Development Process of a Medicinal Cannabidiol Dosing Pen

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Inhalation devices that allow controlled administration of active ingredients are undergoing constant technological evolution. In Brazil, there is a demand for devices that meet the requirements of this treatment modality, as it enables more precise application and improved dose management. The present study describes the development process employed in the medicinal cannabidiol dosing pen, an inhalation device designed for medical treatments with vaporized cannabidiol. Its functionality, based on controlled and standardized doses prescribed by medical professionals, offers the potential for remote treatment of individuals affected by conditions such as Alzheimer's and Parkinson's disease, among others. The method includes a prior art analysis focusing on inhalation-based devices and outlines a prototype development workflow through partial deliverables assigned by the project.
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Inhalation devices are widely utilized in medical practice due to their effectiveness in drug delivery. This approach demonstrates that inhaling vaporized medication offers greater patient treatment efficiency than other administration methods. According to Upadhyay and colleagues [1], oral application, compared to inhalation, is slower and less predictable in absorption, with peak concentration typically occurring between one to three hours. In contrast, the inhalation method allows drugs to penetrate directly into the systemic circulation through the nasal mucosa, which is thin and highly vascularized, resulting in faster access to the brain and a quicker onset of therapeutic effects [1].

Among the medications suited for this method is CBD (cannabidiol), a compound derived from cannabis. Based on various scientific studies, CBD is used in the treatment of anxiety, spasms, acute/severe pain, and seizures, offering a potential alternative to opioid use. Currently, the sale of cannabis-based products in Brazil requires approval and authorization from ANVISA, as outlined in Resolution RDC 327/2019. Considering this context, the technical team developed an electronic system that employs an electrical resistance mechanism to vaporize an active substance (CBD). The goal was to create a prototype that integrates medical functionality, ensures standardized dose administration, and allows for physician control and prescription.

The development process adhered to standards such as ABNT NBR ISO 60601-1:2010 (including Amendment 1:2016) and its collateral standards (Parts 2:2017, 6:2011, 8:2010, 9:2010, and 11:2021), as well as ABNT NBR ISO 80601-2-74:2020. In this light, this article's primary objective is to describe this device's development stages. The project framework aligns with a Technology Readiness Level (TRL) ranging between 2 and 5, focusing on presenting a functional prototype based on a concept tailored to meet project needs.

Materials and Methods

The project involved the development of an electronic device for the controlled administration of medicinal CBD doses via oral inhalation.

The process was divided into four main stages:

a) **Informational Stage –** This stage includes a detailed analysis, disassembly, and functional understanding of similar devices, market and

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management evaluations, and identification of applicable standards and patents.

b) **Conceptual Stage –** This phase focuses on defining the functional characteristics of the device and designing the prototype.

c) **Preliminary Stage –** During this phase, prototypes were tested, and simulations were conducted to evaluate their performance.

d) **Prototyping Stage –** This stage refined the final structure, conducted dose control testing and adjustments, and conducted post-processing for final finishes.

To manage the project effectively, SENAI CIMATEC utilized tools and resources provided by its organizational framework. These included the DIP&T (Department of Innovation and Technology Projects), the TRL classification (based on ISO/FDIS 16290—Space Systems: Definition of Technology Readiness Levels (TRLs) and their criteria for assessment), and product life cycle analysis.

The multidisciplinary technical team consisted of experts in biomedical equipment, embedded electronics, creative industries, and energy efficiency. The project office managed activities and progress throughout the project, providing crucial support in coordination and oversight.

Results and Discussion

The medicinal CBD dosage pen was developed based on market technologies, technical usability concepts, and normative principles. The device is designed in two separable parts: an upper and a lower section connected via a SNAP-type fitting. Additionally, it features USB-C charging, an air duct to facilitate vapor flow, and a system of contact pins enabling electronic communication between the two sections.

The upper section generally houses the storage compartment for vaporizing the substance in contact with an electric coil. The lower section contains the electronic structure, including the microcontroller, charging circuits, and activation mechanisms. Visually, the device's external structure showcases a cylindrical design with an ergonomically flattened mouthpiece at the upper tip (Figure 1). Internally, a magazine component is introduced (Figure 2), which houses and secures most electronic components, including the contact pins, coil, reservoir, and others.

Regarding the pen's logical functioning, it was established that when the user inhales, the heating coil is activated, initiating the process of timed dose control and triggering visual/sensory indicators on the device (such as signals for activation, inhalation, and charging). Thus, when an electrical current passes through the coil, it heats up, vaporizing the CBD fluid, which is then directed to the outlet via the air duct. This approach ensures an efficient, safe, and controlled user experience during the dosage pen's operation. As part of the project's development stages, tests were conducted to validate the

Figure 1. Medicinal CBD dosage pen.

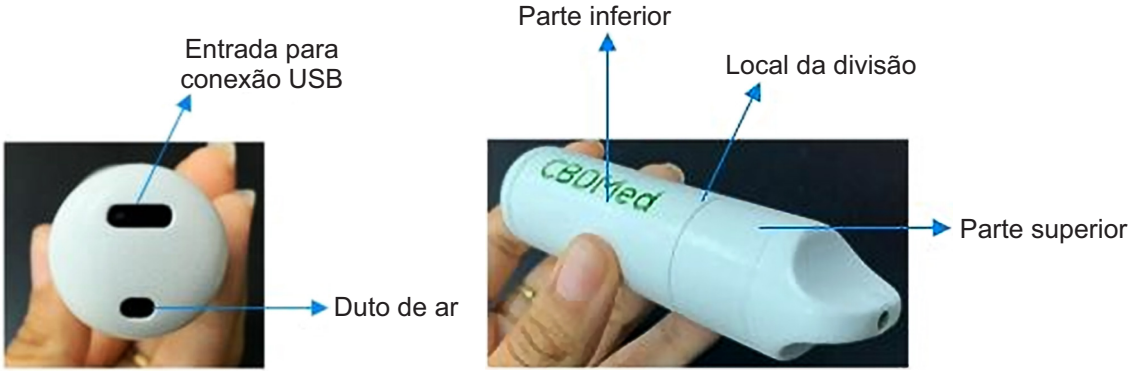
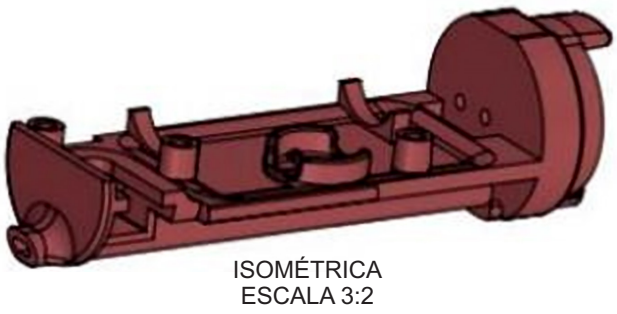


Figure 2. Magazine.



device's functionality (Table 1).

Comprehensive Results Analysis

Table 2 illustrates the data obtained from the vaporization validation in an experimental format. Using a closed-cycle process applied to each power level, the procedure involved charging the battery, activating the system for 4 seconds, performing 10 vaporization cycles, and measuring the mass thrice. For instance, for a dose of 2.15 ± 0.004 mg, there were 10 vaporization cycles, resulting in an individual

Table 1. Tests conducted during the project.

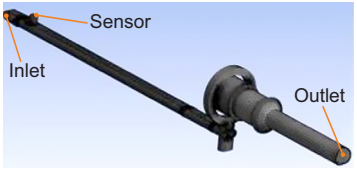
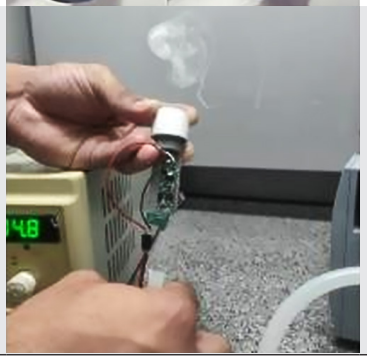
Test Description	Project Stage	Associated Figure	Results
Simulation of airflow through the air duct: Understanding the minimum/maximum airflow required for device activation for different target audiences.	Preliminary Stage		Consolidation of the fluid-dynamic circuit; minimum inhalation established for the entire process.
Validation of the heating system in the laboratory: Assessing the impact of power variation, required heating current, and other factors.	Prototyping Stage		Identification of activation/heating current.
Prototype validation: Usability analysis.	Prototyping Stage		Validation of mouthpiece contact, assembly/ disassembly of upper and lower parts, and connections.
Validation of dose quantity and vaporized amount in the laboratory at power levels of 80%, 90%, and 99%: Using an air propeller, the device was tested at three electrical power levels.	Prototyping Stage		Consolidation of vaporization for one dose of the substance.

Table 2. Relationship between dose and supplied power.

Duty/ Power	Dose (mg)	Battery Voltage Drop
80%	2.1mg ± 0.0004mg	0.218V
90%	4.48 ± 0.085mg	0.130V
99%	5.86mg ± 0.037mg	0.165V

dose of 0.215 ± 0.004 mg. A similar analysis was conducted for the remaining power levels.

Due to the project's scope limitations, it was not possible to present the collected data with greater precision, as this aspect was not included in the initial activity execution plan. In all tests conducted, the cannabidiol used was medicinal oil provided by the client. The cannabidiol was solid at room temperature and became oily when exposed to elevated temperatures.

In a comparative analysis with similar devices (PAX ERA, DOSISTY BATTERY, MEDIPEN, POD SYSTEM ZERO CARE RENOVA EDITION, and others), the device features a partitioned structure in two parts, visual/sensory signaling, battery control, temperature control, a magazine, the use of commercial components for heating, a reservoir for CBD, logical system control through a microcontroller, configuration based on the patient's needs, and operation according to medical prescriptions. The system was designed to be functional for the medical field, incorporating all applicable features for this context.

Conclusion

In summary, this article describes the development of the Cannabidiol Dosage Pen. The final results of the prototype, the designed concept, the applied operating principle, and other aspects are presented. The technical team faced difficulties regarding the availability of parts within the country and using embedded technologies in devices with this dimensional format. Under the management of the company CBDMed Brasil, the following steps include improving the device and conducting a clinical study to compartmentalize the device's actions in a practical context with patients and, ultimately, its commercialization in the national market. The main conflicting factor for this is certification by ANVISA, which, according to its regulations, prohibits products inspired by electronic cigarettes.

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