PCCA UniFlow™ **TECHNICAL REPORT**

Dissolution Profile of T3 and T4 Capsules Compounded with the New Excipient Base and Also with Microcrystalline Cellulose (MCC)

SUMMARY: Dissolution testing of T3 and T4 capsules compounded with the new excipient base (PCCA UniFlow™) was conducted to evaluate their release profile, in comparison to formulations prepared with MCC. The results obtained demonstrate rapid and high cumulative release for both drugs, thus confirming that the new excipient base successfully supports the release of T3 and T4 from solid dosage forms.

Introduction:

Dissolution is a key quality control parameter for assessing the release profile of active pharmaceutical ingredients (APIs) from solid dosage forms, as it directly influences both the rate and extent of drug absorption in the body.

Levothyroxine sodium (T4) 100 micrograms and liothyronine sodium (T3) 25 micrograms capsules (size 1) were compounded using the new excipient base, PCCA UniFlow™, and also microcrystalline cellulose (MCC) for comparison purposes.

Methodology:

Dissolution testing was performed in accordance with USP General Chapter ⟨711⟩ Dissolution, using a modified USP Apparatus 2 (Paddle) with a 100 mL volume vessel, instead of the standard 500–1000 mL, to allow detection of the low amount of APIs released from the tablets. Testing was performed in pH 10.0 ± 0.05 alkaline borate buffer medium, using the Paddle Apparatus at 50 rpm (revolutions per minute) with sampling at 0, 15, 30, 45 and 60 minutes.

Standard stock solutions of T3 and T4 0.1 mg/mL in 80% ethanol were prepared and diluted with medium to obtain calibration ranges of 0.125–0.375 µg/mL for T3, and 0.5–1.5 µg/mL for T4. Sample solutions were filtered through 0.2 µm PVDF membranes, with the dissolution medium replenished after each withdrawal.

Assay quantification was performed on a Waters Acquity UPLC system equipped with a BEH C_{18} column (2.1 × 50 mm, 1.7 µm). Reverse-phase gradient elution was carried out using mobile phase A (0.1% TFA in water) and mobile phase B (0.1% TFA in acetonitrile). Detection was set at 240 nm, with a column temperature of 65°C, a flow rate of 0.7 mL/min and a total run time of 2.5 minutes.

Results and Discussion:

The dissolution profile for T3 in PCCA UniFlow shows a rapid release reaching approximately 85–90% within 20 min, plateauing thereafter (Fig. 1). The release of T4 approached about 90% within 30 min, also stabilizing afterwards (Fig. 2). The dissolution of T3/T4 in MCC showed similar profiles to the new excipient base, which is desired to maintain consistency with established release characteristics to which patients are physiologically adapted.

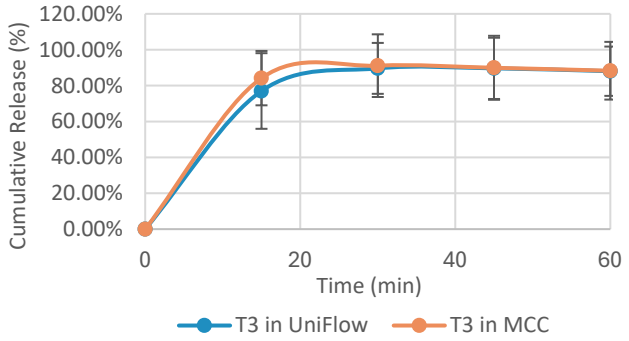

Figure 1. Dissolution profile for T3 in UniFlow versus MCC.

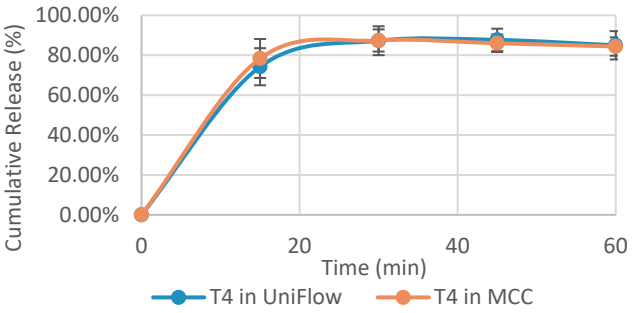

Figure 2. Dissolution profile for T4 in UniFlow versus MCC.

Dissolution testing may be used as a predictor of *in vivo* drug performance by providing insights into the rate and extent of APIs release from the dosage forms. T3 and T4 were successfully released from the capsules compounded with the new excipient base, supporting its suitability for formulation development in pharmaceutical compounding.