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## STABILITY REPORT

**PROGESTERONE/TECHNA 20 SF FORMULATION  
IN SMARTSCRIPPS G2 STABILITY STUDY**

**SP# 1151963, Rev 04**  
Report Effective Date: 23 Sep 2020  
Report Revision 03

### PURPOSE

The purpose of this study is to assess the chemical stability of Progesterone Wettable formulation at 20mg and 400mg concentration per dose in Techna 20 SF (unflavored) in the SmartScripps G2 troche molds.

### STUDY SPONSOR(S)

API: Spectrum Pharmacy Products, 777 Jersey Ave, New Brunswick, NJ 08901

### FORMULATION(S)

- 1) Progesterone Troches (20mg): SRx Procedure No. P2560, R2.
- 2) Progesterone Troches (400mg): SRx Procedure No. P2561, R2.

## REPORT RESULTS

**Samples Condition:** Ambient ( $25 \pm 2^{\circ}\text{C}$ ):

Time Points	Value	Baseline	% Label Claim	Status
Assay 20mg (Day 90)	90-110%	94.7%	94.4%	Pass
Assay 20mg (Day 180)	90-110%	94.7%	103.3%	Pass
Assay 400mg (Day 90)	90-110%	99.5%	98.0%	Pass
Assay 400mg (Day 180)	90-110%	99.5%	97.6%	Pass

**Samples Condition:** Accelerated ( $40 \pm 2^{\circ}\text{C}$ ):

Time Points	Value	Baseline	% Label Claim	Status
Assay 20mg (Day 200)	90-110%	94.7%	91.6%	Pass
Assay 400mg (Day 180)	90-110%	99.5%	91.3%	Pass

For further study details, contact SpecializedRx.