

The stability of lansoprazole and omeprazole in ChocoBase[®]

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Introduction: Previously we have reported on the use of simplified omeprazole suspension (SOS) and simplified lansoprazole suspension (SLS) in the prophylaxis of stress ulcers. Additionally, we have reported on its use in combination with the flavoring agent ChocoBase[®]. We, or others, have reported on the stability of unflavored lansoprazole and omeprazole suspensions (as liquids) finding both products to be stable for 30 days when refrigerated and for 14 days at room temperature (in amber plastic bottles). Previously we have evaluated the ChocoBase[®] powder stored for 18 months at ambient temperature without PPI added and found it to be without degradation (by evaluating pH and 30 day stability of reconstituted product when compounded with lansoprazole or omeprazole and refrigerated). The concentrations evaluated were 1.5, 2, 2.25 and 2.5 mg/mL omeprazole and 1.5, 2, 2.25 and 3 mg/mL lansoprazole. Omeprazole/Chocobase was found to retain > 90% stability at 30 days by HPLC analysis and lansoprazole/ChocoBase for at least 14 days.

Methods: This study was designed to evaluate the stability of ChocoBase[®] combined with lansoprazole or omeprazole in the dry form in amber plastic bottles and syringes as well as in the reconstituted form as the suspension (liquid) in plastic bottles and syringes. Concentrations evaluated were 1.5, 2, 2.25, 2.5 mg/mL. The omeprazole or lansoprazole granules were removed from the gelatin capsule and crushed in a mortar and pestle and the amount weighed to coincide with the weight of the granules prior to crushing. The respective PPI powders were added to the dry ChocoBase[®] and stored at various conditions after reconstitution. Samples were taken after thorough agitation from the stored preparations at the proscribed times. The samples were then stored at 4° C. Samples were agitated for 30 seconds and sample aliquots were analyzed in triplicate according to methods that have been described elsewhere.

Results: Liquid form (after reconstitution) in white opaque HDPE bottle stored at 4° C (refrigerated).

<i>Liquid -Bottles 4° C</i>	<i>Time 0</i>	<i>1 week</i>	<i>2 weeks</i>	<i>4 weeks</i>
Lanso 1.5 mg/mL	1.51	1.49	1.43	1.17
Lanso 2 mg/mL	2.06	2.01	1.87	1.42
Lanso 2.25 mg/mL	2.24	2.29	2.18	1.81
Lanso 3 mg/mL	2.93	2.87	2.79	2.27
Omeprazole 1.5 mg/mL	1.55	1.52	1.47	1.45
Omeprazole 2 mg/mL	2.07	2.02	2.04	1.95
Omeprazole 2.25 mg/mL	2.23	2.19	2.21	2.17
Omeprazole 2.5 mg/mL	2.54	2.44	2.38	2.42