

Prednisone:

2.50g Prednisone raw drug powder from Spectrum chemical (part number PR103, Lot # VJ0325) was added to 50.00g Humco PLO 20 (Humco Holding Group, Texarkana, Texas) and levigated with an electronic mortar and pestle, resulting in a final concentration of 5.0% w/w. This emulsion was then stored at room temperature in the same 50/70 mL Unguator container.

Similar steps were used in preparing samples in Humco PLO 20 Flowable (Humco Holding Group, Texarkana, Texas).

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:

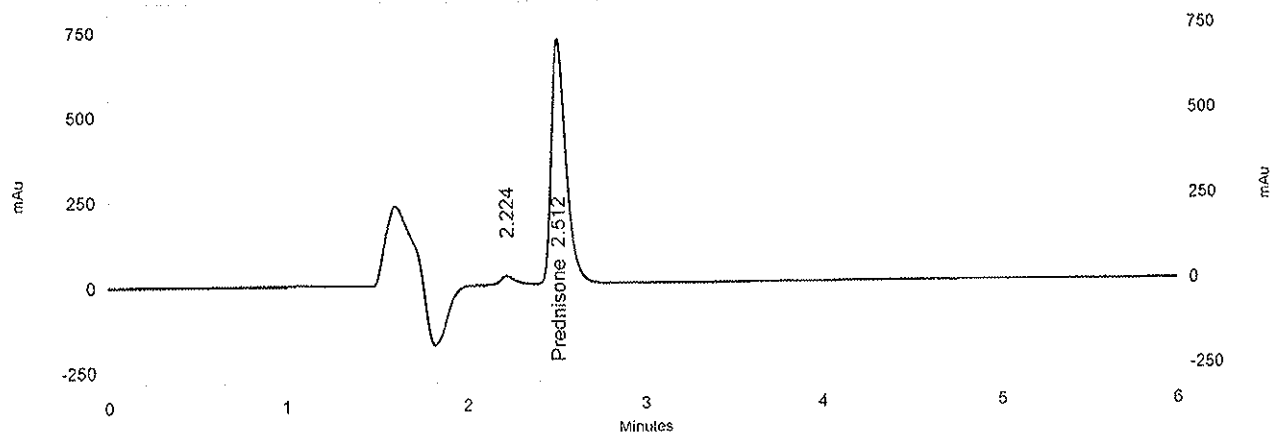
Compounded at 5.0% w/w, stability-indicating HPLC analysis found negligible Prednisone loss in Humco PLO 20 at 90 days.

Compounded at 10.0% w/w, stability-indicating HPLC analysis found less than 1% Prednisone loss in Humco PLO 20 Flowable at 90 days.

Attached are 8 chromatographs of Humco PLO 20 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.

Attached are 8 chromatographs of Humco PLO 20 Flowable 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.

Prdnisone STD 1
 C:\CLASS-VP\Methods\HPLC3\Prednisolne & Prednisone.met
 C:\CLASS-VP\Sequence\2008\November2008\November 22-08
 Prednisone Precision dex.seq
 11/24/2008 8:14:00 AM 1
 11/24/2008 8:14:01 AM
 25

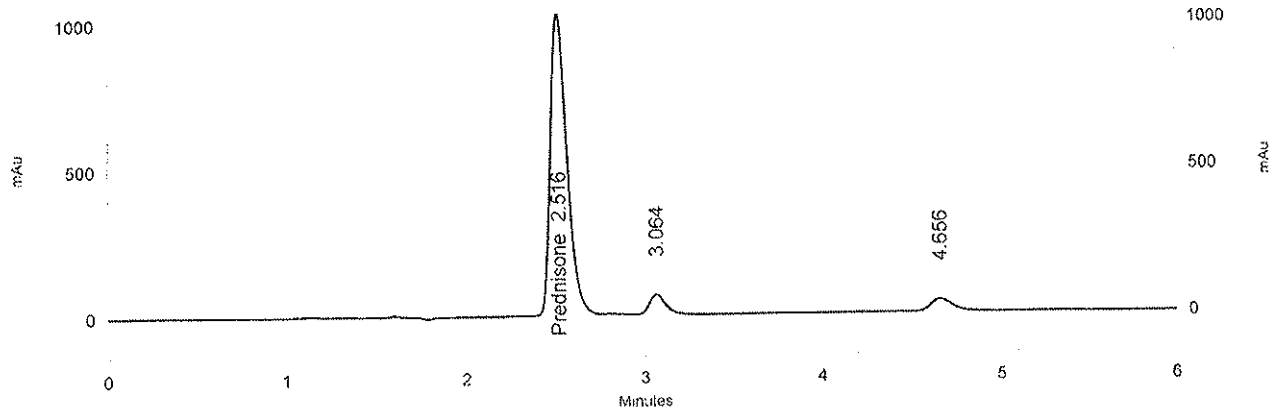


1: 254
 nm, 4 nm

Results
 Name

Name	Retention Time	Area	ESTD concentration	Asymmetry	Resolution (USP)	Theoretical plates (USP)
Prednisone	2.512	4172704	0.100 CAL	1.36967	1.97754	4491

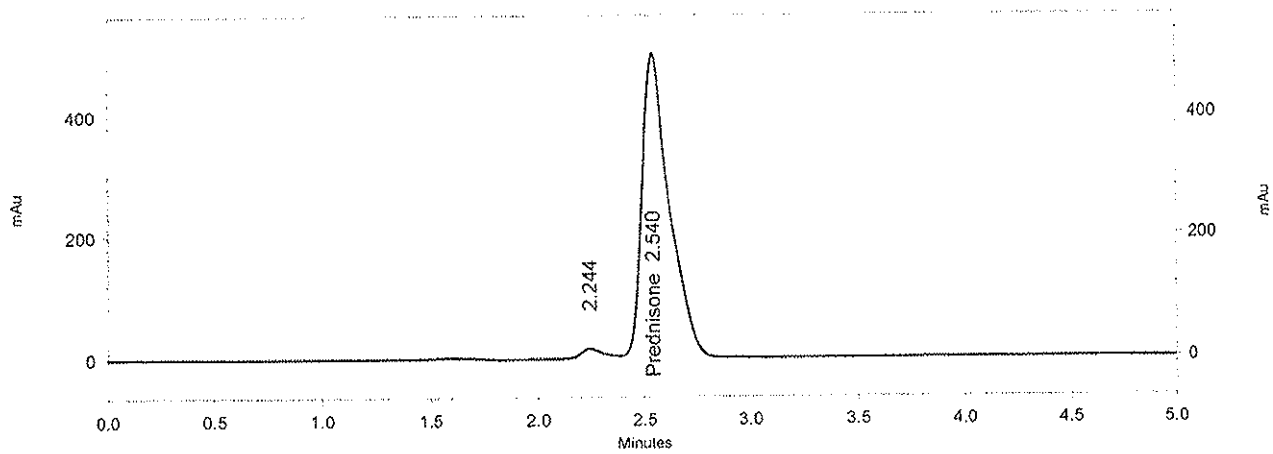
Prednisone Precision 1
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 Prednisone Precision dex.seq
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 11/24/2008 8:14:46 AM
 25



1: 254
 nm, 4 nm
 Results

Name	Retention Time	Area	ESTD concentration	Asymmetry	Resolution (USP)	Theoretical plates (USP)
Prednisone	2.516	6539716	5.022	1.34024	0.00000	3738

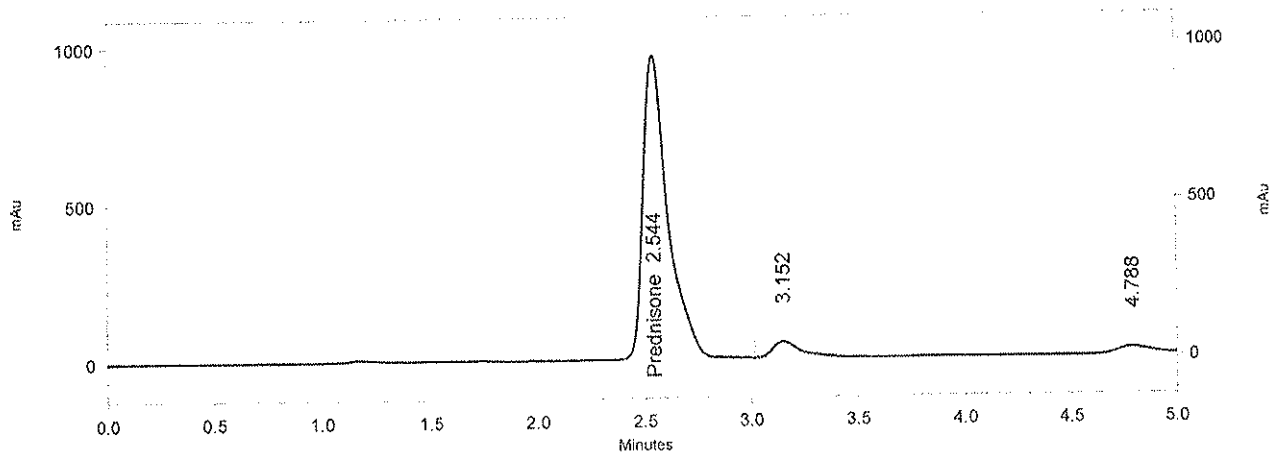
Prednisone STD 1
 C:\CLASS-VP\Methods\HPLC3\Prednisolne & Prednisone.met
 C:\CLASS-VP\Sequence\2008\December 2008\HPLC 3\December 16-08
 Prednisone Stability 30 days.seq
 12/16/2008 10:30:14 AM 1
 12/16/2008 10:30:14 AM
 25



1: 254
 nm, 4 nm
 Results

Name	Retention Time	Area	ESTD concentration	Asymmetry	Resolution (USP)	Theoretical plates (USP)
Prednisone	2.540	4424459	0.100 CAL	1.55404	1.48541	1968

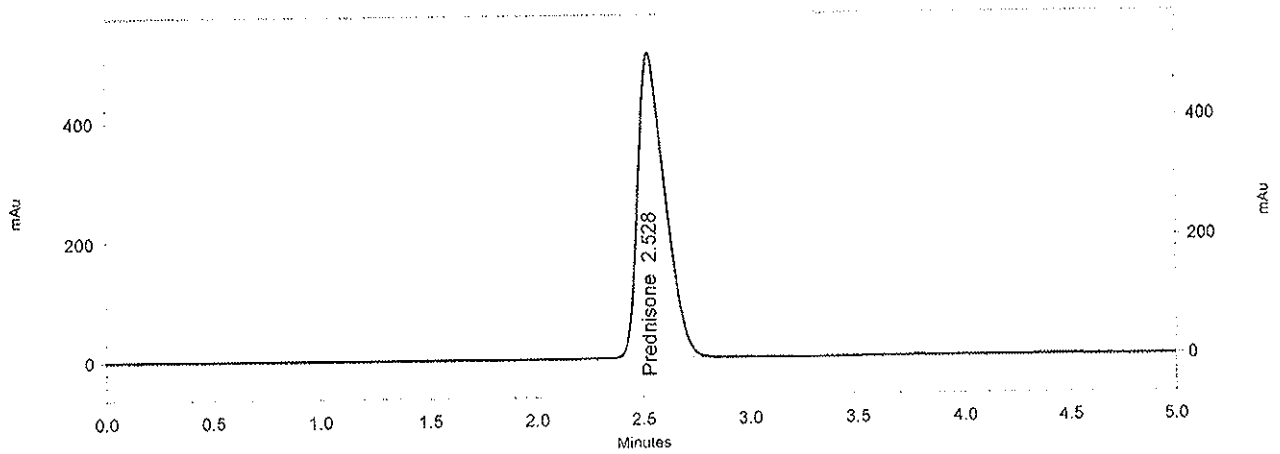
Prednisone Precision 1
 C:\CLASS-VP\Methods\HPLC3\Prednisolne & Prednisone.met
 C:\CLASS-VP\Sequence\2008\December 2008\HPLC 3\December 16-08
 Prednisone Stability 30 days.seq
 12/16/2008 10:30:38 AM 1
 12/16/2008 10:30:39 AM
 25



1: 254
 nm, 4 nm
 Results

Name	Retention Time	Area	ESTD concentration	Asymmetry	Resolution (USP)	Theoretical plates (USP)
Prednisone	2.544	7799106	5.044	1.57601	0.00000	2700

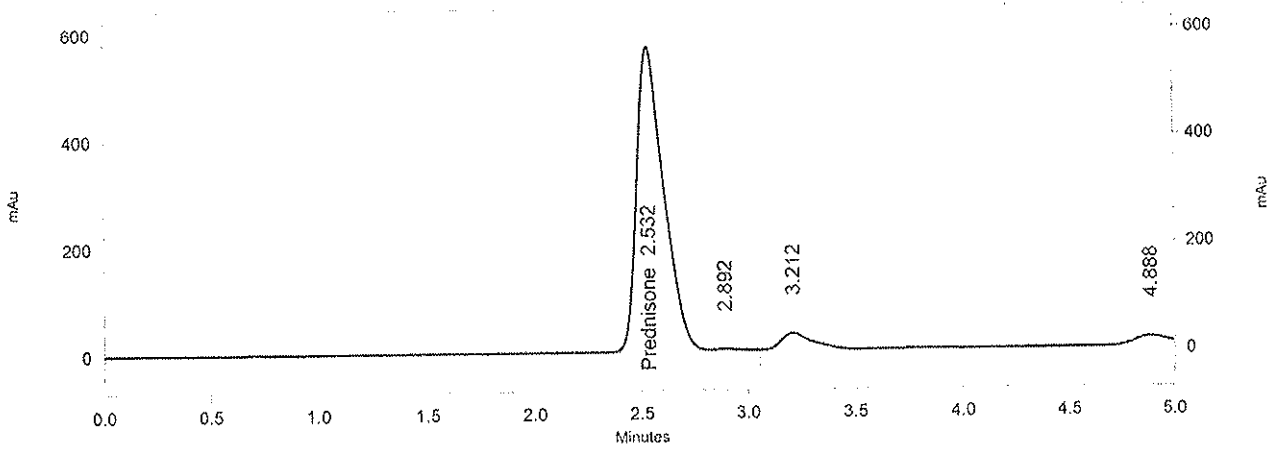
Prednisone STD 1
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 C:\CLASS-VP\Sequence\2009\January\HPLC3\January 16-09
 Prednisone stability 60 days.seq
 1/16/2009 11:36:01 AM 1
 1/16/2009 11:36:01 AM
 25



1: 254
 nm, 4 nm
 Results

Name	Retention Time	Area	ESTD concentration	Asymmetry	Resolution (USP)	Theoretical plates (USP)
Prednisone	2.528	4495671	0.100 CAL	1.42473	0.00000	1713

Prednisone Stability 60 days
 C:\CLASS-VP\Methods\HPLC3\Prednisolne & Prednisone.met
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 Prednisone stability 60 days.seq
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 1/16/2009 11:36:12 AM
 25

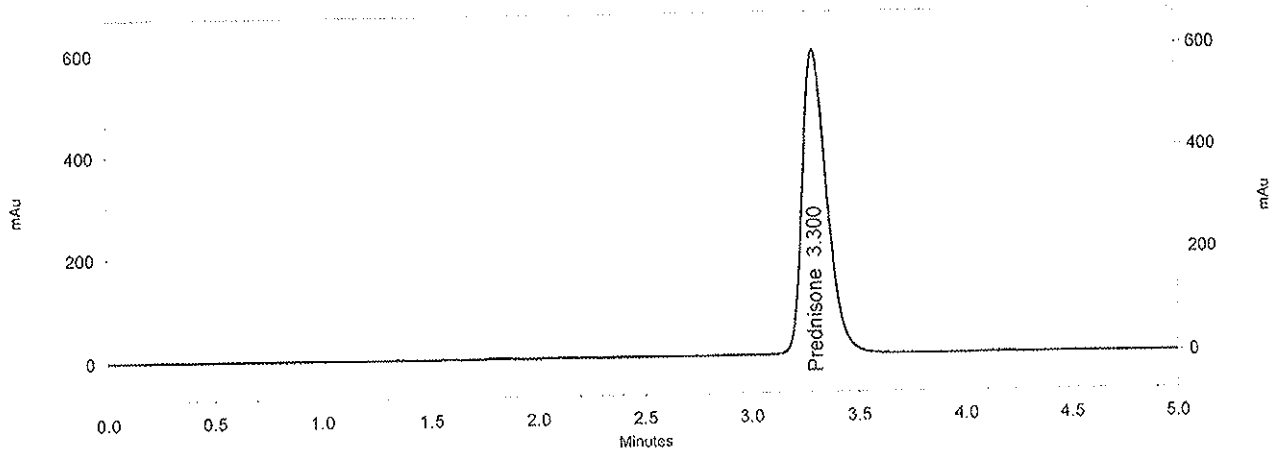


1: 254
 nm, 4 nm

Results

Name	Retention Time	Area	ESTD concentration	Asymmetry	Resolution (USP)	Theoretical plates (USP)
Prednisone	2.532	4960500	5.051	1.41084	0.00000	1854

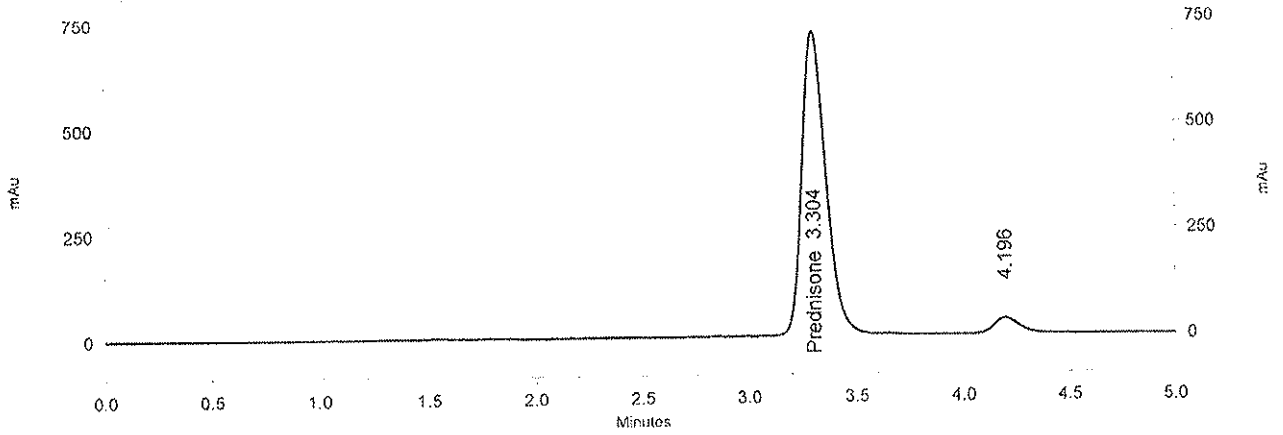
Prednisone STD 1
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 Prednisone stability 90 days.seq
 2/11/2009 8:17:01 AM 1
 2/11/2009 8:17:02 AM
 25



1: 254
 nm, 4 nm
 Results

Name	Retention Time	Area	ESTD concentration	Asymmetry	Resolution (USP)	Theoretical plates (USP)
Prednisone	3.300	4624863	0.100 CAL	1.23396	0.00000	4179

Prednisone Stability 90 days
 C:\CLASS-VP\Methods\HPLC3\Prednisolne & Prednisone.met
 C:\CLASS-VP\Sequence\2009\February\HPLC 3\February 10-09
 Prednisone stability 90 days.seq
 2/11/2009 8:17:16 AM 1
 2/11/2009 8:17:16 AM
 25

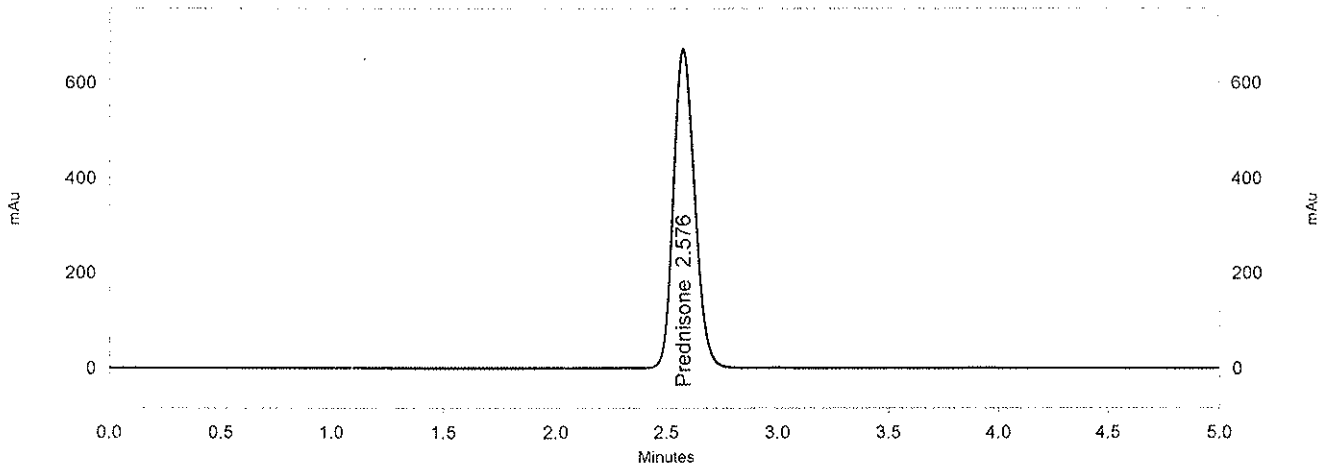


1: 254
 nm, 4 nm

Results
 Name

Name	Retention Time	Area	ESTD concentration	Asymmetry	Resolution (USP)	Theoretical plates (USP)
Prednisone	3.304	5574921	5.028	1.22058	0.00000	4305

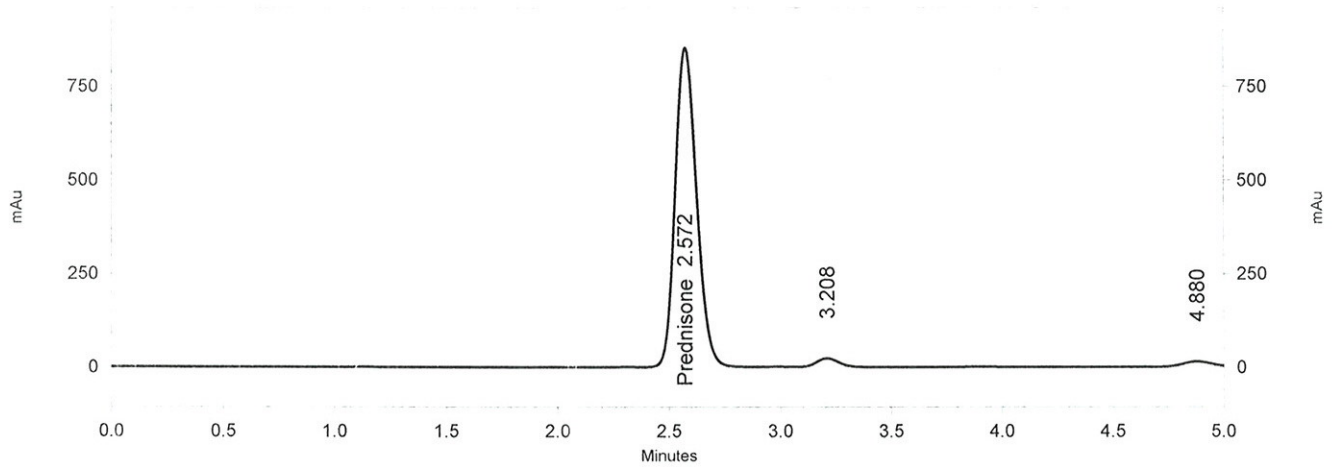
Prednisone STD 1
 C:\CLASS-VP\Methods\HPLC3\Prednisolne & Prednisone.met
 C:\CLASS-VP\Sequence\2010\April\HPLC 3\April 26-10 Prenisone
 stability Zero time.seq
 4/26/2010 12:55:15 PM 1
 4/26/2010 12:55:16 PM
 25



1: 254
 nm, 4 nm
 Results

Name	Retention Time	Area	ESTD concentration	Asymmetry	Resolution (USP)	Theoretical plates (USP)
Prednisone	2.576	4435793	0.100 CAL	1.15669	0.00000	3468

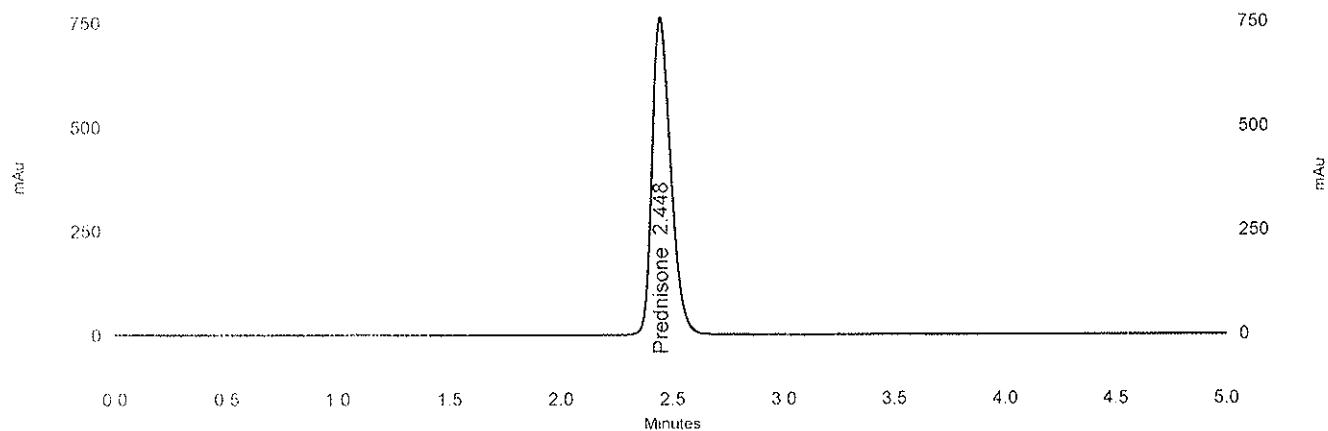
Prednisone 10% in PLO Flowvle Stability 60 days
 C:\CLASS-VP\Methods\HPLC3\Prednisolne & Prednisone.met
 C:\CLASS-VP\Sequence\2010\April\HPLC 3\April 26-10 Prenisone
 stability Zero time.seq
 4/26/2010 12:55:34 PM 1
 4/26/2010 12:55:34 PM
 25



1: 254
 nm, 4 nm
 Results

Name	Retention Time	Area	ESTD concentration	Asymmetry	Resolution (USP)	Theoretical plates (USP)
Prednisone	2.572	5702988	10.019	1.15103	0.00000	3400

Prednisone STD 1
 C:\CLASS-VP\Methods\HPLC3\Prednisolne & Prednisone.met
 C:\CLASS-VP\Sequence\2010\May\HPLC 3\May 26-10 Prednisone 10%
 30 Days Stability.seq
 5/26/2010 2:35:35 PM 1
 5/26/2010 2:35:35 PM
 25



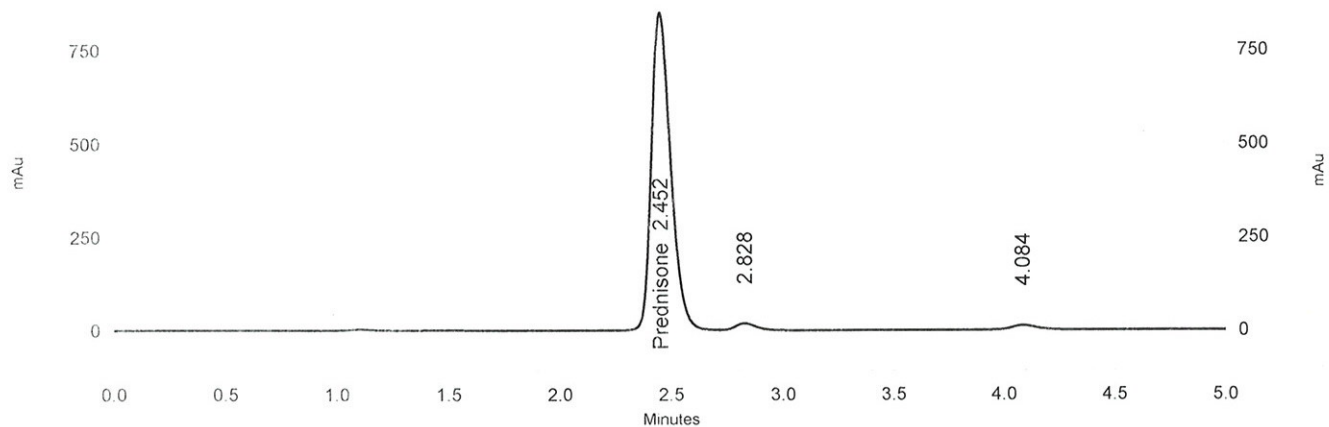
1: 259

nm, 4 nm

Results

Name	Retention Time	Area	ESTD concentration	Asymmetry	Resolution (USP)	Theoretical plates (USP)
Prednisone	2.448	4393583	0.100 CAL	1.26278	0.00000	4233

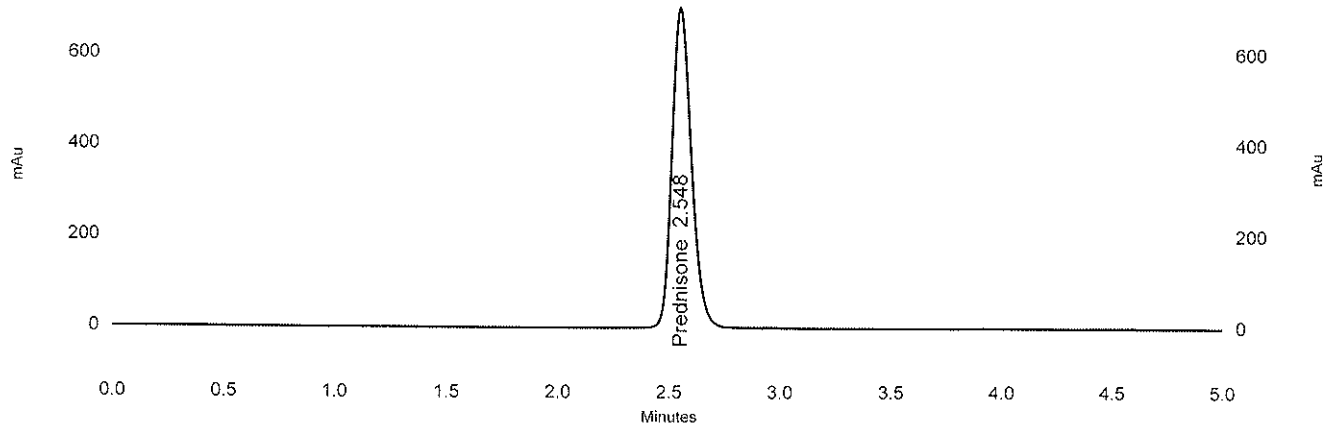
Prednisone 10% in PLO Flowvle Stability 30 days
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 C:\CLASS-VP\Sequence\2010\May\HPLC 3\May 26-10 Prednisone 10%
 30 Days Stability.seq
 5/26/2010 2:35:49 PM 1
 5/26/2010 2:35:50 PM
 25



1: 254
 nm, 4 nm
 Results

Name	Retention Time	Area	ESTD concentration	Asymmetry	Resolution (USP)	Theoretical plates (USP)
Prednisone	2.452	5089155	9.942	1.23795	0.00000	3938

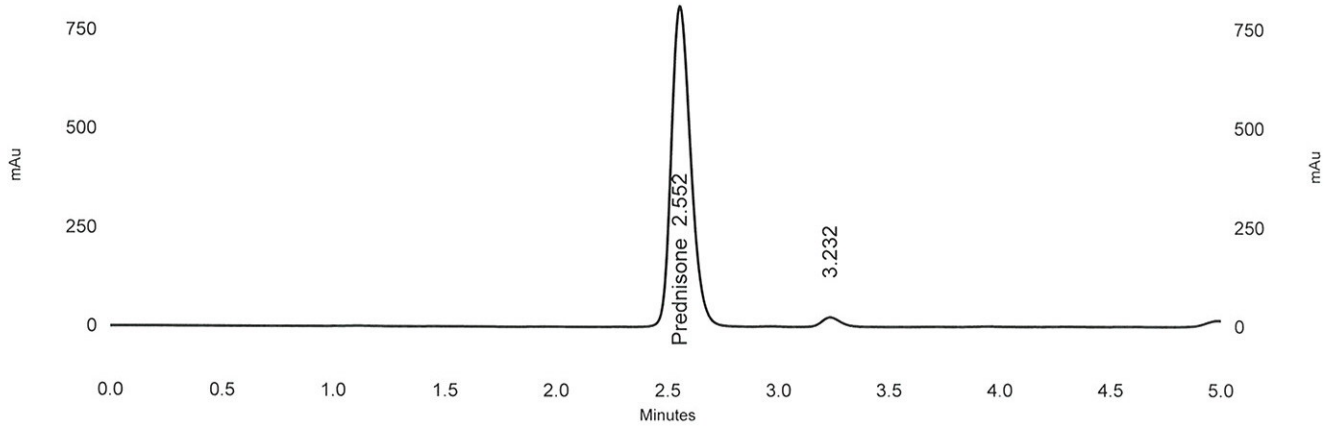
Prednisone STD 1
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 C:\CLASS-VP\Sequence\2010\June\HPLC 3\June 23-10 Prednisone 60
 days.seq
 6/24/2010 8:06:27 AM 1
 6/24/2010 8:06:27 AM
 25



1: 254
 nm, 4 nm
 Results

Name	Retention Time	Area	ESTD concentration	Asymmetry	Resolution (USP)	Theoretical plates (USP)
Prednisone	2.548	4280202	0.100 CAL	1.26009	0.00000	4097

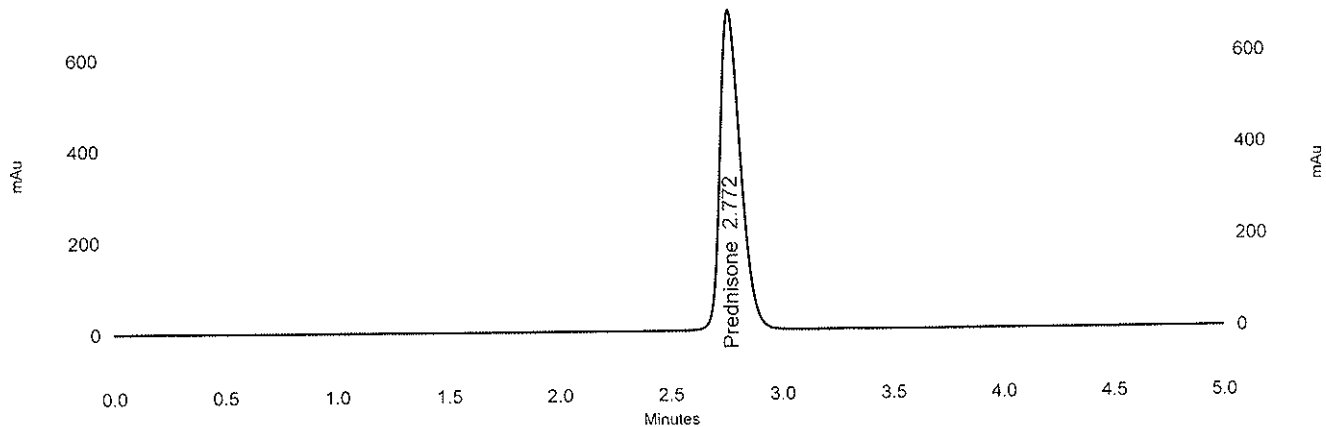
Prednisone 10% in PLO Flowvle Stability 60 days
 C:\CLASS-VP\Methods\HPLC3\Prednisolne & Prednisone.met
 C:\CLASS-VP\Sequence\2010\June\HPLC 3\June 23-10 Prednisone 60
 days.seq
 6/24/2010 8:10:33 AM 1
 6/24/2010 8:10:48 AM
 25



1: 254
 nm, 4 nm
 Results

Name	Retention Time	Area	ESTD concentration	Asymmetry	Resolution (USP)	Theoretical plates (USP)
Prednisone	2.552	4962087	10.054	1.26641	0.00000	4066

Prednisone STD 1
 C:\CLASS-VP\Methods\HPLC3\Prednisolne & Prednisone.met
 C:\CLASS-VP\Sequence\2010\July\HPLC 3\July 29-10 Predison 90
 days.seq
 7/29/2010 10:39:02 AM 1
 7/29/2010 10:39:03 AM
 25

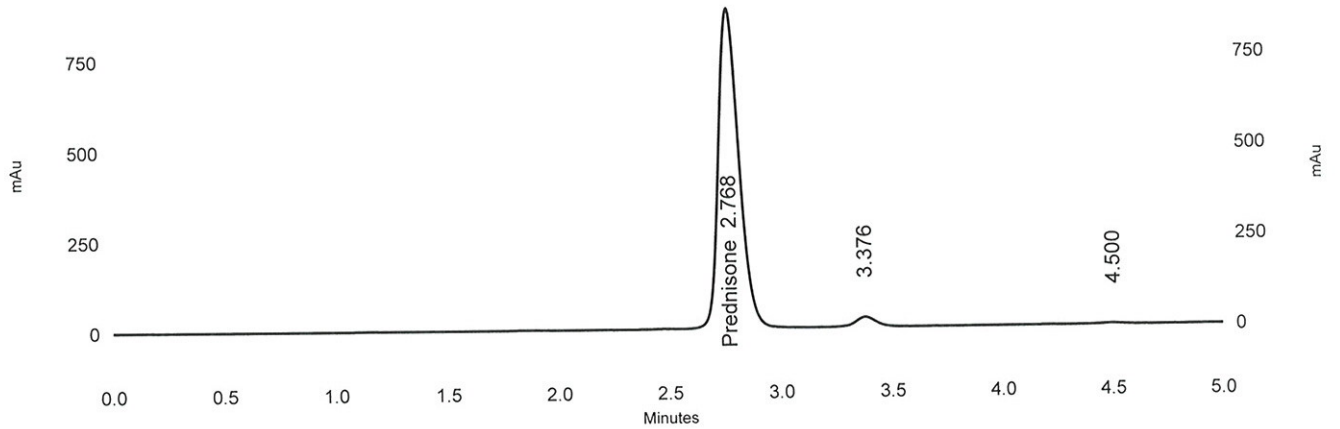


1: 254
 nm, 4 nm

Results

Name	Retention Time	Area	ESTD concentration	Asymmetry	Resolution (USP)	Theoretical plates (USP)
Prednisone	2.772	4463121	0.100 CAL	1.22320	0.00000	4380

Prednisone 10% in PLO Flowvle Stability 90 days
 C:\CLASS-VP\Methods\HPLC3\Prednisolne & Prednisone.met
 C:\CLASS-VP\Sequence\2010\July\HPLC 3\July 29-10 Predison 90
 days.seq
 7/29/2010 10:40:12 AM 1
 7/29/2010 10:40:12 AM
 25



1: 254
 nm, 4 nm

Results

Name	Retention Time	Area	ESTD concentration	Asymmetry	Resolution (USP)	Theoretical plates (USP)
Prednisone	2.768	5624261	9.896	1.21191	0.00000	4406