A Validated Chiral HPLC Method for Resolution of $\Delta^8$ and $\Delta^9$-tetrahydrocannabinol Enantiomers

**Introduction**

**Background**
- $\Delta^8$-THC and $\Delta^9$-THC are the most studied cannabinoids.
- $\Delta^8$-THC may be synthesized from $\Delta^9$-THC.
- For safety and regulatory reasons, industries need to screen for these cannabinoids.
- Limit of Detection (LOD): $0.1 \mu g/mL$.
- Limit of Quantification (LOQ): $1 \mu g/mL$.

**Methodology**

**Chromatographic System**
- Analytical system: Chiral column with mobile phase.
- Injection volume: $10 \mu L$.
- Column temperature: $30^\circ C$.

**System Suitability**

- Baseline separation of all four $\Delta^8$ and $\Delta^9$-THC enantiomers within 25 minutes.
- Analytical accuracy is 99.7%.

**Method Validation**

**Linearity and Range**
- Methodability: produces data that are directly proportional to the concentration of the analyte in the sample within a given range.
- LODs: $0.2 \mu g/mL$ for $\Delta^8$-THC and $1 \mu g/mL$ for $\Delta^9$-THC.

**Accuracy**
- The accuracy of an analytical method is the closeness of the results obtained by the method to the true value or an accepted reference value.
- The intended use of this method is to determine $\Delta^8$-THC by comparing relative peak areas of the (+) and (-) enantiomers within a sample.
- Samples: prepared in triplicates for each study.
- Three levels of $\Delta^8$-THC: 100%, 50%, and 25%.

**Robustness**

- Measured by the method's capacity to remain unaffected by small but deliberate variations in parameters.

**Conclusions**

- The chiral method developed demonstrates simultaneous separation of all four $\Delta^8$ and $\Delta^9$-THC enantiomers.
- Method was successfully validated and is robust to a wide concentration range from 2 to $250 \mu g/mL$.
- Method is suitable for use in determining $\Delta^8$-THC levels in USP.