


FormulaPlus™

Formulations Subjected to Beyond-Use Date Testing

 Methimazole 2.5 mg/0.1 Gm to 10 mg/0.1 Gm Topical Lipoderm® (BUD Bracketed Study)

PCCA Formula #12373

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 Methimazole 2.5 mg/0.1 Gm to 10 mg/0.1 Gm Topical Lipoderm® (BUD Bracketed Study) was kept at a controlled room temperature of 22°–25°C and protected from light.

Equipment Used:

1. Balance, Explorer, 220 Gm x 0.0001 Gm (PCCA Item #35-4721)
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 #12373 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 F12373 Methimazole 2.5 mg/0.1 Gm to 10 mg/0.1 Gm Topical Lipoderm®. 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 oxidation conditions were compared to untreated samples. With careful evaluation of the chromatograms and inspection of response signal, the specificity for the Methimazole in the presence of matrix, degradants and impurities is demonstrated. In conclusion, the method used to analyze F12373 Methimazole 2.5 mg/0.1 Gm to 10 mg/0.1 Gm Topical Lipoderm® 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 Methimazole 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 90 days.

Table 2. Stability Data for Methimazole 2.5 mg/0.1 Gm Topical Lipoderm® stored at room temperature for 91 days

Stability Data for Methimazole 2.5 mg/0.1 Gm Topical Lipoderm®							
Lot: 05162016-02							
Date Compounded: May 16 th , 2016							
Container: plastic jar							
Storage		Room Temperature					
Time Point	Date Analyzed	Color/Appearance	Odor	pH	Assay (mg/gram)	Potency (%)	S.D.
Day 0	05/16/2016	Faint beige, smooth cream	Characteristic	5.20	25.132	100.00	1.064
Day 7	05/23/2016	Faint beige, smooth cream	Characteristic	5.25	24.450	97.29	0.529
Day 15	05/31/2016	Faint beige, smooth cream	Characteristic	5.27	25.692	102.23	1.057
Day 28	06/13/2016	Faint beige, smooth cream	Characteristic	5.29	25.199	100.27	0.906
Day 42	06/27/2016	Faint beige, microbubbles	Characteristic	5.23	25.489	101.42	0.439
Day 63	07/18/2016	Faint beige, microbubbles	Characteristic	5.25	24.808	98.71	0.125
Day 91	08/15/2016	Faint beige, microbubbles	Characteristic	5.77	25.734	102.40	0.362

Figure 2. Graphical presentation of potency in Methimazole 2.5 mg/0.1 Gm Topical Lipoderm® (% Initial) stored at room temperature for the elapsed time of the stability study

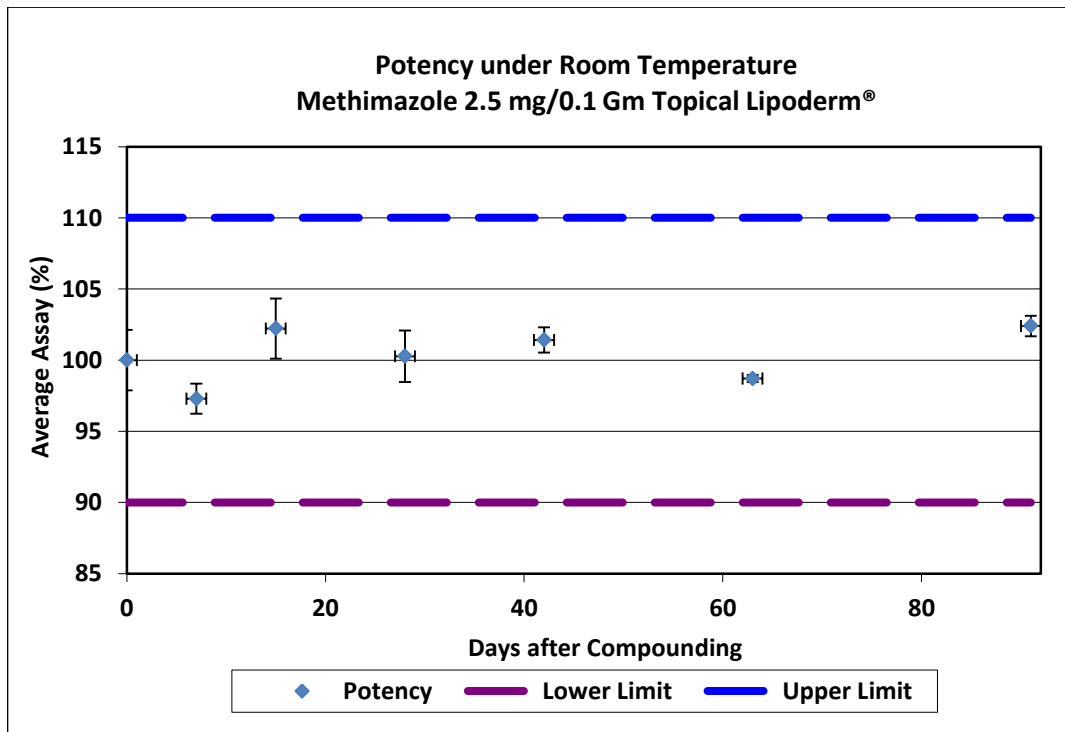


Table 4. Stability Data for Methimazole 10 mg/0.1 Gm Topical Lipoderm® stored at room temperature for 91 days

Stability Data for Methimazole 10 mg/0.1 Gm Topical Lipoderm®							
Lot: 05162016-03							
Date Compounded: May 16 th , 2016							
Container: plastic jar							
Storage		Room Temperature					
Time Point	Date Analyzed	Color/Appearance	Odor	pH	Assay (mg/gram)	Potency (%)	S.D.
Day 0	05/16/2016	Faint beige, smooth cream	Characteristic	5.25	99.725	100.00	0.645
Day 7	05/23/2016	Faint beige, smooth cream	Characteristic	5.42	100.409	100.69	1.047
Day 15	05/31/2016	Faint beige, smooth cream	Characteristic	5.36	102.585	102.87	0.394
Day 28	06/13/2016	Faint beige, smooth cream	Characteristic	5.35	100.824	101.10	0.404
Day 42	06/27/2016	Faint beige, microbubbles	Characteristic	5.45	101.464	101.74	0.622
Day 63	07/18/2016	Faint beige, microbubbles	Characteristic	5.41	98.411	98.68	0.491
Day 91	08/15/2016	Faint beige, microbubbles	Characteristic	5.69	100.196	100.47	0.208

Figure 4. Graphical presentation of potency in Methimazole 10 mg/0.1 Gm Topical Lipoderm® (% Initial) stored at room temperature for the elapsed time of the stability study

