Macedonian Pharmaceutical Bulletin, 72 (Suppl 1) 427 - 428 (2026)
Online ISSN: 1857-8969
DOI: 10.33320/maced.pharm.bull.2026.72.03.206
Short communication

Stability of THC-dominant dry Cannabis flower across multiple cultivars and packaging systems: a 12-month evaluation

Marina Topkoska[1,2*], Aleksandar Micev[1], Kristina Varsamovska[1], Emilija Pockova[1], Elena Gjorgievski Mihajlovska[1]

[1]*New Garden Pharma LLC, Skopje, Street 110 No.104 KO Kjojlija, 1043 Petrovec, Industrial Zone Petrovec, North Macedonia*
[2]*Evolv Health DOOEL, Leninova No. 38/1-2, 1000 Skopje, North Macedonia*

Introduction

Robust primary packaging is critical to protecting pharmaceutical-grade cannabis flower from moisture and oxygen throughout its declared shelf life. New Garden Pharma (NGP) conducted a comprehensive stability programme evaluating four packaging systems across multiple THC-dominant cannabis cultivars (Cannabis sativa L.), in compliance with EU-GMP requirements and relevant pharmacopoeial monographs (DAB, 2018; Ph. Eur. Monograph No. 3028, 2024).

The study examines whether shelf-life stability is driven by cultivar-specific phytochemistry or by standardised manufacturing and packaging barrier properties. Spanning seven batches across six cultivars and four packaging formats, the findings support packaging transition validation and the establishment of a 12-month shelf life applicable across the genus.

Materials and methods

Packaging systems evaluated

Four primary packaging configurations were assessed: Manufacturer No. 1 — Matt-BOPP laminate (BOPP/PET/Al foil 7 μm/LDPE; WVTR ≈ 0.1 g/m²/day), historical standard, discontinued; Manufacturer No. 2 — PET/Al laminate (PET/Al foil 12 μm/LDPE; WVTR ≈ 0.1–0.2 g/m²/day), current production standard; Manufacturer No. 3 — Metallized PET pouch (matt PET/PET met/EVOH-PE; WVTR 0.5–5.0 g/m²/day), used for stability studies only; Manufacturer No. 4 — Rigid HDPE jar with PP induction liner (WVTR ≈ 0 g/m²/day at seal), specialty rigid format with tamper evidence (NGP, 2026a).

Batches and cultivars

An initial assessment (NGP, 2026[b]) evaluated three commercial-scale batches (FP00XX, FP00XY, FP00YY) packaged in Manufacturer No. 1 pouches under long-term ICH Zone II conditions (25°C ± 2°C / 60% ± 5% RH) at T3, T6, and T9 months, demonstrating full compliance at all time-points, with extrapolation to 12 months supported per ICH Q1A(R2) and ICH Q1E (EMA, 2003).

The extended stability programme (NGP, 2026[a]) enrolled seven batches across six cultivars: Batch No. 1 (CB) and Batch No. 2 (WC) and Batch No. 3 (AA) in HDPE jars (Manufacturer No. 4); Batch No. 4 (MT), Batch No. 5 (JH), and Batch No. 6 (JOG) in metallized PET pouches (Manufacturer No. 3); and

*marina.topkoska@newgardenpharma.com

Batch No. 7 (MT) in PET/Al laminate pouches (Manufacturer No. 2). Batch No. 7 was initiated three months after Batches No. 1–6 and incorporated into the comparative analysis upon completion of its 12-month time-point.

Study design

Long-term storage conditions followed ICH Zone II guidelines: 25°C ± 2°C / 60% ± 5% RH, with testing at T0, T1, T3, T6, T9, and T12 months. Quality attributes were evaluated per DAB (2018) and Ph. Eur. 3028 (2024) Cannabis flos monographs, including organoleptic assessment, microscopy (Identity B), TLC (Identity C; Ph. Eur. 2.2.27), and HPLC. Critical quality attributes included total THC content, CBN content, loss on drying, and microbiological contamination.

Results and discussion

All seven batches across all four packaging systems remained within specification at 12 months under long-term storage conditions. No cultivar- or potency-related degradation was observed, confirming that shelf-life is governed by standardised EU-GMP processing and packaging barrier technology rather than cultivar-specific phytochemistry (NGP, 2026[a]; NGP, 2026[b]).

Manufacturer No. 1 pouches established the scientific baseline, with three batches demonstrating full compliance over 9 months, stable total THC, and CBN formation ≤0.08% w/w. As the thinnest foil evaluated (Al 7 µm), this data supports extrapolation of shelf-life conclusions to equivalent or superior systems. Manufacturer No. 2 (PET/Al 12 µm; WVTR ≈ 0.1–0.2 g/m²/day) offered the strongest moisture barrier and represents the optimal commercial choice. Notably, Manufacturer No. 3 (metallized PET; WVTR 0.5–5.0 g/m²/day), despite its comparatively higher transmission rate, maintained product integrity across all 12-month batches — making compliance of the superior Manufacturer No. 2 laminate technically inevitable. Manufacturer No. 4 (HDPE jars) delivered satisfactory stability, despite inherent limitations in oxygen and light barrier performance.

Consistent with DAB (2018) and Ph. Eur. 3028 (2024), stability is demonstrated at the genus level, requiring no further taxonomical differentiation for shelf-life purposes (GMP Journal, n.d.).

Conclusion

This 12-month stability evaluation demonstrates that THC-dominant dry cannabis flower across six cultivars remains stable when packaged in all four evaluated primary packaging systems. Building upon the initial 9-month stability data obtained with Manufacturer No. 1 pouches, a 12-month shelf life is validated for all product presentations within the genus *Cannabis* processed under NGP's EU-GMP-compliant manufacturing and quality management systems. Manufacturer No. 2 (PET/Al foil laminate) is identified as the optimal primary packaging solution for commercial batches, offering superior barrier performance and maximum product integrity. The results confirm that shelf-life is primarily determined by standardized processing and packaging barrier technology, rather than the phytochemical characteristics of individual cultivars.

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