Stability of Omeprazole in SyrSpend SF Alka (Reconstituted)

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ABSTRACT
Omeprazole is used in the treatment of dyspepsia, peptic ulcer disease, gastroesophageal reflux disease, laryngopharyngeal reflux, and Zollinger–Ellison syndrome. Omeprazole is marketed by AstraZeneca under a number of names, most notably Prilosec and Losec, as well as being available from a number of generic manufacturers. Omeprazole is available in both tablet and capsule form, with varying strengths of each. The need for other administration options for those patients who cannot take tablets or capsules has led compounding pharmacies to seek other alternatives. One possible alternative is the use of a suspending agent to create an oral solution or suspension. In the past, this has been accomplished using a sodium bicarbonate solution as the vehicle. However, sodium bicarbonate/omeprazole combination imparts a bitter and unpleasant taste. SyrSpend SF Alka (reconstituted) is a vehicle for making a suspension which has a pleasant taste, thus increasing palatability and compliance. The objective of this study was to determine the stability of omeprazole in SyrSpend SF Alka (for reconstitution). The study sample was compounded into a 2-mg/mL suspension and stored in a low-acetic plastic prescription bottle at temperatures between 2°C and 8°C. Six samples were assayed at each time point out to 92 days by a stability-indicating high-performance liquid chromatography method. The method was validated for its specificity through forced degradation studies. The shelf life of this product is at least 92 days, based on data collected when refrigerated and protected from light.

INTRODUCTION
Omeprazole is a proton pump inhibitor used in the treatment of dyspepsia, peptic ulcer disease (PUD), gastroesophageal reflux disease (GERD), laryngopharyngeal reflux (LPR), and Zollinger–Ellison syndrome. It is used to treat a wide range of the patient population, including both infant and geriatric patients. These two groups in particular may experience difficulty in swallowing whole capsules or tablets. In the past, sodium bicarbonate has been used with omeprazole to create an oral solution. Sodium bicarbonate does little to mask the bitter taste of omeprazole. An alkaline suspending agent containing a sweetener masks the bitter taste and increases the palatability of omeprazole. This is of particular importance when considering the treatment of infants, as the masking of the taste increases end-user compliance. Some compounding vehicles contain alcohol and sorbitol. SyrSpend SF Alka (for reconstitution) (Pagtron formerly Gallipot, St. Paul, Minnesota) is a sorbitol- and alcohol-free alkaline suspending agent which could serve as an appropriate vehicle for compounding an omeprazole oral suspension.

The objective of this study was to examine the stability of omeprazole when prepared in an oral suspension using SyrSpend SF Alka (for reconstitution). The suspension was stored in a low-acetic plastic prescription bottle at a concentration of 2 mg/mL under United States Pharmacopeia (USP) refrigerated (2°C to 8°C) storage conditions. Stability was assessed by percent recovery studies performed at varying time points throughout 92 days.

MATERIALS AND METHODS

Chemical Reagents

Omeprazole raw powder was obtained from Gallipot (Lot 090914F312; St. Paul, Minnesota). High-performance liquid chromatographic (HPLC) grade acetonitrile (Lot CZ829; Burdick and Jackson, Kalamazoo, Michigan), 85% phosphoric acid ACS-grade (Lot 201103115; CCI, New Delhi, India), monosodium phosphate monohydrate (Lot 107148; Fisher Scientific, Pittsburgh, Pennsylvania), disodium phosphate heptahydrate (Lot B0131737; Acros Organics, Geel, Belgium), and octanesulfonic acid (Lot 03R068160; Sigma Aldrich, St. Louis, Missouri) were used in the study. HPLC-grade water was supplied by filtering deionized water from a Millipore Elix through a Millipore Simplicity (Billerica, Massachusetts).

Equipment and Chromatographic Conditions

Two different types of HPLCs were used. The first, used for validation and the stability study, was a Perkin Elmer 200-Series (Waltham, Massachusetts) equipped with a quaternary gradient solvent delivery system, a dual wavelength UV/VIS detector, and a 100-vial programmable autosampler with a Peltier tray, 200-nL sample loop, and 250-nL syringes. The second LC system, used for forced degradation studies, was a Varian Prostar (Palo Alto, California) equipped with a tertiary gradient solvent delivery system, a photodiode array detec-