

Supplementary Material

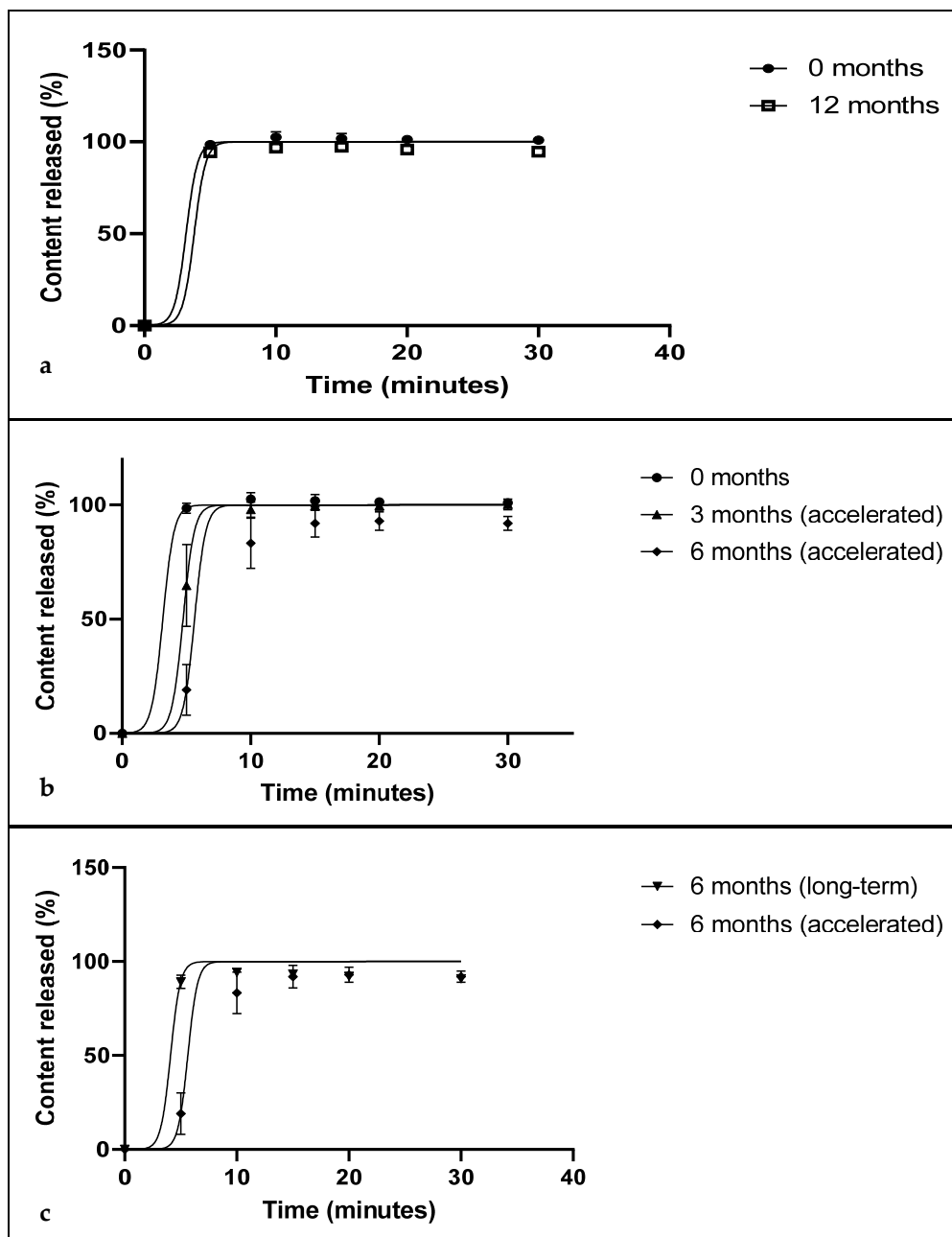


Figure S1. Dissolution profiles of 25 mg CA capsules: (a) Dissolution profile of 25 mg CA capsule at T0 vs. T12, stored under long-term storage conditions (25°C ± 2°C / 60% ± 5% RH); (b) Dissolution profile of 25 mg CA capsule at T0 vs. T3 and T6, stored under accelerated storage conditions (40°C ± 2°C / 75% ± 5% RH) ; (c) Dissolution profile of 25 mg CA capsule at T6 stored under long-term (25°C ± 2°C / 60% ± 5% RH) vs. accelerated storage conditions (40°C ± 2°C / 75% ± 5% RH).

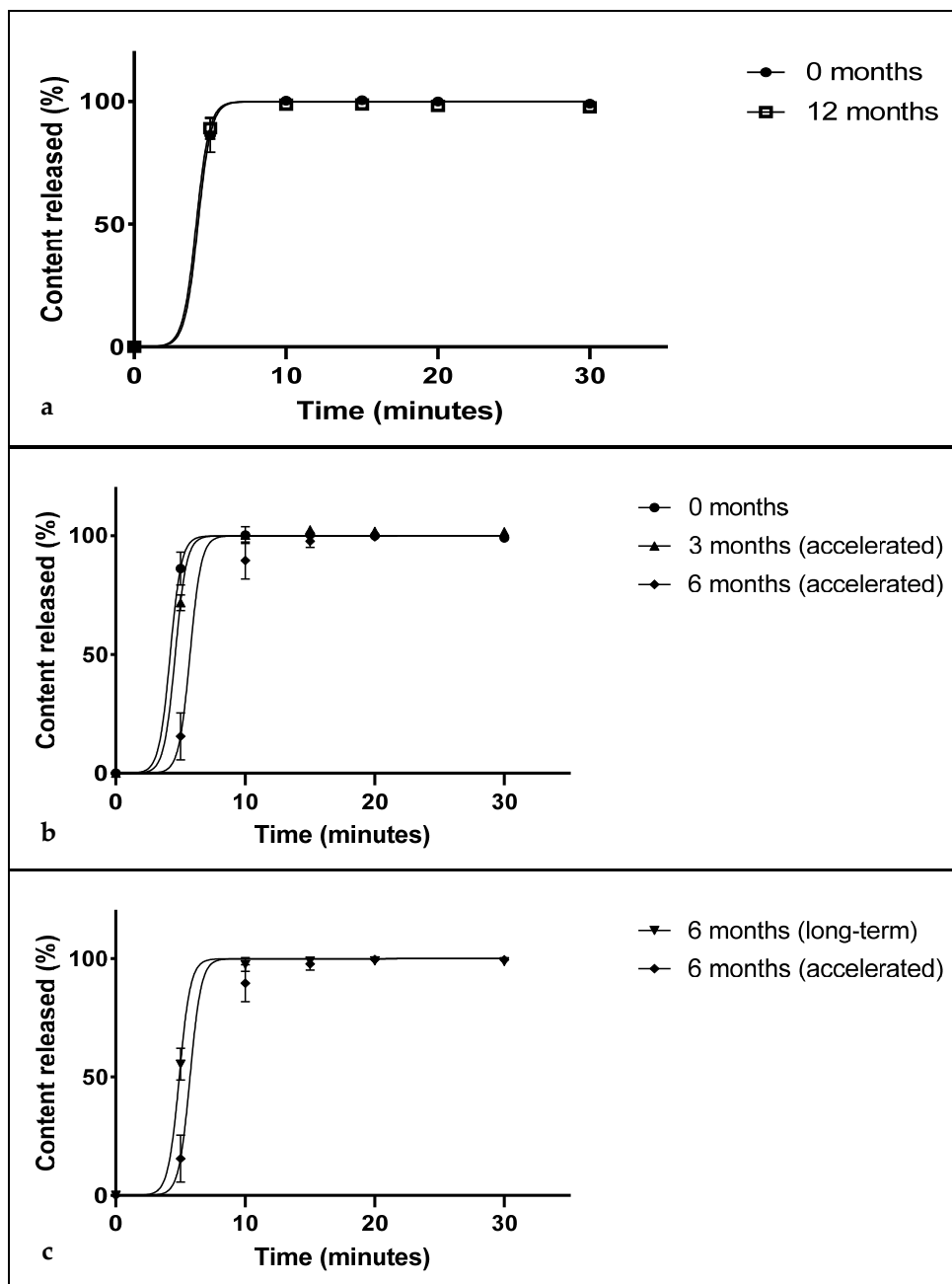


Figure S2. Dissolution profiles of 250 mg CA capsules: (a) Dissolution profile of 250 mg CA capsule at T0 vs. T12, stored under long-term storage conditions (25°C ± 2°C / 60% ± 5% RH) ; (b) Dissolution profile of 250 mg CA capsule at T0 vs. T3 and T6, stored under accelerated storage conditions (40°C ± 2°C / 75% ± 5% RH) ; (c) Dissolution profile of 250 mg CA capsule at T6 stored under long-term (25°C ± 2°C / 60% ± 5% RH) vs. accelerated storage conditions (40°C ± 2°C / 75% ± 5% RH).

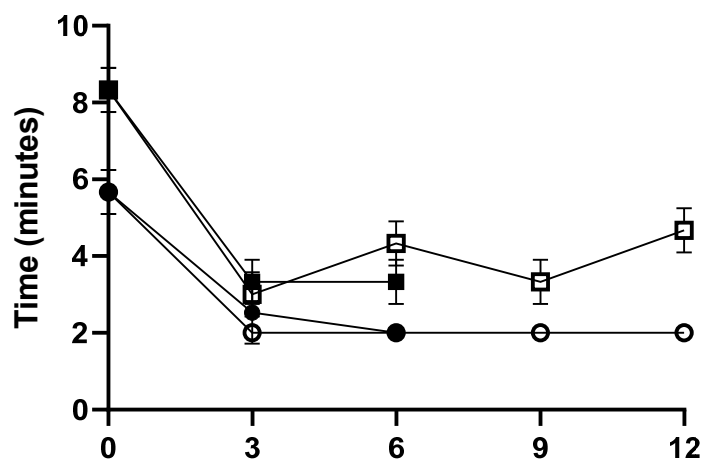


Figure S3. Disintegration times of 25 and 250 mg CA capsules stored over time under long-term conditions ($25^{\circ}\text{C} \pm 2^{\circ}\text{C} / 60\% \pm 5\% \text{ RH}$) and accelerated (stressed) storage conditions ($40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\% \text{ RH}$) (mean \pm SD, $n=3$). o 25 mg CA capsule under long-term storage condition; • 25 mg CA capsule under accelerated storage condition; □ 250 mg CA capsule under long-term storage condition; ■ 250 mg CA capsule under accelerated storage condition.

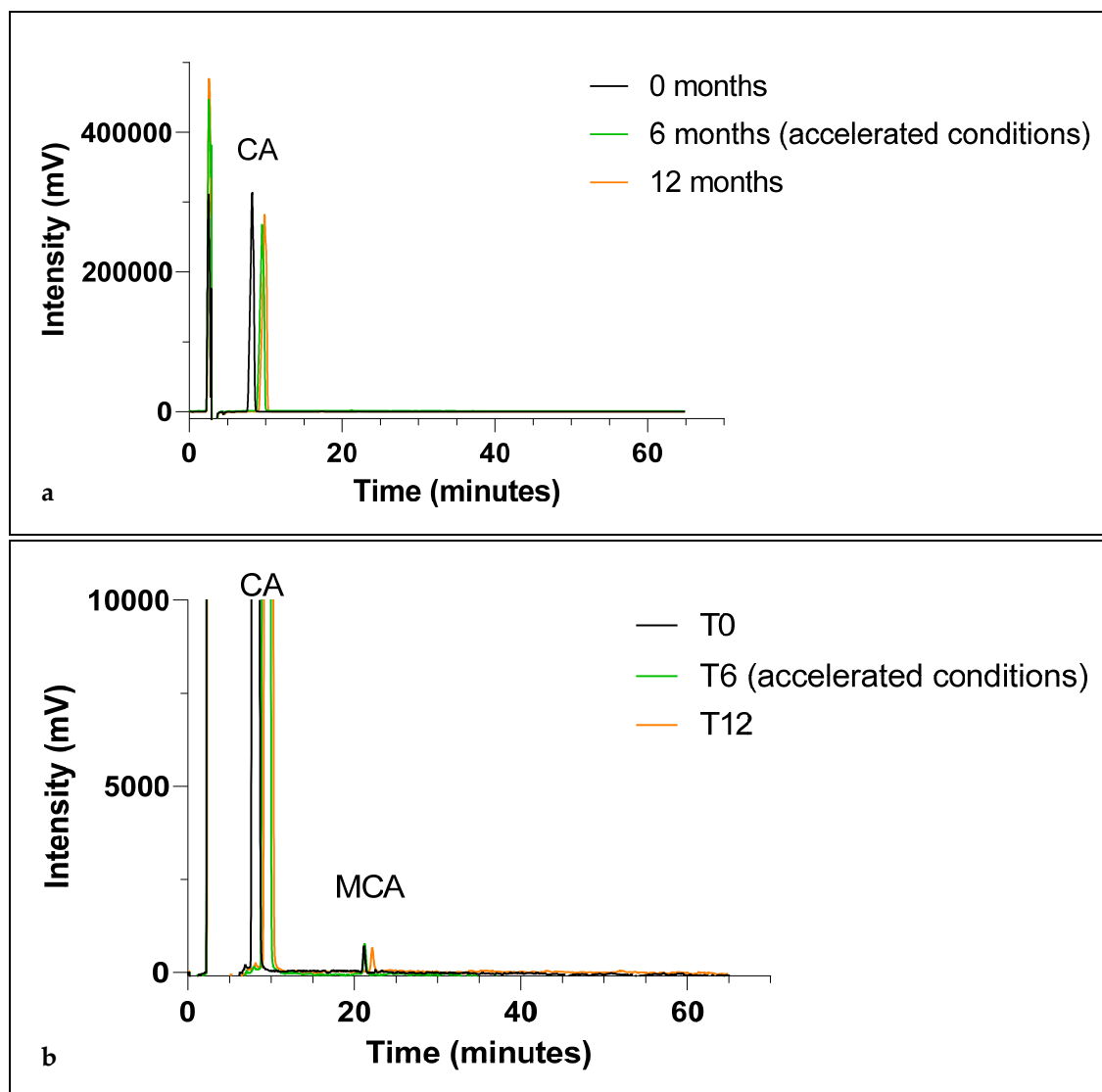


Figure S4. Representative chromatograms of related substance HPLC-RI analysis of 25 mg CA capsules at T0 and T12, stored under long-term storage conditions ($25^{\circ}\text{C} \pm 2^{\circ}\text{C}$ / $60\% \pm 5\%$ RH), and T6, stored under accelerated (stressed) storage conditions ($40^{\circ}\text{C} \pm 2^{\circ}\text{C}$ / $75\% \pm 5\%$ RH). HPLC-RI analysis using RID-10A detector and a reversed phase X-bridge BEH phenyl column $250 \times 4.6 \times 3.5 \mu\text{m}$ ($30^{\circ}\text{C} \pm 2^{\circ}\text{C}$), injection volume: $30 \mu\text{L}$, flow rate: 1.0 mL/min , mobile phase: 30 mmol/L potassium dihydrogen phosphate (KH_2PO_4) and $600 \mu\text{L}$ phosphoric acid in a 1 liter mixture of water/acetonitril (ACN)(60:40); (a) CA peaks at $\pm 8,3$ minutes; (b) MCA peaks at ± 22 minutes (chromatogram enlarged).

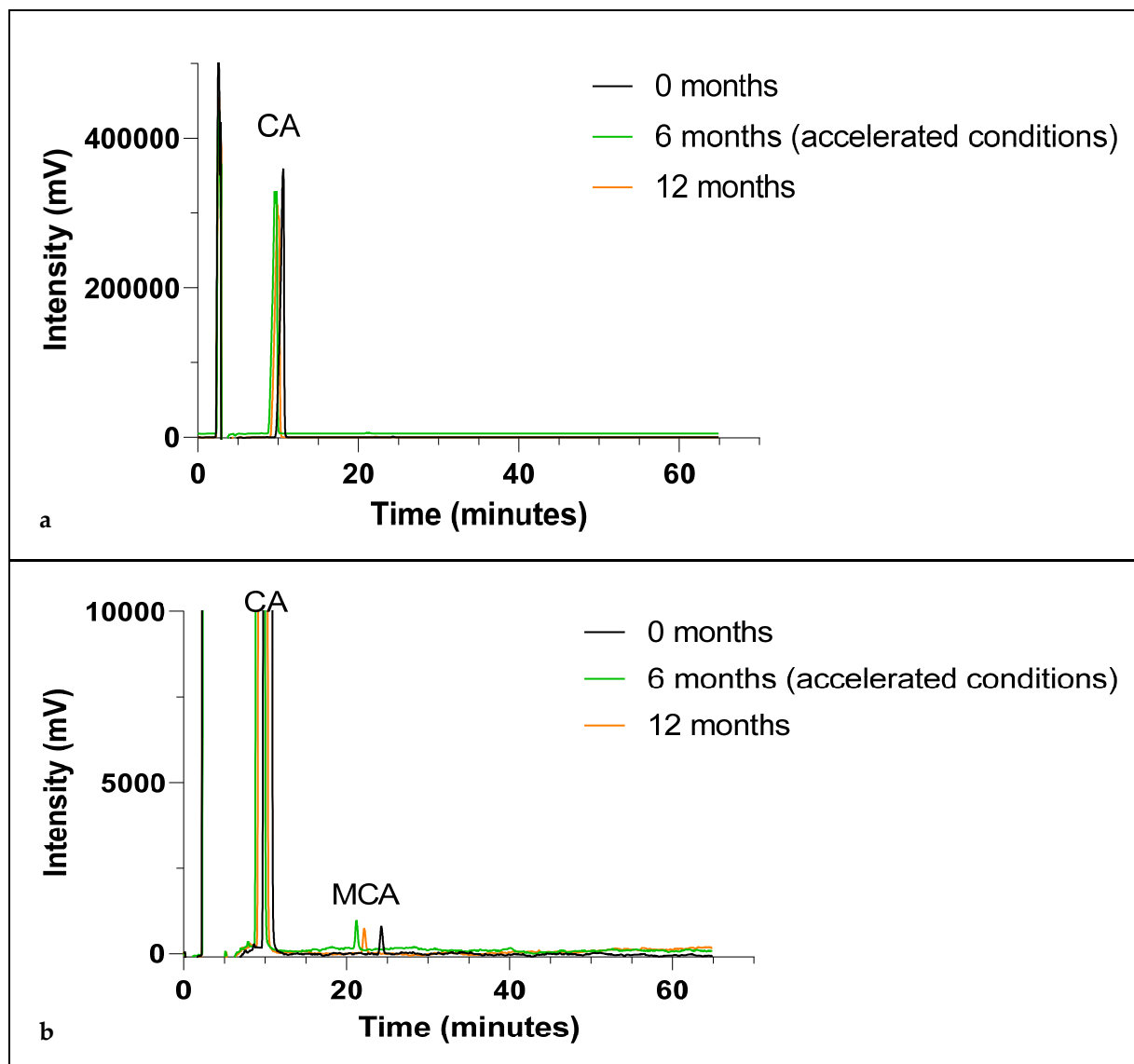


Figure S5. Representative chromatograms of related substance HPLC-RI analysis of 250 mg CA capsules at T0 and T12, stored under long-term storage conditions ($25^{\circ}\text{C} \pm 2^{\circ}\text{C}$ / $60\% \pm 5\%$ RH), and T6, stored under accelerated (stressed) storage conditions ($40^{\circ}\text{C} \pm 2^{\circ}\text{C}$ / $75\% \pm 5\%$ RH). HPLC-RI analysis using RID-10A detector and a reversed phase X-bridge BEH phenyl column $250 \times 4.6 \times 3.5 \mu\text{m}$ ($30^{\circ}\text{C} \pm 2^{\circ}\text{C}$), injection volume: $30 \mu\text{L}$, flow rate: 1.0 mL/min , mobile phase: 30 mmol/L potassium dihydrogen phosphate (KH_2PO_4) and $600 \mu\text{L}$ phosphoric acid in a 1 liter mixture of water/acetonitril (ACN)(60:40); (a) CA peaks at $\pm 8,3$ minutes; (b) MCA peaks at ± 22 minutes (chromatogram enlarged).