

Proton Pump Inhibitors:

OMEPRAZOLE (PRILOSEC) / HUMCO BUFFER CREAM 2MG/ML

0.4 GMS Omeprazole raw drug powder from Spectrum chemical (part number O1405, Lot # WJ0888) was added to 150 ML Sodium Bicarbonate (8.4%), refrigerated until dissolved (about 1 hour), and added to 90 GMS Buffer Cream to QS to 200 ML, resulting in a final concentration of 0.2% Omeprazole. This suspension was stored at room temperature in an amber PET bottle at 25°C.

OMEPRAZOLE (PRILOSEC) / HUMCO BUFFER CREAM 4MG/ML

0.8 GMS Omeprazole raw drug powder from Spectrum chemical (part number O1405, Lot # WJ0888) was added to 150 ML Sodium Bicarbonate (8.4%), refrigerated until dissolved (about 1 hour), and added to 90 GMS Buffer Cream to QS to 200 ML, resulting in a final concentration of 0.4% Omeprazole. This suspension was stored at room temperature in an amber PET bottle at 25°C.

LANSOPRAZOLE (PREVACID) / HUMCO BUFFER CREAM 3MG/ML

0.6 GMS Lansoprazole (twenty 30 MG Lansocap delayed release capsules from German Remedies (Lot # AF9002) were emptied and added to 150 ML Sodium Bicarbonate (8.4%), refrigerated until dissolved (about 1 hour), and added to 90 GMS Buffer Cream to QS to 200 ML, resulting in a final concentration of 0.3% Lansoprazole. This suspension was stored at room temperature in an amber PET bottle at 25°C.

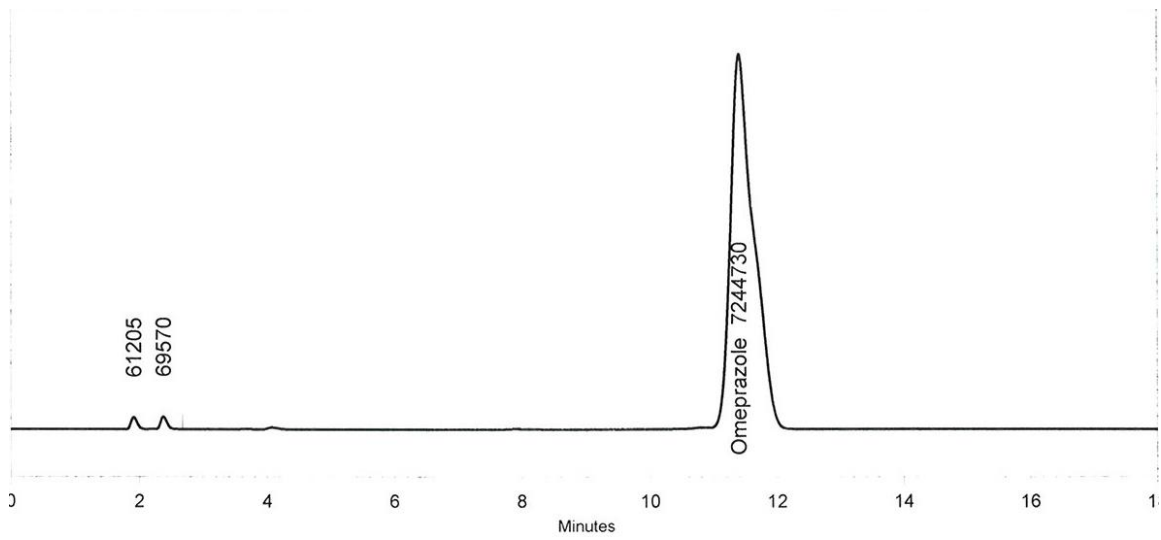
LANSOPRAZOLE (PREVACID) / HUMCO BUFFER CREAM 4MG/ML

0.8 GMS Lansoprazole (twenty-seven 30 MG Lansocap delayed release capsules from German Remedies (Lot # AF9002) were emptied and added to 150 ML Sodium Bicarbonate (8.4%), refrigerated until dissolved (about 1 hour), and added to 90 GMS Buffer Cream to QS to 200 ML, resulting in a final concentration of 0.4% Lansoprazole. This suspension was stored at room temperature in an amber PET bottle at 25°C.

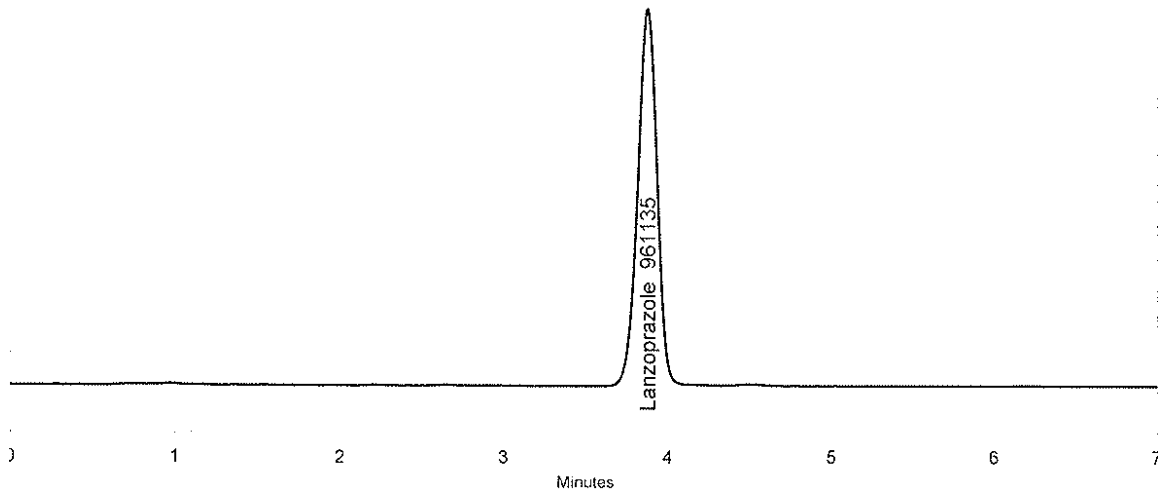
PANTOPRAZOLE (PROTONIX) / HUMCO BUFFER CREAM 2MG/ML

0.4 GMS Lansoprazole (ten 40 MG Pantozec tablets from Micro Labs Limited (Lot # PTZD9001) were crushed and added to 150 ML Sodium Bicarbonate (8.4%), refrigerated until dissolved (about 1 hour), and added to 90 GMS Buffer Cream to QS to 200 ML, resulting in a final concentration of 0.2% Lansoprazole. This suspension was stored at room temperature in an amber PET bottle at 25°C.

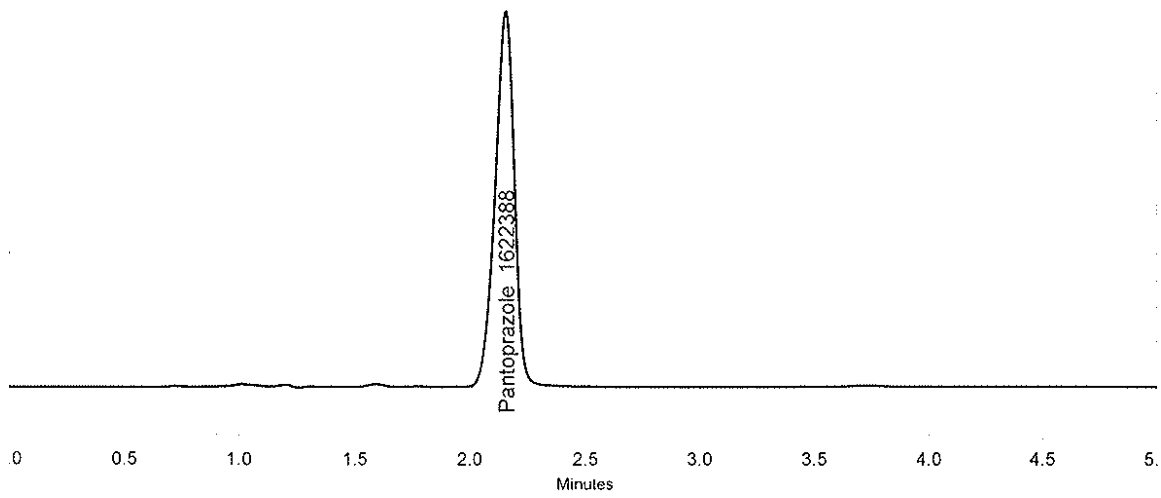
Samples were prepared every 7 days by rapid inversion of each sample bottle and accurately weighing sample into a volumetric flask. The contents of the flask were diluted to volume with matrix matched mobile phase for HPLC determination. Results were compared and samples were analyzed each 7 day interval. The limits of acceptance of results were to be < 90% theoretical concentration of initial prepared sample. The results were tabulated for each 7 day interval and examples of chromatography are attached which show standard preparations, initial interval, and latest passing interval to illustrate no co-elution or baseline interference, as well as degradation products.



Sample Chromatogram of Omeprazole



Sample Chromatogram of Lansoprazole



Sample Chromatogram of Pantoprazole

Final Summary:

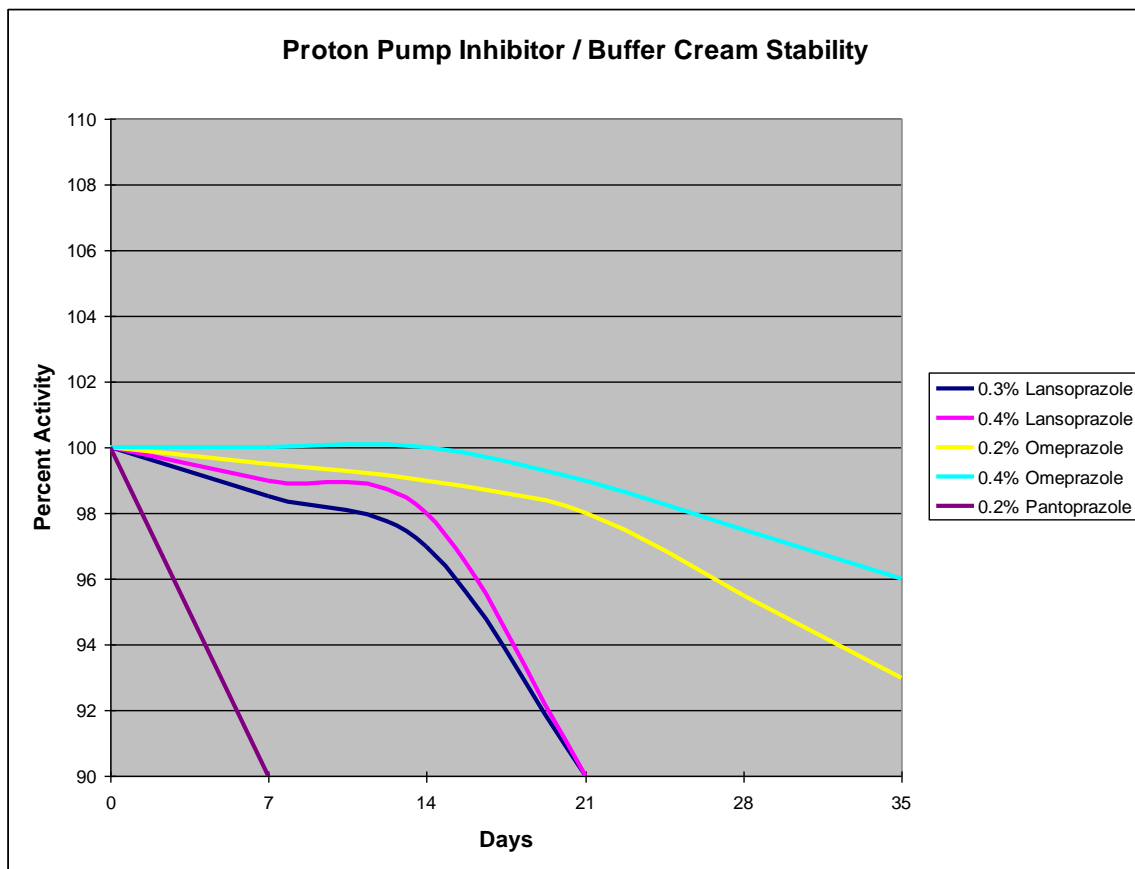
Compounded at 0.2%, stability-indicating HPLC analysis found less than 7% Omeprazole loss at 35 days.

Compounded at 0.4%, stability-indicating HPLC analysis found less than 4% Omeprazole loss at 35 days.

Compounded at 0.3%, stability-indicating HPLC analysis found less than 10% Lansoprazole loss at 21 days.

Compounded at 0.4%, stability-indicating HPLC analysis found less than 10% Lansoprazole loss at 21 days.

Compounded at 0.2%, stability-indicating HPLC analysis found less than 10% Pantoprazole loss at 7 days.



Based on stability-indicating HPLC analysis, the data rank orders the beyond-use-dates as Omeprazole > Lansoprazole > Pantoprazole.