2) – ‘other foreign elements’. A risk assessment shall be carried out for the control of moulds. The sampling procedure and the expected appearance of the herbal drug are defined. Mould control is also covered by GACP (Good Agricultural and Collection Practice).

Other applicable tests according to the general monograph Herbal Drugs (1433) are:

Other tests from the general monograph Herbal Drugs (1433)	Comment/Background Information
Pesticides	If cultivation takes place in a closed environment where contamination with pesticides is not possible, the manufacturer may justify not testing for pesticides by the design and agricultural method of production. This approach must be agreed with the competent authority.
Aflatoxin B ₁	According to the general chapter <i>Determination of aflatoxin B₁ in herbal drugs</i> (2.8.18) herbal drugs must not contain more than 2 µg/kg of aflatoxin B ₁ .
Microbial contamination	If the herbal drug is used as a medicinal product, the limits in Ph. Eur. chapters 5.1.8 <i>Microbiological quality of herbal medicinal products for oral use and extracts used in their preparation</i> and 5.1.4 <i>Microbiological quality of non-sterile pharmaceutical preparations and substances for pharmaceutical use</i> apply.

Figure 2 Other test from the monograph Herbal Drugs (1433)

Test for **other aflatoxins** than aflatoxin B₁ are not included in the monograph because Cannabis flower does not present a particularly high risk of being affected by fungal infections. Cannabis flos does not have a particularly high sugar content.

A test for **total ash** is not included in the monograph because mineral contamination of Cannabis flower is expected to be very low.

Sources

Ph. Eur. Monograph on Cannabis flower (3028)


EDQM-Webinar: The new Ph. Eur. Cannabis flower monograph (3028), Thu, Dec 14, 2023

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