# Ph. Eur. Monograph 3028

*The technical requirements of the European Pharmacopoeia for medical cannabis flower*

### WHAT IT IS

The first common European pharmaceutical standard dedicated specifically to *cannabis* flower.

*Ph. Eur. 07/2024:3028*

### WHEN IT ENTERED INTO FORCE

Adopted in June 2023, published in Supplement 11.5 (January 2024), mandatory since 1 July 2024.

*EDQM*

### WHAT IT MEASURES

Cannabinoid content (including CBN), certain specific impurities, and the physical quality of dried flower.

*Ph. Eur. 3028*

### WHERE IT APPLIES

Where the flower is classified as a herbal drug/pharmaceutical material in a jurisdiction in which the Ph. Eur. has legal force, not automatically to every *cannabis* product.

*EDQM*

## INTRODUCTION

Until 2024, every European state that permitted the medical use of *cannabis* flower relied on separate national monographs, those of Germany, Denmark, the Netherlands, Switzerland and others, with requirements that were not always identical for cannabinoid content or impurity limits. This fragmentation created uncertainty for producers targeting multiple markets.

The European Pharmacopoeia (Ph. Eur.), administered by the European Directorate for the Quality of Medicines & HealthCare (EDQM), closed this gap by adopting the first common monograph for *cannabis* flower, Ph. Eur. 3028, "*Cannabis* flower / *Cannabis* flos" adopted in June 2023, published in Supplement 11.5 in January 2024, and mandatory where the Ph. Eur. has legal effect, since July 2024.

The precise scope deserves particular clarification: the monograph applies where *cannabis* flower is classified as a herbal drug or pharmaceutical material in a jurisdiction in which the European Pharmacopoeia has binding legal force. It does not apply automatically to every *cannabis* product in circulation (e.g. cosmetic or food products); the scope depends on the regulatory status that each jurisdiction assigns to the specific product.
The monograph is always read together with the general monograph **"Herbal drugs" (1433)** and with the horizontal general chapters of the Ph. Eur., which supplement the requirements for aspects not addressed with specific figures in monograph 3028 itself, which is of particular importance for pesticides, microbiology and certain aspects of aflatoxins, as explained below.

## DEFINITION OF THE MATERIAL

The monograph defines *cannabis* flower as the dried, whole or fragmented, fully developed female inflorescence of the *Cannabis* sativa L. plant. This material is distinct from other parts of the plant (separated leaves, stems, seeds), to which different provisions would apply.

**IMPORTANT CLARIFICATION**

The definition does not absolutely exclude every trace of other materials. The monograph permits a minimal amount of rachis (the central axis of the inflorescence), and sets additional specific requirements for the product intended directly for the patient; for this form, the absence of seeds and of leaves larger than 1 cm is required.

## CLASSIFICATION BY CANNABINOID CONTENT

One of the main innovations of monograph 3028 is the formal division of *cannabis* flower into three types according to the THC/CBD ratio, which allows a common classification language across the European market.

| Type | Total THC (dried material) | Total CBD (dried material) |
|---|---|---|
| THC-dominant | minimum 5.0% | maximum 1.0% |
| Intermediate THC/CBD | minimum 1.0% (ratio 0.2-5.0 with CBD) | minimum 1.0% |
| CBD-dominant | maximum 1.0% | minimum 5.0% |

## CONTENT TOLERANCE AND THE CBN TEST

For products intended directly for patients, the measured total THC and CBD content may not deviate from the value declared on the label by more than ±10%, a markedly stricter limit than the previous national tolerances, some of which allowed deviations of up to ±20%. The monograph also includes a limit for total cannabinol (CBN): maximum 1.0% (dried material). CBN is a degradation product of THC that increases over time and under sub-optimal storage conditions; its presence in high amounts serves as an indirect indicator of the age of the product or of unsuitable storage conditions. The clinical importance of the ±10% tolerance relates directly to the nature of medical *cannabis* dosing: since the product is often administered by inhalation or in home preparations, the patient and the physician rely on the label to assess the effective dose. A large deviation may lead to under-dosing or over-dosing.

## HEAVY METAL LIMITS

The heavy metal limits are the part of the monograph that requires the greatest attention, because they do not apply identically in every case: the monograph sets two different groups of limits, according to the intended destination of the product.

| Metal | General use | Direct prescription to the patient |
|---|---|---|
| Arsenic (As) | — | maximum 0.2 ppm |
| Cadmium (Cd) | maximum 1.0 ppm | maximum 0.3 ppm |
| Lead (Pb) | maximum 5.0 ppm | maximum 0.5 ppm |
| Mercury (Hg) | maximum 0.1 ppm | maximum 0.1 ppm |

## AFLATOXINS

Contrary to what a quick reading might suggest, monograph 3028 does not treat aflatoxin control as a single, universal test automatically mandatory for every batch. The aflatoxin requirements are linked to general monograph 1433 and to the horizontal chapters of the Ph. Eur., and apply as a function of a risk assessment specific to the product and its intended use. The aflatoxin B1 limit (2 µg/kg, under general chapter 2.8.18) remains an important reference, but the competent authority may require, depending on the case, control of the sum of the four aflatoxins (B1+B2+G1+G2) as well, with a maximum limit of 4 µg/kg. Precisely which of these tests applies depends on the product dossier and on the requirements of the importing country.

## MICROBIOLOGICAL QUALITY AND PESTICIDES

For pesticides and microbiological quality, monograph 3028 does not set separate numerical limits within its own text, but refers to the relevant general chapters: chapter 2.8.13 for pesticide residues, and chapters 5.1.8 or 5.1.4 for microbiological quality, depending on the route of administration of the final product. The specific requirements therefore derive from these general texts and from the intended use of the product, not from monograph 3028 as such. The EDQM currently has a revision in progress intended to set additional specific limits for flower destined for vaporisation (under the Ph. Eur. work programme for 2026). This revision has not yet entered into force and should not be presented as a currently applicable standard.

## WHAT IS NOT REQUIRED

The monograph does not require testing for total ash, since mineral contamination of *cannabis* flower is considered naturally low. The limit for foreign matter is a maximum of 2%, and the maximum loss on drying is 12%; these two requirements remain specific and direct requirements of monograph 3028 itself.

## IDENTIFICATION AND TESTING METHODS

The monograph sets out specific laboratory methods for verifying identity and content:

- Macroscopic and microscopic examination, to verify the morphological characteristics of the flower (glandular trichomes, characteristic hairs specific to *Cannabis* sativa L.).
- High-performance thin-layer chromatography (HPTLC, chapter 2.8.25), for comparative identification of the sample against certified reference substances.
- Quantitative methods (typically high-performance liquid chromatography, HPLC), for the precise determination of the total content of THC, CBD and CBN, including their acidic forms (THCA, CBDA), which are mathematically converted into the "total" value during calculation.

## LABORATORY COMPETENCE

Ph. Eur. 3028 sets the analytical standard, what must be measured and within which limits, but does not itself impose a universal requirement as to the competence or qualification of the laboratory carrying out the testing. This means that the monograph states what must be tested, not how it must be demonstrated that the laboratory itself is capable of doing so correctly. The requirement as to which laboratory is considered acceptable may come from the national legislation of the producing or importing country, from the contract between the parties, or from the specific importing authority, not from the text of the European monograph itself.

In practice, this means that two laboratories may apply exactly the same method described by the monograph, yet only one of them be considered acceptable by a given market, because verification of its competence comes from a process entirely external to, and separate from, the pharmaceutical text itself.

## CONCLUSION

Ph. Eur. monograph 3028 marks the transition from differing national monographs towards a more harmonised European standard, linking the pharmaceutical quality of *cannabis* flower to patient safety. An accurate knowledge of its requirements, and in particular of the distinction between the limits for "general use" and those for "direct prescription to the patient", of the conditional nature of the aflatoxin and microbiological requirements, and of the fact that laboratory competence is verified outside the monograph itself, is an essential element for any entity seeking to produce and export a product acceptable on the European market.

## REFERENCES

[1] European Pharmacopoeia 11.5. Cannabis flower / Cannabis flos, monograph 07/2024:3028.

[2] European Directorate for the Quality of Medicines & HealthCare (EDQM). Ph. Eur. pre-publishes Cannabis flower monograph, 2023.

[3] European Pharmacopoeia. Herbal drugs, general monograph 1433.

[4] EDQM. Ph. Eur. Work Programme, 2026 (revisions in progress, including specifications for vaporised flower).

[5] European Pharmacopoeia, general chapters: 2.8.18 (Aflatoxin B1), 2.8.13 (Pesticide residues), 5.1.8/5.1.4 (Microbiological quality), 2.8.25 (HPTLC).

[6] Law no. 61/2023 "On the cultivation and processing of the *cannabis* plant for medical and industrial purposes", Republic of Albania.