WORLD JOURNAL OF PHARMACEUTICAL RESEARCH
Coden USA: WJPRAP Impact Factor 8.453
Volume 15, Issue 1, 1225-1228. Research Article ISSN 2277–7105

ACCURACY OF DOSAGE IN NEGENT MICELLAR DROPS, CE MEDICAL DEVICE: A COMPARISON BETWEEN PIPETTE DROPPERS AND GRAVITY DROPPERS

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Article Received on 05 Dec. 2025,
Article Revised on 25 Dec. 2025,
Article Published on 01 Jan. 2026,

https://doi.org/10.5281/zenodo.18152103

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How to cite this Article: Tullio Scrimali* (2026). Accuracy Of Dosage In Negent Micellar Drops, Ce Medical Device: A Comparison Between Pipette Droppers And Gravity Droppers. World Journal of Pharmaceutical Research, 15(1), 1225-1228.

ABSTRACT

Dosage accuracy is a critical requirement for medical devices based on cannabidiol microemulsions. Some users of *NegEnt Micellar Drops*, CE Medical Device, reported a shorter-than-expected duration of the bottle equipped with a pipette dropper, suggesting possible variability in drop formation. This study compares the precision and homogeneity of drops delivered by a pipette dropper versus a pharmaceutical-grade gravity dropper. Twenty subjects participated in a controlled drop-weight test, followed by a 30-day longitudinal assessment. Results show significantly lower variability with the gravity dropper (SD ±2 mg) compared to the pipette dropper (SD ±5 mg), with statistical significance ($p < 0.05$). The second phase confirms the stability of the gravity system over time. We conclude that the gravity dropper ensures more accurate and reproducible dosing, improving the clinical reliability of the medical device.

KEYWORDS: NegEnt Micellar Drops; CE Medical Device; Micellar Cannabidiol; Precision Dosing; Dropper Systems; Dosage Variability; Pharmaceutical Technology.

INTRODUCTION

Dosage accuracy is essential for medical devices based on microemulsions, particularly when the active ingredient is present in micellar form. The pharmaceutical literature indicates that drop formation is influenced by multiple physical and rheological factors (Lachman et al., 1986; Washington, 1996).

Furthermore, European regulations require medical devices to ensure stable and reproducible delivery throughout their entire period of use (European Commission, 2017).

To verify the hypothesis that the pipette dropper was intrinsically less precise than a gravity dropper, a two-phase experimental study was conducted (see the two different devices at Figure n.1).

Figure 1: The two droppers tested.

SUBJECTS, MATERIALS AND METHODS

Twenty subjects (10 males and 10 females), young adults with a mean age of 34 ± 6 years, were enrolled and divided into two groups of 10 participants each.

Each subject was instructed to.

1. Dispense 10 drops onto a laboratory precision scale
2. Record 10 individual weight measurements
3. Repeat the procedure using the assigned dropper (pipette or gravity)

In the second phase, 10 volunteers used a bottle equipped with a gravity dropper for 30 days, taking five drops twice daily and recording drop weight at three time points (beginning, middle, and end of the month).

The methodology follows EMA standards for the evaluation of oral solutions (European Medicines Agency, 2020).

RESULTS

Phase 1

The gravity dropper showed significantly lower variability (SD ±2 mg) compared to the pipette dropper (SD ±5 mg), with statistical significance ($p < 0.05$).

These findings are consistent with the literature on microemulsions and surfactant-based delivery systems (Torchilin, 2006).

Phase 2

Subjects who previously showed high variability with the pipette dropper displayed values similar to those of the gravity dropper group. The drop weight remained stable across all 30 days, indicating that.

- bottle opening
- daily use
- progressive emptying did not affect the amount delivered.

DISCUSSION

The pipette dropper proved less precise and less reproducible than the gravity dropper.

The greater variability observed with the pipette dropper is consistent with Washington's (1996) findings on the sensitivity of drop formation to operational conditions.

CONCLUSIONS

The gravity dropper ensures more accurate and reproducible dosing, in accordance with European regulatory requirements (European Commission, 2017).

For this reason, the gravity dropper has been adopted as the standard dispensing system for *NegEnt Micellar Drops*, CE Medical Device.

ACKNOWLEDGMENTS

The author also wishes to emphasise, for the purpose of developing new scientific methodologies, that advanced artificial intelligence tools were employed in conducting the research presented, in drafting the present article, and in translating it from Italian into English. Scientific, methodological, and interpretative responsibility for all content remains entirely with the human author.

Funding & Disclosure Statement

Herbal Neurocare funded this research. The author declares no conflicts of interest other than the institutional relationship with the funding company.

Author Contributions

- **Tullio Scrimali:** study design, scientific supervision, data interpretation, manuscript drafting.
- **Advanced artificial intelligence tools:** support in text structuring, linguistic optimisation, formal revision, and translation.

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