

Metoclopramide Hydrochloride:

1.00g Metoclopramide Hydrochloride raw drug powder from Spectrum chemical (part number ME176, Lot # VG0216) was added to 50.00g Humco PenCream (Humco Holding Group, Texarkana, Texas) and levigated with an electronic mortar and pestle, resulting in a final concentration of 2.0% w/w. This emulsion was then stored at room temperature in the same 50/70 mL Unguator container.

Samples were prepared every 14 days by a 5.00 g accurately weighed sample being transferred to a 50.0 ml 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 14 day interval. The limits of acceptance of results were to be < 90% theoretical concentration of initial prepared sample. The results were tabulated for each 14 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.

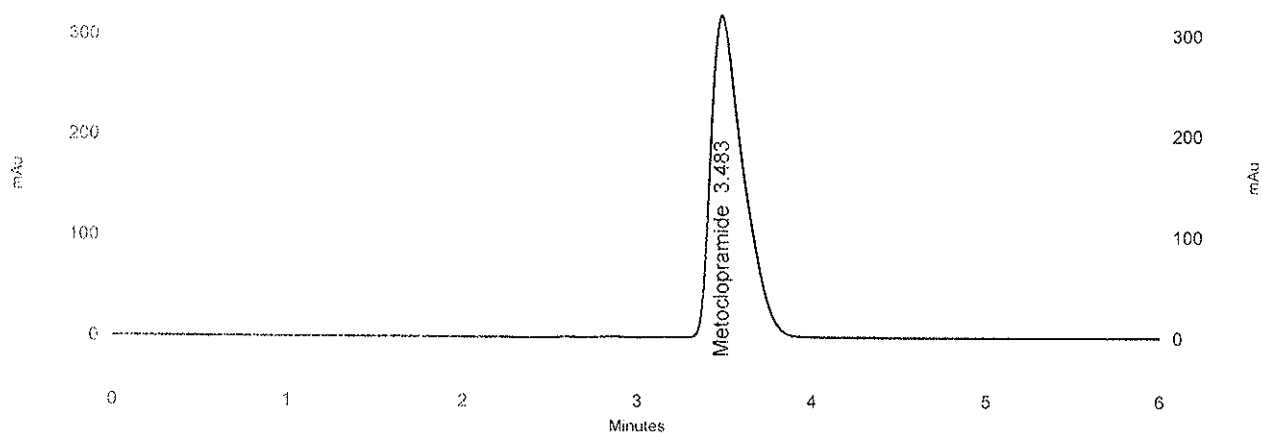
90-Day Summary:

Compounded at 2.0% w/w, stability-indicating HPLC analysis found negligible Metoclopramide Hydrochloride loss in Humco PenCream at 90 days.

Attached are 8 chromatographs of Humco PenCream showing in order: Initial Standard, Initial Sample, 30-Day Standard, 30-Day Sample, 60-Day Standard, 60-Day Sample, 90-Day Standard, and 90-Day Sample.

Sample ID: Capsaicin Std 1

Method Name: C:\CLASS-VP\Methods\HPLC3\Metoclopramide Hydrochloride.met
Sequence: C:\CLASS-VP\Sequence\2010\May\HPLC 3\May 12-10 Metoclopramide Precision .seq
Filename: C:\CLASS-VP\Enterprise\Projects\Default\Data\May 12-10 Metoclopramide Precision 101-Rep1
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Printed: 5/13/2010 8:32:07 AM
Vial: 2



1: 280 nm,

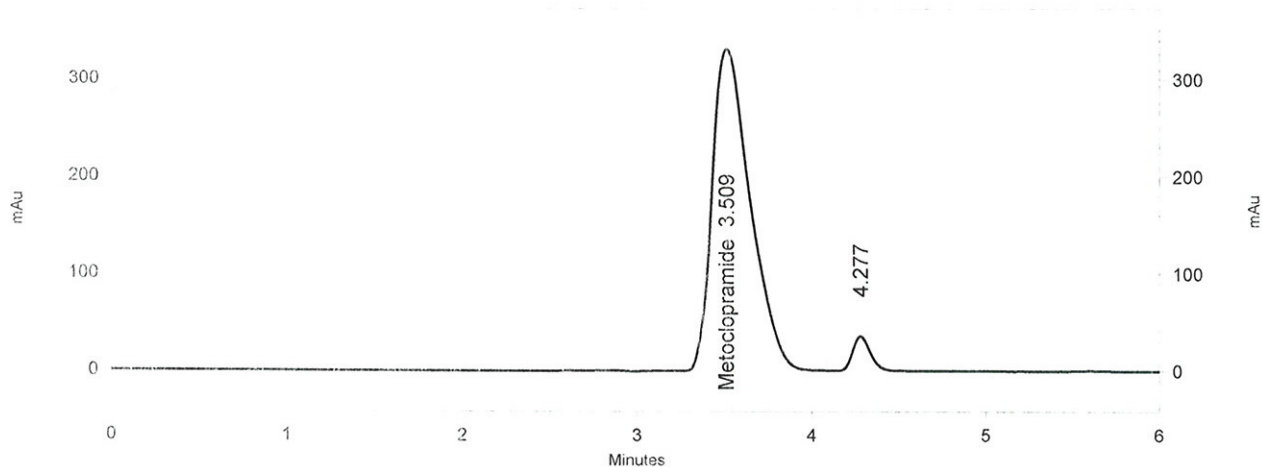
4 nm

Results

Name	Retention Time	Area	ESTD concentration	Resolution (USP)	Asymmetry
Metoclopramide	3.483	4073945	0.100300 CAL	0.00000	1.74559

Sample ID: *Presicion 1*

Method Name: C:\CLASS-VP\Methods\HPLC3\Metoclopramide Hydrochloride.met
Sequence: C:\CLASS-VP\Sequence\2010\May\HPLC 3\May 12-10 Metoclopramide Presicion .seq
Filename: C:\CLASS-VP\Enterprise\Projects\Default\Data\May 12-10 Metoclopramide Presicion 103
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Printed: 5/13/2010 8:32:23 AM
Vial: 4



1: 280 nm,

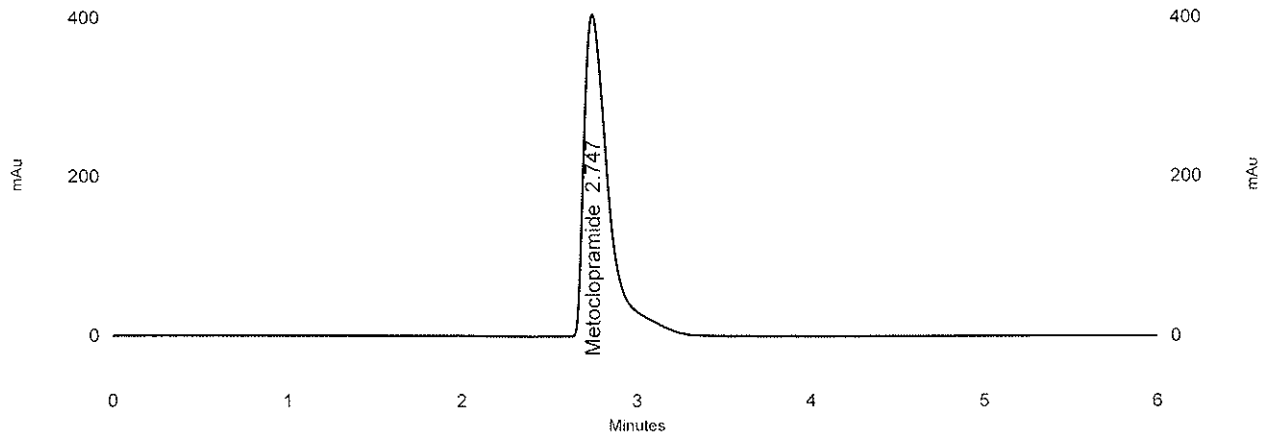
4 nm

Results

Name	Retention Time	Area	ESTD concentration	Resolution (USP)	Asymmetry
Metoclopramide	3.509	4991765	2.005600	0.00000	1.46642

Sample ID: Metoclopramide Std 1

Method Name: C:\CLASS-VP\Methods\HPLC3\Metoclopramide Hydrochloride.met
Sequence: C:\CLASS-VP\Sequence\2010\June\HPLC 3\Jun 10-10 Metoclopramide 30 days Stability.seq
Filename: C:\CLASS-VP\Enterprise\Projects\Default\Data\June-10-10 Metoclopramide 30 days Staab 101-Rep1
Acquired: 6/10/2010 4:50:20 PM
Printed: 6/11/2010 7:48:39 AM
Vial: 92



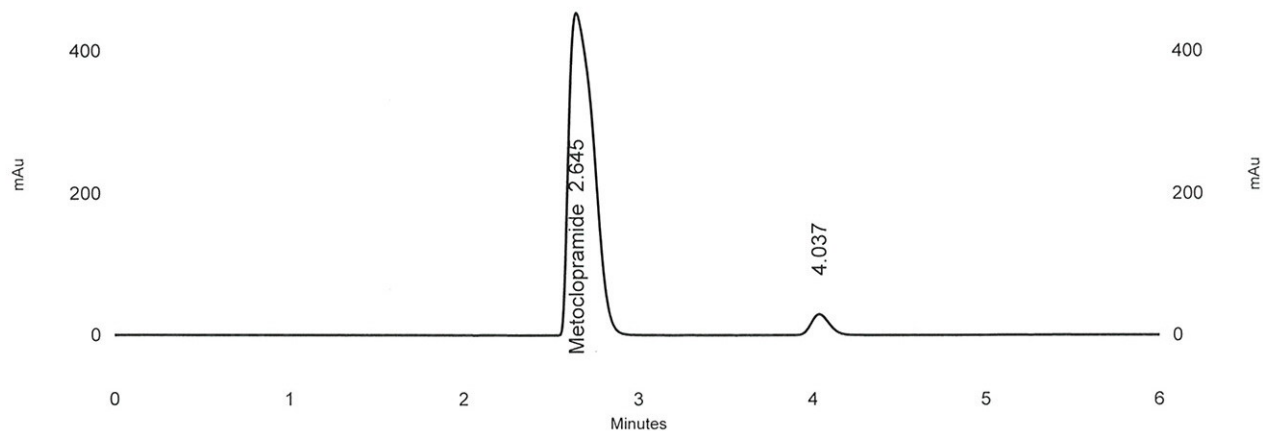
1: 280 nm,
4 nm

Results

Name	Retention Time	Area	ESTD concentration	Resolution (USP)	Asymmetry
Metoclopramide	2.747	3953760	0.100300 CAL	0.00000	2.39863

Sample ID: Metoclopramide 2% in PEN Cream 30 days Stab.

Method Name: C:\CLASS-VP\Methods\HPLC3\Metoclopramide Hydrochloride.met
Sequence: C:\CLASS-VP\Sequence\2010\June\HPLC 3\Jun 10-10 Metoclopramide 30 days Stability.seq
Filename: C:\CLASS-VP\Enterprise\Projects\Default\Data\June-10-10 Metoclopramide 30 days Staab 103
Acquired: 6/10/2010 5:52:25 PM
Printed: 6/11/2010 7:48:53 AM
Vial: 94



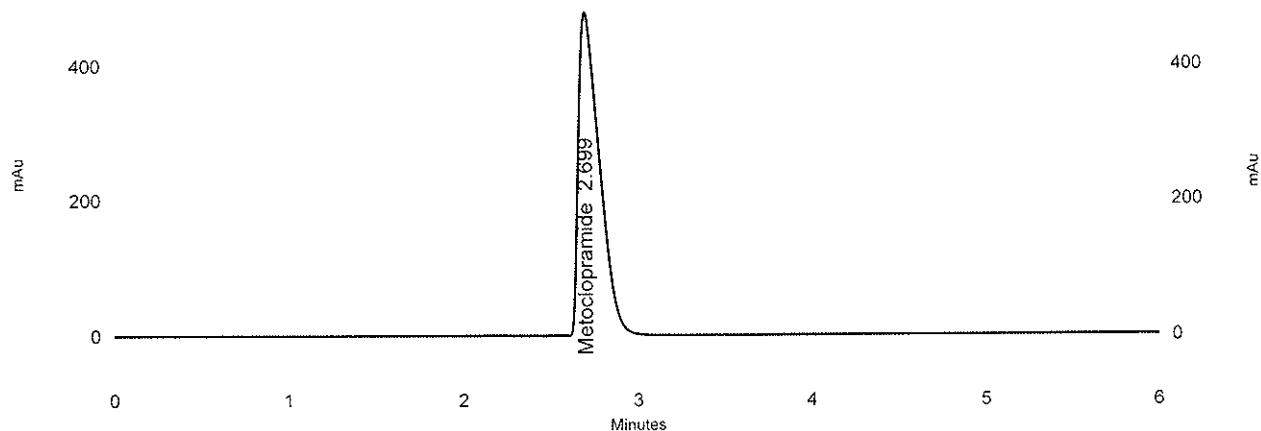
1: 280 nm,
4 nm

Results

Name	Retention Time	Area	ESTD concentration	Resolution (USP)	Asymmetry
Metoclopramide	2.645	4399867	2.000419	0.00000	1.77004

Sample ID: Metoclopramide Std 1

Method Name: C:\CLASS-VP\Methods\HPLC3\Metoclopramide Hydrochloride.met
Sequence: C:\CLASS-VP\Sequence\2010\July\HPLC 3\July 09-10 Methoclopramide 60 days Stability.seq
Filename: C:\CLASS-VP\Enterprise\Projects\Default\Data\July-09-10 Metoclopramide 60 days Stab 11-Rep1
Acquired: 7/9/2010 3:07:55 PM
Printed: 7/12/2010 8:28:31 AM
Vial: 92



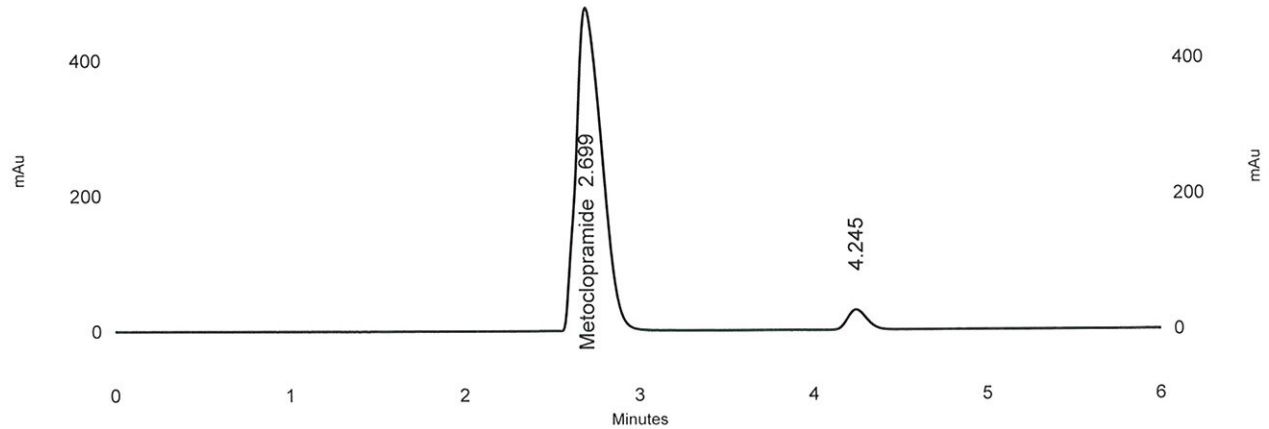
1: 280 nm,
4 nm

Results

Name	Retention Time	Area	ESTD concentration	Resolution (USP)	Asymmetry
Metoclopramide	2.699	3999377	0.100300 CAL	0.00000	1.94734

Sample ID: Metoclopramide 2% in PEN Cream 60 days Stab.

Method Name: C:\CLASS-VP\Methods\HPLC3\Metoclopramide Hydrochloride.met
Sequence: C:\CLASS-VP\Sequence\2010\July\HPLC 3\July 09-10 Methoclopramide 60 days Stability.seq
Filename: C:\CLASS-VP\Enterprise\Projects\Default\Data\July-09-10 Metoclopramide 60 days Stab 13
Acquired: 7/9/2010 4:09:53 PM
Printed: 7/12/2010 8:29:20 AM
Vial: 94



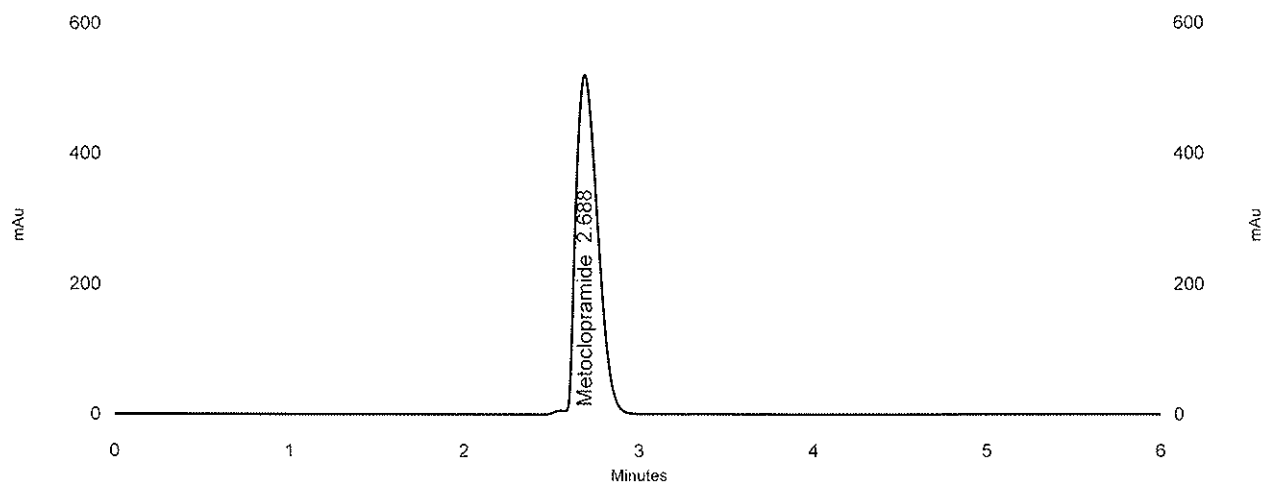
1: 280 nm,
4 nm

Results

Name	Retention Time	Area	ESTD concentration	Resolution (USP)	Asymmetry
Metoclopramide	2.699	4832002	2.083901	0.00000	1.35786

Sample ID: Metoclopramide Std 1

Method Name: C:\CLASS-VP\Methods\HPLC3\Metoclopramide Hydrochloride.met
Sequence: C:\CLASS-VP\Sequence\2010\August\HPLC 3\August 11-10 Metoclopramine 90 day Stability A.seq
Filename: C:\CLASS-VP\Enterprise\Projects\Default\Data\August-11-10 Metoclopramide 90 days Stab 201-Rep1
Acquired: 8/11/2010 11:57:25 AM
Printed: 8/11/2010 1:34:41 PM
Vial: 2



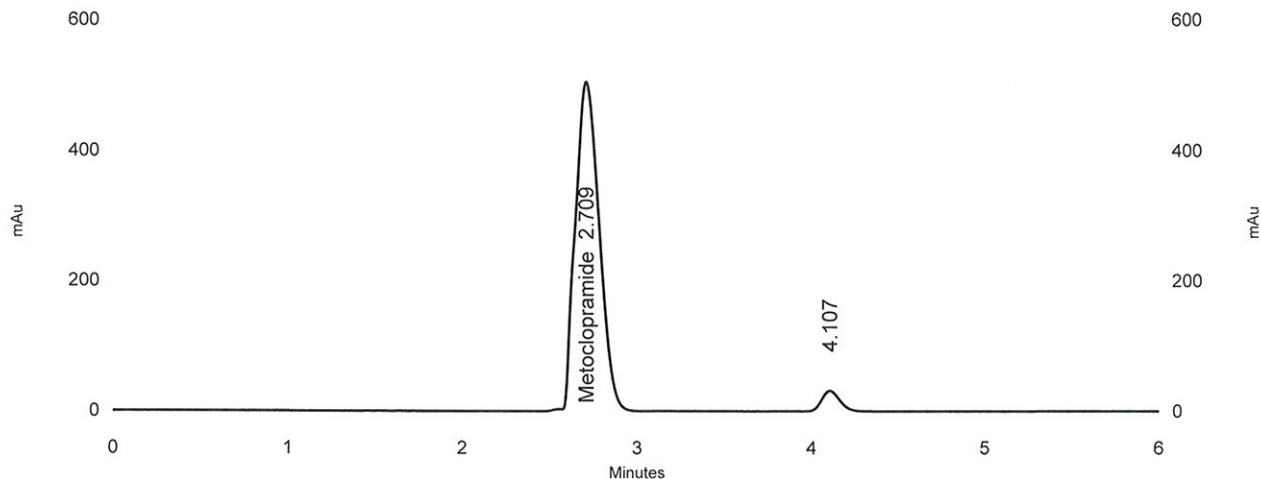
1: 280 nm,
4 nm

Results

Name	Retention Time	Area	ESTD concentration	Resolution (USP)	Asymmetry
Metoclopramide	2.688	4444792	0.100300 CAL	0.00000	1.50756

Sample ID: Metoclopramide 2% in PEN Cream 90 days Stab.

Method Name: C:\CLASS-VP\Methods\HPLC3\Metoclopramide Hydrochloride.met
Sequence: C:\CLASS-VP\Sequence\2010\August\HPLC 3\August 11-10 Metoclopramide 90 day Stability A.seq
Filename: C:\CLASS-VP\Enterprise\Projects\Default\Data\August-11-10 Metoclopramide 90 days Stab 203
Acquired: 8/11/2010 12:59:26 PM
Printed: 8/11/2010 1:36:00 PM
Vial: 4



1: 280 nm,
4 nm

Results

Name	Retention Time	Area	ESTD concentration	Resolution (USP)	Asymmetry
Metoclopramide	2.709	4749231	2.153635	0.00000	1.23126