


FormulaPlus™

Formulations Subjected to Beyond-Use Date Testing

 Omeprazole 5 mg/mL Oral Suspension

PCCA Formula #11319

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 Omeprazole 5 mg/mL Oral Suspension was kept at a controlled refrigerated temperature of 2°–8°C and protected from light.

Equipment Used:

1. Balance, Explorer, 420 Gm × 0.001 Gm (PCCA Item #35-4720)
2. 2 oz. Glass Mortar & Pestle Set (Clear) (PCCA Item #35-1845)
3. Scraper Spatula with Stainless Steel Handle, Small – 9" (White, Soft Rubber) (PCCA Item #35-2088)
4. Griffin Beaker, 150 mL (PCCA Item #35-1103)
5. SpinBar® – White, Medium - 1-1/2" x 5/16" (PCCA Item #35-1060)
6. Reynold's Wrap® Aluminum Foil (Pharmacy Stock)
7. pH Meter, Twin pH (PCCA Item #35-1936)

Closure System:

1. One (1) 4 oz (24 mm.) Prescription Oval Amber Plastic Bottle (PCCA Item #35-1975)

Procedure: See Formula #11319 for process.

Lab Report: Following is Laboratory Data from Eagle Analytical.

Degradation Study:

This study was performed to establish if the instrumental method used for F11319 Omeprazole 5 mg/mL Oral Suspension was stability-indicating. For this purpose, a stressed degradation study was conducted; sample preparations and analyses were accomplished using the same conditions as those used for the BUD study. The percent degradation and retention time of the drug and degradants under acidic and thermal conditions were compared to untreated samples. With careful evaluation of the chromatograms and inspection of response signal, the specificity for the Omeprazole in the presence of matrix, degradants and impurities is demonstrated. In conclusion, the method used to analyze F11319 Omeprazole 5 mg/mL Oral Suspension was determined to be stability-indicating.

Beyond Use Date/Potency Testing:

The graphical presentations below show the potency of Omeprazole in the aforementioned formula, stored at a controlled refrigerated temperature of 2°–8°C in the stated closure system and protected from light, remain within the recommended USP <795> specification range of 90 – 110% for 180 days.

LABORATORY REPORT

LABORATORY TEST RESULTS

<u>Chemical Tests:</u>	<u>Date</u>	<u>Reported</u>	<u>Measured</u>	<u>Potency</u>
Omeprazole	3/26/2014	5 mg/mL	4.90 mg/mL	98.0 %
xExtended Analysis 1	4/11/2014	5 mg/mL	5.05 mg/mL	101 %
xExtended Analysis 2	4/24/2014	5 mg/mL	4.96 mg/mL	99.1 %
xExtended Analysis 3	5/27/2014	5 mg/mL	4.88 mg/mL	97.6 %
xExtended Analysis 4	6/26/2014	5 mg/mL	4.91 mg/mL	98.2 %
xExtended Analysis 5	9/27/2014	5 mg/mL	4.97 mg/mL	99.4 %

