


FormulaPlus™

Formulations Subjected to Beyond-Use Date Testing

 Progesterone 10 mg/Gm to 100 mg/Gm Topical Cream (VersaBase®) (BUD Bracketed Study)

PCCA Formula #12114

What is FormulaPlus™?

At PCCA, your practice is our passion. We realize that there is nothing more important to your patients than the quality of the preparations you provide. State and Federal regulators, along with the United States Pharmacopeia (USP), have stepped up efforts to ensure compounding pharmacies are providing high quality and safe preparations. In response to these efforts, and because of our commitment to our members, PCCA has initiated a program to study the chemical beyond-use date (BUD) of our most popular formulas. This program, called Formula-Plus™, is designed to evaluate the chemical potency of a formula using a stability-indicating assay, over the course of 6 months, at refrigerated and room temperature. Formulas that have gone through this study are denoted in our database with the “BUD Study”  designation.

The data listed below can be used to validate the Beyond-Use Date on the PCCA Formula.

PCCA’s Blue Box Warning:

Attention: This formula has been tested in the PCCA Lab using only PCCA chemicals and proprietary bases (except when noted). Any variations to this formulation, including substitution with a non-PCCA chemical or non-PCCA base, may affect physical integrity, solubility, organoleptic properties or result in potency or content uniformity issues. This type of substitution will cause the assigned BUD to be invalid.

Storage:

The Progesterone 10 mg/Gm to 100 mg/Gm Topical Cream (VersaBase®) (BUD Bracketed Study) was kept at a controlled room temperature of 22°–25°C and protected from light.

Equipment Used:

1. Balance, Explorer, 420 Gm x 0.001 Gm (PCCA Item #35-4720)
2. Electronic Mortar & Pestle – Unguator® e/s (PCCA Item #35-2417)
3. 100 Gm Mixing Blade for Electronic Mortar & Pestle (PCCA Item #35-1969)
4. Ointment Mill Exakt™ 50 (PCCA Item #35-1605) or PCCA Ointment Mill (PCCA Item #35-4250)

Closure System:

1. 100 Gm Mixing Jar for Electronic Mortar & Pestle (White Jar / Blue Cap) (PCCA Item #35-2686)

Procedure: See Formula #12114 for process.

Lab Report: Following is Laboratory Data from PCCA’s R&D Analytical.

Method Validation:

This study was performed to validate the instrumental method used for the determination of Beyond-Use Date (BUD) for Progesterone 10 mg/Gm to 100 mg/Gm Topical Cream (VersaBase™). A Degradation study under stressed conditions and validation in compliance to USP acceptable criteria was conducted for this purpose. A Beyond-Use Date study was completed using the validated sample preparation and instrumental conditions. The percent degradation and peak separation of the drug and degradants under thermal and acidic conditions were compared to untreated samples. With careful evaluation of the chromatograms and inspection of response signal, the specificity for the Progesterone in the presence of matrix, degradants and impurities is demonstrated. In conclusion, the method used to analyze Progesterone 10 mg/Gm to 100 mg/Gm Topical Cream (VersaBase™) met all the validation criteria; and was determined to be stability-indicating.

Beyond Use Date/Potency Testing:

The graphical presentations below show the potency of Progesterone in the aforementioned formula, stored at a controlled room temperature of 22°–25°C in the stated closure system and protected from light, remain within the recommended USP <795> specification range of 90 – 110% for 180 days.

Table 1. Stability data for Progesterone Topical Cream (VersaBase®) – 10 mg/Gm stored at 25°C for 183 days

Stability Data For Progesterone Topical Cream – 10 mg/Gm							
Lot: 05142015-01							
Date Compounded: May 14 th , 2015							
Container: plastic pump							
Storage		Room Temperature (25°C/60%RH)					
Time Point	Date Analyzed	Appearance	Color	Odor	pH	Assay (mg/gram)	Potency (%)
Day 1	5/15/2015	Smooth cream	White	Odorless	4.84	9.846±0.118	100.00%
Day 8	5/22/2015	Smooth cream	White	Odorless	4.94	9.966±0.069	101.22%
Day 15	5/29/2015	Smooth cream	White	Odorless	5.15	9.914±0.060	100.69%
Day 29	6/12/2015	Smooth cream	White	Characteristic	5.07	9.912±0.039	100.67%
Day 43	6/26/2015	Smooth cream	White	Characteristic	4.98	10.298±0.120	104.59%
Day 64	7/17/2015	Smooth cream	White	Characteristic	4.84	10.136±0.073	102.95%
Day 92	8/14/2015	Smooth cream	White	Characteristic	5.03	10.402±0.112	105.64%
Day 120	9/11/2015	Smooth cream	White	Characteristic	5.11	10.510±0.271	106.74%
Day 183	11/13/2015	Smooth cream	White	Characteristic	5.14	10.181±0.089	103.41%

Figure 1. Graphical presentation of assay in Progesterone Topical Cream (VersaBase®) – 10 mg/Gm (% Initial) stored at room temperature for the elapsed time of the stability study

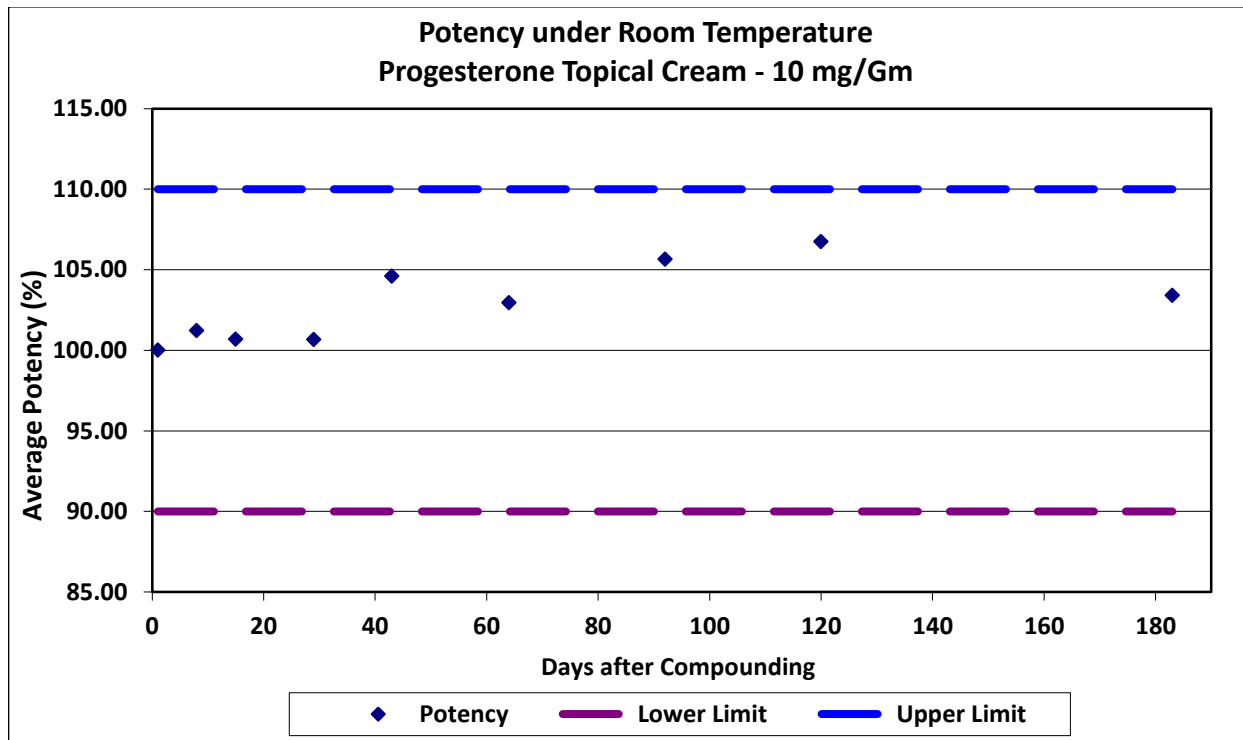


Table 2. Stability data for Progesterone Topical Cream (VersaBase®) – 100 mg/Gm stored at 25°C for 183 days

Stability Data For Progesterone Topical Cream – 100 mg/Gm							
Lot: 05142015-02							
Date Compounded: May 14 th , 2015							
Container: plastic pump							
Storage		Room Temperature (25°C/60%RH)					
Time Point	Date Analyzed	Appearance	Color	Odor	pH	Assay (mg/gram)	Potency (%)
Day 1	5/15/2015	Smooth cream	White	Odorless	4.88	99.309±0.418	100.00%
Day 8	5/22/2015	Smooth cream	White	Odorless	4.94	99.094±0.205	99.78%
Day 15	5/29/2015	Smooth cream	White	Odorless	4.79	99.915±0.367	100.61%
Day 29	6/12/2015	Smooth cream	White	Characteristic	5.00	100.205±1.072	100.90%
Day 43	6/26/2015	Smooth cream	White	Characteristic	4.85	103.193±1.035	103.91%
Day 64	7/17/2015	Smooth cream	White	Characteristic	4.96	96.494±3.611	97.17%
Day 92	8/14/2015	Smooth cream	White	Characteristic	4.92	98.883±0.555	99.57%
Day 120	9/11/2015	Smooth cream	White	Characteristic	5.07	105.232±2.104	105.96%
Day 183	11/13/2015	Smooth cream	White	Characteristic	5.22	102.648±0.477	103.36%

Figure 2. Graphical presentation of assay in Progesterone Topical Cream (VersaBase®) – 100 mg/Gm (% Initial) stored at room temperature for the elapsed time of the stability study

