# Evaluation of the Content Uniformity of 7 SubMagna™ Sublingual Suspensions

## Introduction:

Suspensions are pharmaceutical dosage forms consisting of insoluble active pharmaceutical ingredients (APIs) dispersed in a liquid medium (suspending vehicle). Sublingual suspensions are intended to be absorbed into the blood through the mucous membranes of the oral cavity. It is important to evaluate the content uniformity of sublingual suspensions to ensure that each dose is equivalent in the concentration/amount of APIs. The content uniformity is defined as the consistency in the amount of API(s) among dosage units. Content uniformity is highly dependent on the characteristics of the dosage forms. The purpose of this study is to evaluate if SubMagna, a viscous liquid dosage form, contributes to suspensions that are uniform in content. A total of 7 sublingual suspensions were selected based on popularity, each containing one API incorporated in SubMagna SL HMW.

## Methodology:

The evaluation of the content uniformity was divided in two stages:

1. Elaboration of the 7 sublingual suspensions according to the corresponding PCCA formulas (Tables 1 and 2).

2. Potency testing by Ultra-Performance Liquid Chromatography (UPLC) assay. The test samples were stored at room temperature and were analyzed by the analytical laboratory in the PCCA Research & Development department or by Eagle Analytical Services, Inc. For each sample, 10 sampling points were taken for analysis and the value reported is the average of all sampling points.

| ***Rx*** | ***112 mL*** |
|---|---|
| Rybelsus® (semaglutide) 14 mg Tablets | 24 Tablets |
| Flavor, Natural Caramel | 2.24 mL |
| Flavor, Banana Creme, Artificial | 1.12 mL |
| Base, PCCA SubMagna™ SL HMW | q.s. 112 mL |

**Table 1.** PCCA Formula 15041: Semaglutide (CADP) 3 mg/mL Sublingual Suspension (SubMagna™ SL HMW)

## Results and Discussion:

The potency testing showed that all sublingual suspensions (SubMagna SL HMW) were within the 90.0%–110.0% potency specification (USP <621> chapter: Chromatography), as displayed in Table 2. As such, the innovative compounding base SubMagna successfully contributed to the content uniformity of sublingual suspensions with APIs in variable strengths.

**Table 2.** Mean potency (percentage of recovery) at room temperature for 7 SubMagna sublingual suspensions.

| ***Sublingual Suspensions (SubMagna SL HMW)*** | ***PCCA Formula*** | ***Mean Potency (%)*** | ***Standard Deviation*** |
|---|---|---|---|
| **Ketotifen** 4 mg/mL | 15258 | 98.629 | 0.993 |
| **Loperamide HCl** 8 mg/mL | 15260 | 94.076 | 0.588 |
| **Naltrexone HCl** 7.5 mg/mL | 15254 | 100.989 | 2.042 |
| **Promethazine HCl** 100 mg/mL | 15255 | 96.413 | 0.577 |
| **Semaglutide (CADP*)** 1 mg/mL | 15043 | 109.277 | 1.474 |
| **Semaglutide (CADP*)** 3 mg/mL | 15041 | 97.215 | 1.480 |
| **Testosterone** 1 mg/0.1 mL | 15031 | 104.512 | 2.337 |

*CADP: Commercially Available Drug Product

## Conclusion:

This study has demonstrated that all 7 SubMagna sublingual suspensions were uniform in content. By following the corresponding PCCA formulas, compounding pharmacists are likely to meet the requirements of content uniformity and, as a result, dispense innovative sublingual suspensions (SubMagna SL HMW) in accordance with the corresponding labeled claims.