Royal Decree 903/2025, of 7 October, establishing the conditions for the preparation and dispensing of specified magistral formulas containing standardised cannabis preparations.

Ministry of Health
"BOE" (Official State Gazette) No 243, of 9 October 2025.
Reference: BOE-A-2025-20077

TABLE OF CONTENTS

CONSOLIDATED TEXT
Latest amendment: no amendments

I

Cannabis contains a wide variety of components, including, for their well-known pharmacological activity, tetrahydrocannabinol (THC), which is the main psychoactive component, and cannabidiol (CBD), which is considered to have no psychotropic effect.

Scientific evidence has revealed a varying degree of benefit from cannabis and its extracts in some therapeutic indications. At present, the indications for which there is more evidence and consensus in the scientific community are spasticity due to multiple sclerosis, severe forms of refractory epilepsy, chemotherapy-induced nausea and vomiting, and refractory chronic pain. For the first three indications, industrially manufactured medicinal products containing either cannabis extracts with the active ingredients THC and/or CBD, or synthetic cannabinoids have been authorised. These medicinal products have been authorised according to the usual procedures applicable to industrially manufactured medicinal products, after a full evaluation of the studies proving their quality, safety, and efficacy in certain therapeutic indications, including the mandatory clinical trials. The authorisation of these medicinal products by the European national authorities, the European Commission or regulatory authorities with equivalent requirements ensures a favourable risk-benefit balance for the indications and conditions of use included in their summary of product characteristics. For the indication of refractory chronic pain, there are no authorised medicinal products in Spain based on cannabis. Although a wide range of medicinal products and therapeutic strategies are available to treat all types of pain, sometimes sufficient pain control is not achieved for patients. In cases where authorised treatments are not sufficiently effective, using specified magistral formulas containing standardised cannabis extracts may be an option for consideration.

At the request of the Health and Consumer Affairs Committee of the Congress of Deputies, in its session on 13 May 2021, and in order to analyse experiences of regulating cannabis for medicinal use, a Sub-Commission was created, whose conclusions indicate that cannabis-derived preparations could be useful as a therapeutic option for some patients. Consequently, the Sub-Commission’s recommendations included urging for the adoption of the necessary measures to allow for the availability of standardised cannabis preparations to accommodate certain patients, for whom these medicinal products may entail an improvement when authorised treatments have not been effective. They also recognised that the existence of standardised preparations with a defined composition is an advantage in terms of dosage, stability, and handling, compared to other possible types of cannabis use.

The use of specified magistral formulas containing standardised cannabis preparations, registered with the state body, the "Spanish Agency for Medicines and Medical Devices" (hereinafter, AEMPS), ensures the quality of these formulas, their reproducibility, and homogeneity, allowing for a more predictable dosage and use. These formulas are prepared after the issuing of a medical prescription and, under the direction of a pharmaceutical professional, by hospital dispensaries, complying with the applicable Good Manufacturing Practices.

The National Formulary contains the specified magistral formulas; the inclusion of a monograph in the National Formulary addresses the need to standardise the preparation of these medicinal products and establish a series of uses and indications in which the specified magistral formulas containing cannabis preparations could be an alternative in the event that other therapeutic options fail.

In order to guarantee the quality of these preparations, this royal decree establishes the conditions for the prescription, preparation, dispensing, and use of specified magistral formulas containing standardised cannabis preparations, as well as a register of the standardised cannabis preparations used in the preparation of these magistral formulas.

II

This royal decree is structured into ten articles, two additional provisions, three final provisions and an annex.

Articles 1 and 2 establish the purpose of the decree, the conditions for the prescription, preparation, and dispensing of standardised cannabis preparations, and the establishment of a register for these preparations. A list of definitions used in this decree is also drawn up.

Article 3 regulates the control conditions applicable to the preparations covered by this decree.

Article 4 concerns the need for, and regulations applicable to, the publication in the National Formulary of the corresponding monograph of the specified magistral formulas containing standardised cannabis preparations.

Articles 5 and 6 lay down the obligations of pharmaceutical laboratories that manufacture the standardised cannabis preparations with regard to compliance with good manufacturing practices and good distribution practices, as well as the obligation of pharmaceutical laboratories to apply to the AEMPS for registration in the register of standardised cannabis preparations.

Articles 7, 8, and 9 establish the conditions for prescription by medical specialists, and their obligation to justify the treatment with specified magistral formulas containing standardised cannabis preparations by means of the required documentation, as well as the conditions for preparation by the legally established hospital dispensaries, in accordance with the requirements of the National Formulary. The decree also covers the conditions for dispensing and pharmacotherapeutic monitoring by hospital dispensaries and the medical team.

Finally, Article 10 establishes the need for health professionals to report suspected adverse reactions to the specified magistral formulas to the corresponding Autonomous Centre for Drug Safety Monitoring.

This royal decree is in accordance with the principles for good regulation referred to in Article 129 of Law 39/2015, of 1 October, on the Common Administrative Procedure of Public Administrations, particularly the principles of necessity, effectiveness, proportionality, legal certainty, transparency and efficiency.

It complies with the principles of necessity and effectiveness as it is justified by the reasons of general interest described in the preceding paragraphs, and is the most appropriate instrument for ensuring the achievement of the proposed targets.

As regards compliance with the principle of proportionality, this regulation contains the legislation necessary to meet the identified needs, so that in order to achieve the objectives set, there are no other measures that are less restrictive of rights or impose fewer obligations on the addressees. In addition, any possible limitations on rights comply with the provisions of Law 14/1986, of 25 April, on General Health, and the consolidated text of the Law on guarantees and rational use of medicines and medical devices, approved by Royal Legislative Decree 1/2015, of 24 July.

The draft law complies with the principle of legal certainty, since it is respectful and consistent with the national legal system, and is specifically designed to regulate, update, develop and supplement the existing legislation on medicinal products and magistral formulas, in particular with regard to standardised cannabis preparations, ensuring the quality, safety and correct use of said preparations.

Furthermore, in accordance with the principle of transparency, during the drafting procedure of the draft royal decree, the active participation of potential recipients of the regulation, including healthcare professionals, hospital pharmacy services and manufacturing laboratories, was ensured through consultation and public information procedures.

In compliance with the principle of efficiency, the draft law introduces only the administrative burdens essential to ensure the proper regulation of the prescription, preparation, dispensing, registration and pharmacovigilance of standardised cannabis preparations, at the same time guaranteeing the protection of the general interest, without introducing additional or different procedures to those provided for in Law 39/2015, of 1 October.

This royal decree does not introduce or establish procedures additional to or other than those provided for in Law 39/2015, of 1 October. However, specialities of the specific procedure are maintained due to the subject matter, relating to time-limits and reports to be obtained, already present in the procedures governed by the previous legislation.

This royal decree has been the subject of a prior report by the Advisory Committee and the entire Interterritorial Council of the National Health System. In the process of drafting this regulation, the Autonomous Communities, the cities of Ceuta and Melilla, and the affected sectors have been consulted, among others.

In compliance with the provisions of Article 149.1.16 of the Spanish Constitution, this royal decree is issued in accordance with the exclusive competence of the State in matters of legislation on pharmaceutical products, and by virtue of the provisions of the consolidated text of the Law on guarantees and rational use of medicines and medical devices, approved by Royal Legislative Decree 1/2015, of 24 July, in particular its Chapter IV of Title II, on health guarantees for magistral formulas, and its second final provision, which authorises the Government, within the scope of its powers, to approve regulations and rules for the application and development of said law.

Accordingly, on the proposal of the Minister for Health, with the prior approval of the Minister for Digital Transformation and the Civil Service, in agreement with the Council of State, and after deliberation by the Council of Ministers, at its meeting on 7 October 2025,

I HEREBY DECREE THE FOLLOWING:

Article 1. *Purpose and scope of application.*

1. This royal decree establishes the conditions for the prescription, preparation, dispensing, and use of specified magistral formulas containing standardised cannabis preparations. In addition, it establishes a register of the standardised cannabis preparations used in the preparation of these specified magistral formulas, in order to guarantee the quality of these preparations.
2. Authorised industrially manufactured medicinal products, and cannabis-based medicinal products under investigation, which will be governed by the respective specific regulations, fall outside the scope of this royal decree. Cannabinoids obtained by synthetic processes, or from sources other than cannabis, also fall outside the scope of this royal decree.

Article 2. *Definitions.*

For the purposes of this royal decree, the following definitions will apply:

a) Standardised cannabis preparation: a product with a defined amount of THC and/or CBD, containing one or more standardised cannabis extracts, registered by the AEMPS, for use in the preparation of a specified magistral formula.

b) Cannabinoids: organic compounds, belonging to the terpenophenol group, present in cannabis and responsible for its main pharmacological effects.

c) Delta-9-tetrahydrocannabinol (THC): cannabinoid component of cannabis, present in variable quantities, the main chemical substance responsible for its psychoactive effects and which has the legal status of psychotropic substance, included in Schedule II of Annex 1 to Royal Decree 2829/1977, of 6 October, regulating psychotropic medicinal substances and preparations, as well as the control and inspection of its manufacture, distribution, prescription, and dispensing.

d) Cannabidiol (CBD): cannabinoid component of cannabis, present in varying quantities, chemical responsible for various pharmacological effects.

e) Specified magistral formula: the magistral formula included in the National Formulary, due to its frequent use and its usefulness.

Article 3. *Control conditions for standardised cannabis preparations.*

Standardised cannabis preparations with a THC content equal to or greater than 0.2% by weight will be considered psychotropic and will be subject to the control measures and restrictions derived from the 1971 Convention on Psychotropic Substances, provided for in Royal Decree 2829/1977, of 6 October, regulating psychotropic medicinal substances and preparations, as well as the control and inspection of their manufacture, distribution, prescription and dispensing.

Article 4. *Monographs of the National Formulary of specified magistral formulas containing cannabis preparations.*

1. The AEMPS will publish in the National Formulary the corresponding monograph to which the specified magistral formulas containing standardised cannabis preparations must conform.
2. The monographs must in any case include the contents provided for in Article 4 of Royal Decree

294/1995, of 24 February, regulating the Royal Spanish Pharmacopoeia, the National Formulary and the advisory bodies of the Ministry of Health and Consumer Affairs in this field, as well as the legally recognised indications for these medicinal products for the purposes provided for in Article 42 of the consolidated text of the Law on guarantees and rational use of medicines and medical devices.

Article 5. *Obligations of pharmaceutical laboratories that manufacture standardised cannabis preparations.*

1. Pharmaceutical laboratories that manufacture standardised cannabis preparations must carry out all manufacturing and/or control operations in accordance with the European Union good manufacturing practices for medicinal products. These laboratories must be established in the European Union.
2. Pharmaceutical laboratories are obliged to ensure that the suppliers or manufacturers of the starting materials used in the manufacture of standardised preparations comply with good manufacturing practices and good distribution practices. To this end, the suppliers or manufacturers will be audited at regular intervals. They will also document the supply chain of each starting material, which will be of lawful origin and comply with the legislation applicable to narcotic and/or psychotropic substances, as appropriate.
3. The pharmaceutical laboratories that manufacture standardised cannabis preparations may only supply such preparations to legally established hospital dispensaries or for export.
4. If these preparations are considered psychotropic due to their THC content, in accordance with Article 3, the manufacturing pharmaceutical laboratories must have the corresponding authorisation, in accordance with the provisions of Royal Decree 2829/1977, of 6 October.
5. Furthermore, when these manufacturers have obtained psychotropic preparations from narcotic substances (cannabis), they must have the corresponding authorisation in accordance with the provisions of Law 17/1967, of 8 April, which updates the current regulations on narcotics and adapts them to the provisions of the 1961 United Nations convention.

Article 6. *Register of standardised cannabis preparations.*

1. The register of standardised cannabis preparations is created, which will be public, under the responsibility and management of AEMPS, where standardised cannabis preparations used in the preparation of specified magistral formulas must be registered.
2. All phases of the procedure will be carried out by electronic means, in accordance with the provisions of Articles 14.2 and 16.1 and 4 of Law 39/2015, of 1 October, on the Common Administrative Procedure of Public Administrations. Likewise, notifications will be made in accordance with the provisions of Article 42.5 of the Regulation on the performance and functioning of the public sector by electronic means, approved by Royal Decree 203/2021, of 30 March.
3. In order to be entered in the register, the pharmaceutical laboratories responsible for the manufacture and placement on the market of such preparations must submit the corresponding application to the AEMPS, which must be provided through the electronic registry of the agency accompanied by the information on the preparations included in the Annex.
4. If the application does not meet the requirements, the applicant concerned will be required to, within ten days, remedy the deficiency or submit the required documents, being informed that if they fail to do so, they will be deemed to have withdrawn their application prior resolution.
5. Prior to the resolution, the interested party will be granted a hearing, in accordance with the provisions of Article 82 of Law 39/2015, of 1 October. The resolution of the proceedings will be issued by the head of the AEMPS Management.
6. The maximum period for issuing and notifying the resolution of the proceedings will be 6 months from the date on which the application was entered in the electronic register of the AEMPS. Otherwise, the application will be deemed to have been rejected.

The person in charge of the AEMPS Directorate is responsible for issuing the resolution that terminates the proceedings. Against the resolution that terminates the proceedings, an optional appeal for reconsideration may be lodged within one month of the day following that on which the notification of the resolution takes place, in accordance with the provisions of Articles 123 and 124 of Law 39/2015, of 1 October, or an administrative appeal before the Central Administrative Court of Madrid, within two months of the day following the notification of the decision, in accordance with Law 29/1998, of 13 July, regulating the Contentious-Administrative Jurisdiction, without prejudice to the possibility of exercising any other appeal that may be deemed appropriate.

7. Modifications to the registration conditions for standardised cannabis preparations must be subject to a specific variation procedure, which will be assessed and resolved by the AEMPS, upon request from the responsible laboratory. The general principles laid down in Commission Regulation (EC) No 1234/2008, of 24 November, on the examination of modifications to the terms of marketing authorisations for medicinal products for human use and veterinary medicinal products will apply. Based on their scope, and the impact on the quality of the preparation, it may require re-registration as referred to in paragraph 2.

8. The application for registration of standardised cannabis preparations will be subject to the fee set out in heading 1.2 of Group I: medicinal products for human use, of Article 123 of the consolidated text of the Law on guarantees and rational use of medicines and medical devices.

Article 7. *Prescription of specified magistral formulas containing standardised cannabis preparations.*

1. The specified magistral formulas containing standardised cannabis preparations will be used for the indications set out in the corresponding monograph of the National Formulary in cases where there are no industrially manufactured medicinal products authorised and marketed, or where these do not allow for the satisfactory treatment of a specific patient.

2. The prescription is limited to medical specialists, within the scope of hospital care, who treat patients with the indications detailed in the corresponding monograph of the National Formulary, in the cases described in paragraph 1 of this article.

3. The justification for treatment with specified magistral formulas containing cannabis preparations, in relation to other treatments received by the patient, will be documented in the medical record. The patient should also be informed of the available clinical evidence, the expected benefits and the possible risks. All this in accordance with Basic Law 41/2002, of 14 November, regulating the autonomy of the patient, and rights and obligations regarding information and clinical documentation.

4. The doctor or prescribing doctor will periodically assess the therapeutic utility and safety of the prescribed specified magistral formula and consider discontinuation of treatment if sufficient clinical benefit is not obtained or if the risk-benefit balance is unfavourable.

Article 8. *Preparation of specified magistral formulas containing standardised cannabis preparations by hospital dispensaries.*

1. The preparation of the specified magistral formulas will be limited to legally established hospital dispensaries, which have the necessary means for their preparation in accordance with the requirements established in the National Formulary and in the regulatory established good manufacturing practices and quality control practices.

2. Those standardised preparations that are considered psychotropic, due to their THC content, as well as the magistral formulas that are prepared using them, will be governed by their specific regulations.

Article 9. *Conditions for pharmacotherapeutic dispensing and monitoring.*

1. The dispensing will be carried out by the hospital dispensaries, which will provide pharmaceutical care and, in collaboration with the medical team, will conduct a comprehensive monitoring of the patient.

2. The need for continued treatment will be evaluated periodically, based on the clinical benefit obtained and the occurrence of adverse reactions, in accordance with paragraph 4 of Article 7.

3. When the clinical situation of dependence, vulnerability, risk, or physical distance of the patient to the centres referred to in paragraph 1 of this article arises, the competent bodies or authorities of the Autonomous Communities may establish the distance dispensing measures provided for in paragraph 8 of Article 3 of the consolidated text of the Law on guarantees and rational use of medicines and medical devices, approved by Royal Legislative Decree 1/2015, of 24 July.

Article 10. *Pharmacovigilance.*

1. Healthcare professionals are obliged to communicate suspected adverse reactions to the specified magistral formulas that contain standardised cannabis preparations to the Autonomous Centre for Pharmacovigilance corresponding to their field of care, in accordance with the procedure established by the Spanish Pharmacovigilance System for Medicinal Products for Human Use (SEFV-H).

2. Users may report suspected adverse reactions through the channels authorised for this purpose by the AEMPS, either by informing health professionals who, after carrying out their clinical assessment,

will inform the Spanish Pharmacovigilance System, or by informing the Spanish Pharmacovigilance System directly. The latter will be done via an electronic form on the website.

First additional provision. *Effects of the publication of the monographs of specified magistral formulas containing cannabis.*

No later than 3 months after the entry into force of this royal decree, the monographs of the specified magistral formulas to which such formulas must conform will be published.

Second additional provision. *Preparation and dispensing by dispensing pharmacies of specified magistral formulas containing cannabis preparations.*

The preparation and dispensing by dispensing pharmacies of specified magistral formulas containing standardised cannabis preparations may be subject to specific regulation, without prejudice to their exceptional participation as third-party processors for hospital dispensaries, pursuant to of the provisions of Article 66 of the consolidated text of the Law on guarantees and rational use of medicines and medical devices, approved by Royal Legislative Decree 1/2015, of 24 July.

First final provision. *Attribution of powers.*

This royal decree is issued under Article 149.1.16 of the Spanish Constitution, which confers exclusive competence on the State in matters of legislation on pharmaceutical products.

Second final provision. *Legislative development.*

The head of the Ministry of Health is authorised to make all necessary provisions for the implementation and development of this royal decree, in particular to make the provisions for the development of the register of standardised cannabis preparations referred to in Article 6, as well as to update its annex in accordance with the progress of scientific and technical knowledge, in accordance with the guidance and guidelines of the European Union.

Third final provision. *Entry into force.*

This royal decree will enter into force on the day after its publication in the "Official State Gazette".

Issued on 7 October 2025.

FELIPE R.

The Minister of Health,
MÓNICA GARCÍA GÓMEZ

ANNEX

Information to be sent to the state body, the "Spanish Agency for Medicines and Medical Devices", for the registration of standardised cannabis preparations

The data and documents to accompany an application for registration pursuant to Article 6 will be provided in accordance with the requirements set out in this Annex.

When compiling the registration application dossier, applicants will also take into account the general chapters and monographs of the European Pharmacopoeia applicable to them, as well as the specific guidelines for herbal substances and preparations published by the European Medicines Agency.

For the purposes of this Annex, the Spanish term "extracto" will be considered equivalent to the English term "herbal drug extracts" as defined in the European Pharmacopoeia.

Module 1: Administrative information

1.1 The Registration Form will include:

- Identification of the standardised cannabis preparation by its name, the name of the herbal substance (according to the European Pharmacopoeia) and the definition of the extract(s) (including the physical state and the extraction solvent(s); in the case of standardised extracts, the THC and/or CBD content and the excipients, if any, must be indicated; likewise, the equivalent quantity of genuine plant preparation must be indicated, as a range, if applicable).

- The name and address of the applicant, the name and address of the suppliers of the herbal substance, as well as the name and address of the manufacturers and the places where the various stages of manufacture of the standardised extract(s) and of the standardised preparation of cannabis are carried out and their control.

1.2 The application will be accompanied by the Manufacturing and Import Authorisation of the manufacturer(s) of the standardised cannabis preparation. The latest certificate of Good Manufacturing Practice (GMP) or other proof of compliance with the GMP (reference number in the EudraGDMP database) will also be attached.

1.3 The proposed text for the label for the primary packaging to be supplied to hospital dispensaries will be provided. The labelling of such packaging will contain at least the following information:

- Name of the standardised preparation of cannabis, as well as the name of the herbal substance (according to the European Pharmacopoeia) and the definition of the extract(s) (including the physical state and the extraction solvent(s); in the case of standardised extracts, the THC and/or CBD content and the excipients, if any, must be indicated; likewise, the equivalent quantity of the genuine plant preparation, must be indicated, as a range, if applicable).
- For the excipients that have recognised action or effect and that are subject to mandatory reporting, in accordance with the applicable guidelines of the European Commission, the amount present in the standardised cannabis preparation will be indicated.
- Expiry date.
- Storage conditions.

Module 2: Chemical and pharmaceutical information

2.1 Standardised cannabis extract.

2.1.1 General information:

- Herbal substance: must comply with the provisions of the monograph of the European Pharmacopoeia of *Cannabis flos* (3028). The chemotype will be indicated.
- Extract: for the nomenclature of the extract, the binomial scientific name of the plant will be included (*Cannabis sativa* L.), as well as its chemotype, the parts of the plant used, the definition of the extract, the ratio of the plant substance to the extract, the extraction solvent(s).

The physical form will be indicated.

The content of components with known therapeutic activity (THC and CBD), and other component(s), will be indicated. Where applicable, the excipients used will be indicated.

2.1.2 Manufacturing:

2.1.2.1 Manufacturers:

- Herbal substance: the name, address, and responsibility of each supplier, including contractors and each proposed place or facility for the production/harvesting and control of the herbal substance, will be indicated. It must be confirmed that the herbal substance complies with good agricultural and harvesting practices for starting materials of plant origin.
- Extract: the name, address, and responsibility of each manufacturer, including contractors, and each proposed place of manufacture or installation for the manufacture and testing of the extract will be indicated.

2.1.2.2 Description of the manufacturing process and process controls:

- Herbal substance: for each one of the producers, information will be provided to adequately describe the production and harvesting of the plants, including their geographical origin and growing conditions, pre- and post-harvest treatments, drying and storage conditions, as well as batch size.
- Extract: a detailed description of each stage of the manufacturing process, including a flowchart, will be provided. It will be indicated how the extract is standardised to the declared THC/CBD content and, if excipients are used for the standardisation of the extract, the amount that can be added. The batch size will be indicated.

2.1.2.3 Control of the starting materials:

- Herbal substance: not applicable.

- Extract: a list of all materials used in the manufacture of the extract (herbal substance, solvents and reagents, as well as excipients, if used) will be provided, identifying the stage of the process at which each of them is used. Information on the quality and control of these materials will also be provided, and must comply with the requirements established in the monographs of the European Pharmacopoeia applicable to them.

2.1.2.4 Control of critical and intermediate steps.

- Herbal substance: not applicable.
- Extract: information on the critical steps will be provided. Information on the quality and control of intermediate process steps, if any, will be provided.

2.1.2.5 Manufacturing process validation and/or evaluation.

- Herbal substance: not applicable.
- Extract: validation data of the manufacturing process will be provided.

2.1.2.6 Development of the manufacturing process. A brief summary will be provided.

2.1.3 Characterisation:

2.1.3.1 Structural elucidation and other characteristics:

- Herbal substance: information on botanical, macroscopical, microscopical, and phytochemical characterisation will be provided.
- Extract: information on the phytochemical and physicochemical characterisation will be provided.

2.1.3.2 Impurities:

- Herbal substance: the potential contaminants/impurities arising from the cultivation of the herbal substance and post-harvest treatments (residues of pesticides and fumigants, toxic metals, aflatoxins etc.) will be indicated, and their origin described.
- Extract: the potential contaminants/impurities of the extract will be indicated, and their origin described.

2.1.4 Control of the active substance:

2.1.4.1 Specifications.

- Herbal substances: detailed information on the specifications used for the control of the herbal substance will be provided and must comply with the provisions of the monograph of the European Pharmacopoeia of *Cannabis flos (3028),* as well as with the general application monograph (*Herbal drugs,* 1433).
- Extract: detailed information on the specifications used for the control of the extract will be provided. Those specifications will be established in accordance with the European application guidelines or the specific monograph of the European Pharmacopoeia, if any.

2.1.4.2 Analytical procedures. The analytical procedures used for the control of both the herbal substance and the extract will be described in sufficient detail so that they can be reproduced in tests carried out at the request of the competent authority. In the case of testing procedures included in the European Pharmacopoeia, this description may be replaced by the corresponding reference to the monograph(s) and general chapter(s).

2.1.4.3 Validation of the analytical procedures. The validation results of the analytical procedures used for the control of the herbal substance and extract will be provided, where appropriate.

2.1.4.4 Batch analyses: for both the herbal substance and the extract, results of analyses of representative batches will be provided.

2.1.4.5 Justification of the specifications. The specifications of the herbal substance, where relevant, and those of the extract will be justified.

2.1.5 Standards and reference materials: the standards and reference materials used in the control of both the herbal substance and the extract will be identified and described in detail. Where available, the European Pharmacopoeia reference standards will be used.

2.1.6 Container and closure system: for both the herbal substance and the extract, the description of the container and the closure system and its specifications will be provided. These must comply with European legislation on plastic materials and objects intended to come into contact with food, or with the general chapters of the European Pharmacopoeia applicable to them.

2.1.7 Stability: information on the stability studies carried out, and their conclusions (retest period

or shelf life and storage conditions), will be provided. In the absence of such studies and, thus, where no retest period or shelf life has been established for the herbal substance and/or extract, these will comply with the specifications immediately prior to use.

2.2 Standardised cannabis preparation.

If the standardised cannabis preparation contains more than one standardised extract, the above-mentioned information will be provided for each of them.

Where the manufacturing process of the standardised cannabis preparation includes the mixing of different standardised extracts and/or their dilutions, the following information will also be provided:

2.2.1 Description and composition of the mixture of standardised extracts and/or their dilutions.

2.2.2 Manufacture of the mixture of standardised extracts and/or their dilutions:

- Manufacturers involved in the process.
- Batch formula: the detailed batch formula of the proposed size will be provided.
- Description of the manufacturing process and the process controls.

2.2.3 Control of the excipients: Information should be provided on the quality and control thereof, if necessary.

2.2.4 Control of the mixture of standardised extracts and/or their dilutions:

2.2.4.1 Specifications: detailed information on the specifications used for their control will be provided.

2.2.4.2 Analytical procedures: the analytical procedures used for the control will be described in sufficient detail so that they can be reproduced in the tests carried out at the request of the competent authority. In the case of testing procedures included in the European Pharmacopoeia, this description may be replaced by the corresponding reference to the monograph(s) and general chapter(s).

2.2.4.3 Validation of analytical procedures: the validation results of the analytical procedures used for their control will be provided.

2.2.4.4 Batch analyses: results of analyses of representative batches will be provided.

2.2.4.5 Justification of specifications: the proposed specifications will be justified.

2.2.5 Standards and reference materials: the standards and reference materials used in their control will be identified and described in detail, in the event that they do not coincide with those used for the control of the extract.

2.2.6 Packaging material: the description of the container and the closure system and its specifications will be provided. These must comply with European legislation on plastic materials and objects intended to come into contact with food, or with the general chapters of the European Pharmacopoeia applicable to them.

2.2.7 Stability: information on the studies carried out and their conclusions (validity period and storage conditions) will be included.