

Prednisolone:

2.50g Prednisolone raw drug powder from Spectrum chemical (part number PR101, Lot # WK0699) 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 HRT Base Botanical (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:

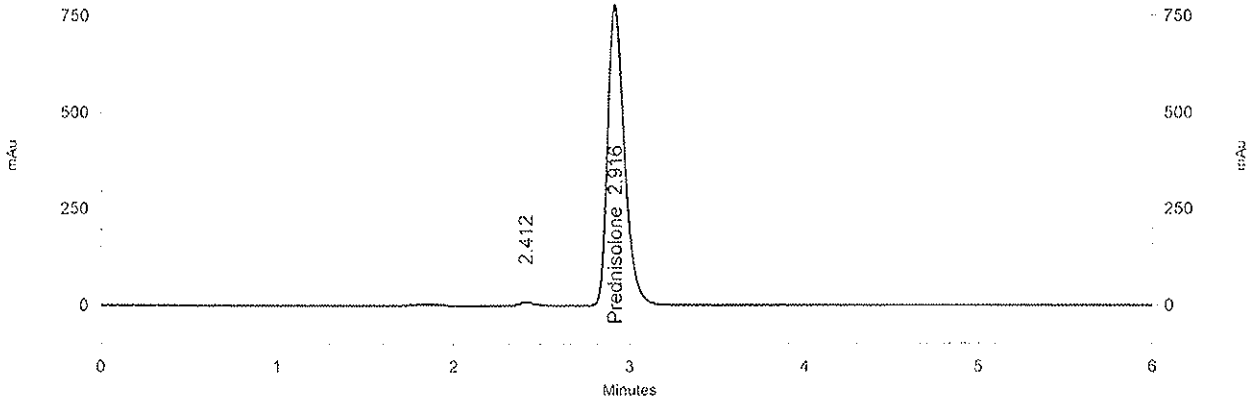
Compounded at 5.0% w/w, stability-indicating HPLC analysis found negligible Prednisolone loss in Humco PLO 20 at 90 days.

Compounded at 5.0% w/w, stability-indicating HPLC analysis found negligible Prednisolone loss in Humco HRT Base Botanical 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 HRT Base Botanical 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.

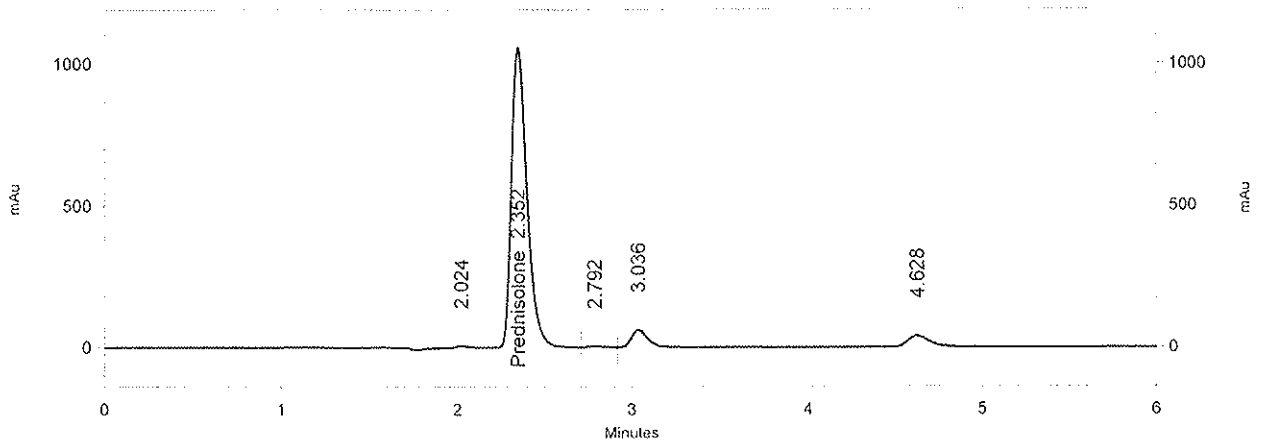
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 21-08Prednisolone Linearity dex.seq
 11/22/2008 12:03:37 PM 1
 11/22/2008 12:03:37 PM
 25



1: 254
 nm, 4 nm
 Results

Name	Retention Time	Area	ESTD concentration	Asymmetry	Resolution (USP)	Theoretical plates (USP)
Prednisolone	2.916	5120135	0.100 CAL	1.33570	3.17212	4568

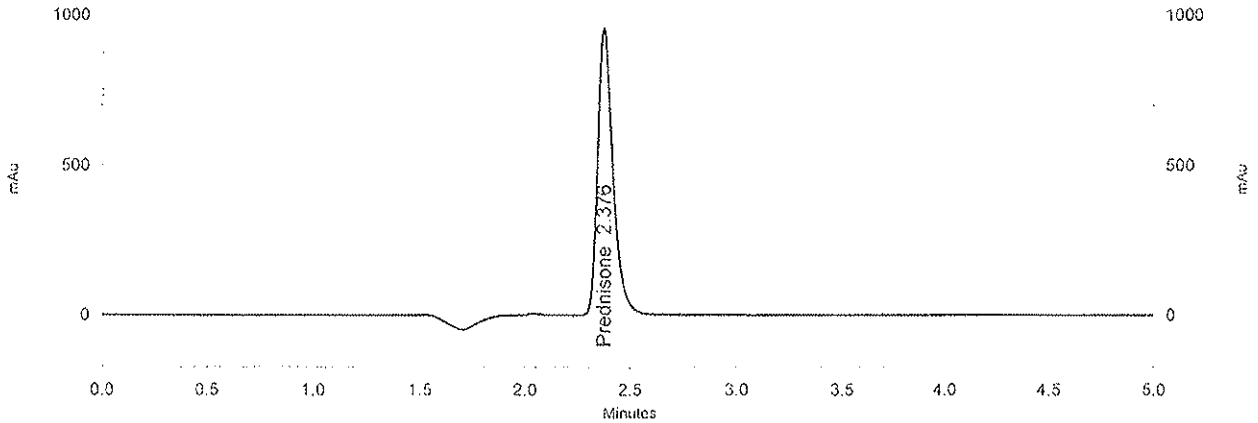
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 11/22/2008 12:27:09 PM 1
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 nm, 4 nm
 Results

Name	Retention Time	Area	ESTD concentration	Asymmetry	Resolution (USP)	Theoretical plates (USP)
Prednisolone	2.352	6628911	4.872	1.38583	1.55584	3362

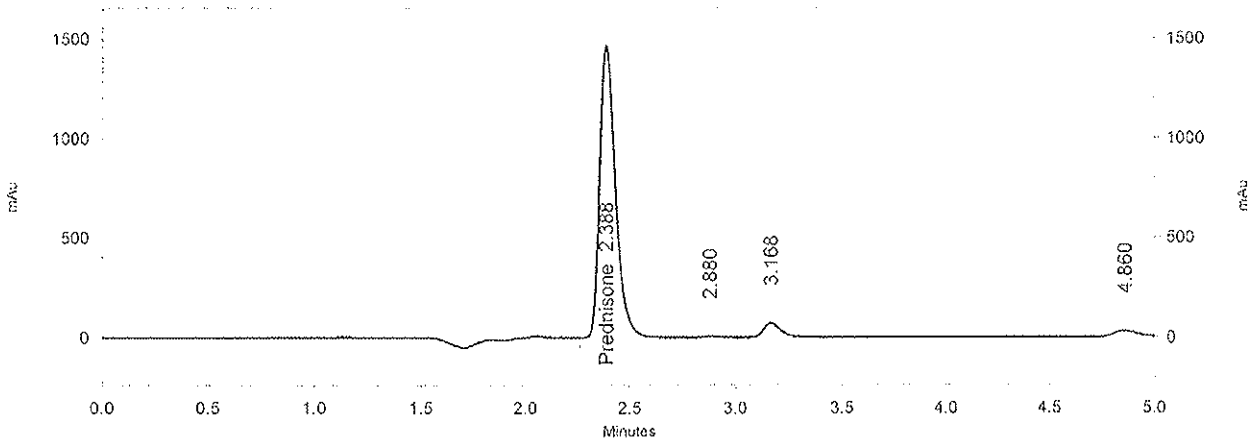
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 Prednisolone Stability 30 days.seq
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 12/16/2008 1:24:06 PM
 25



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 nm, 4 nm
 Results

Name	Retention Time	Area	ESTD concentration	Asymmetry	Resolution (USP)	Theoretical plates (USP)
Prednisone	2.376	4839409	0.100 CAL	1.40411	0.00000	5364

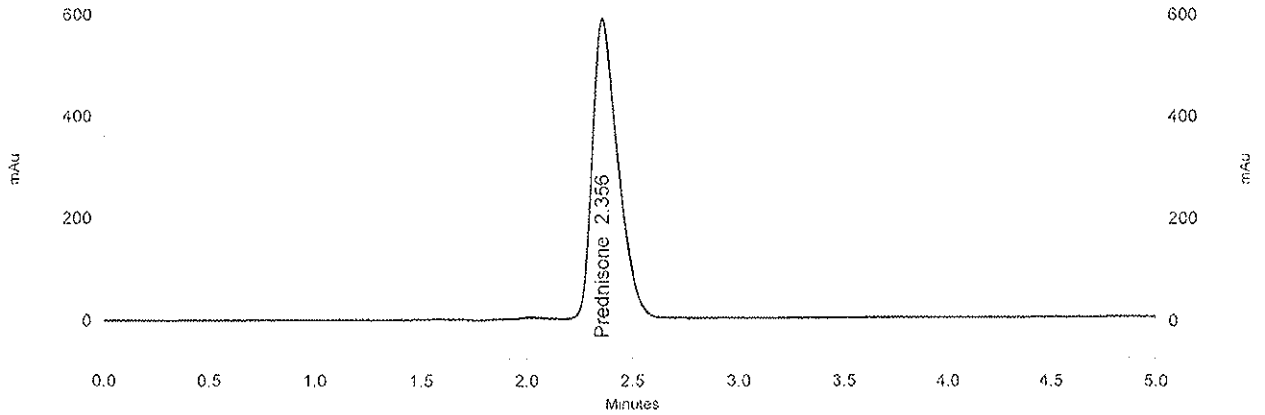
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 Results

Name	Retention Time	Area	ESTD concentration	Asymmetry	Resolution (USP)	Theoretical plates (USP)
Prednisone	2.388	7651127	4.942	1.42527	0.00000	5145

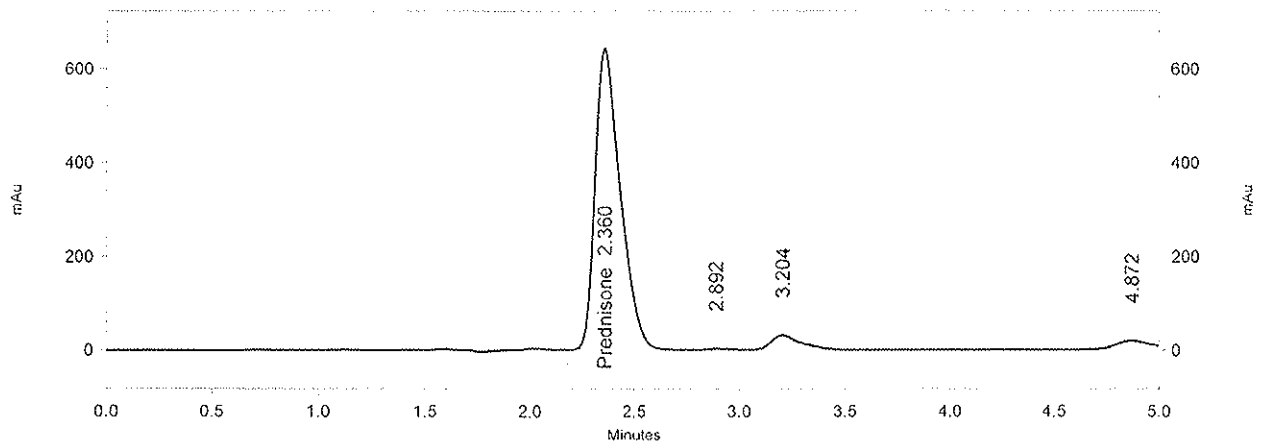
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 Results

Name	Retention Time	Area	ESTD concentration	Asymmetry	Resolution (USP)	Theoretical plates (USP)
Prednisone	2.356	4902121	0.100 CAL	1.45562	0.00000	1745

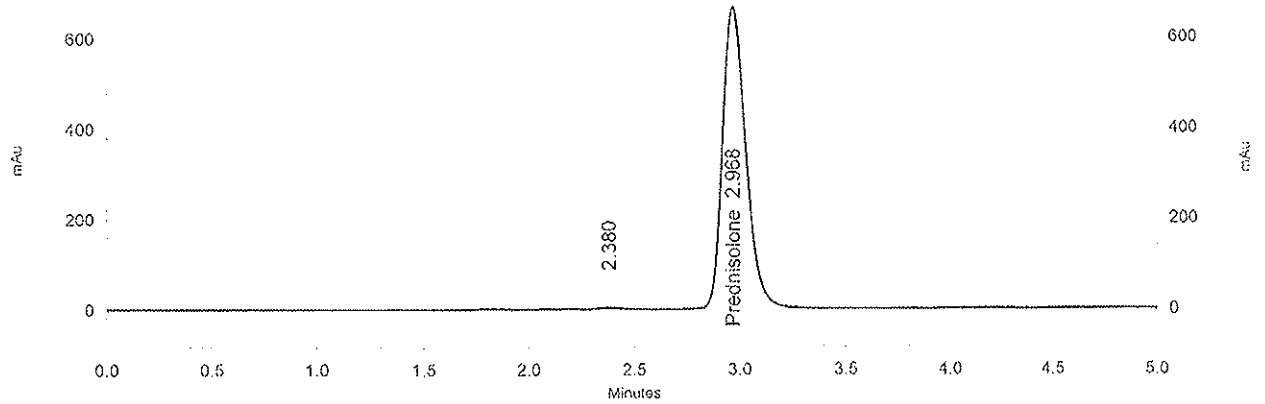
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Name	Retention Time	Area	ESTD concentration	Asymmetry	Resolution (USP)	Theoretical plates (USP)
Prednisone	2.360	5350707	5.036	1.42710	0.00000	1774

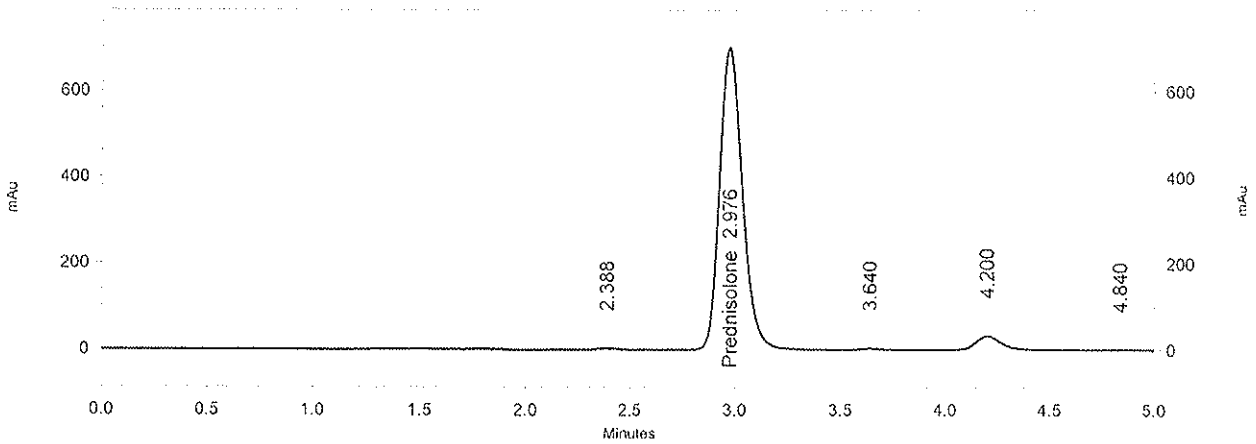
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 Results

Name	Retention Time	Area	ESTD concentration	Asymmetry	Resolution (USP)	Theoretical plates (USP)
Prednisolone	2.968	5062650	0.100 CAL	1.28310	3.09603	3555

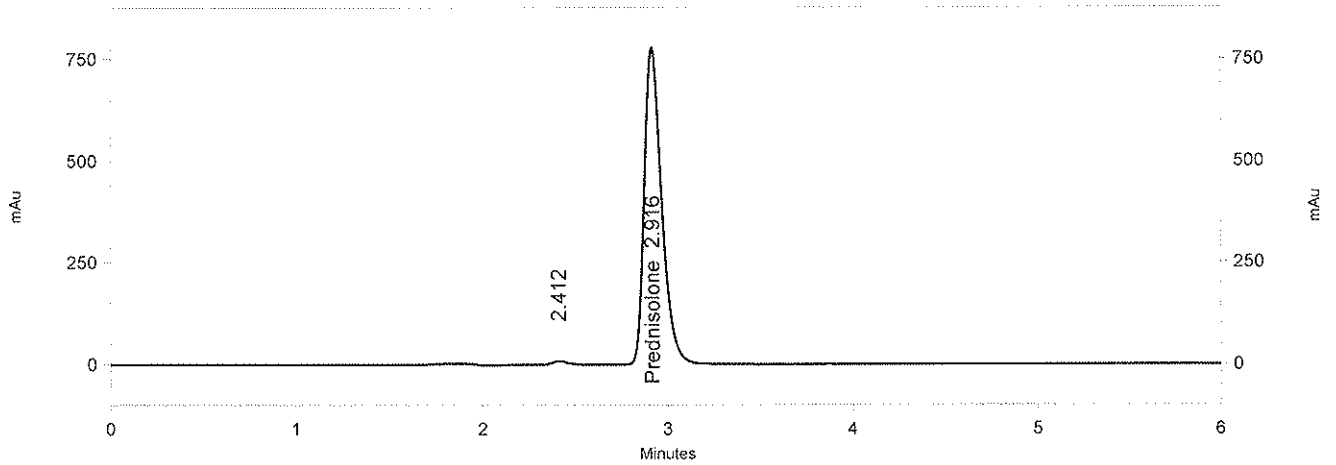
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Name	Retention Time	Area	ESTD concentration	Asymmetry	Resolution (USP)	Theoretical plates (USP)
Prednisolone	2.976	5260743	5.185	1.23368	3.12745	3647

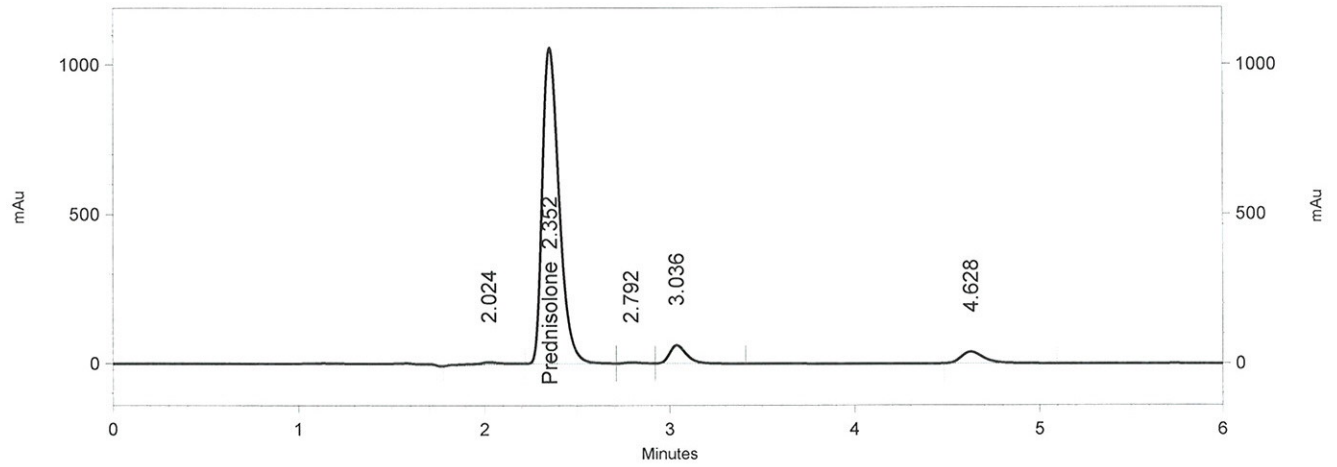
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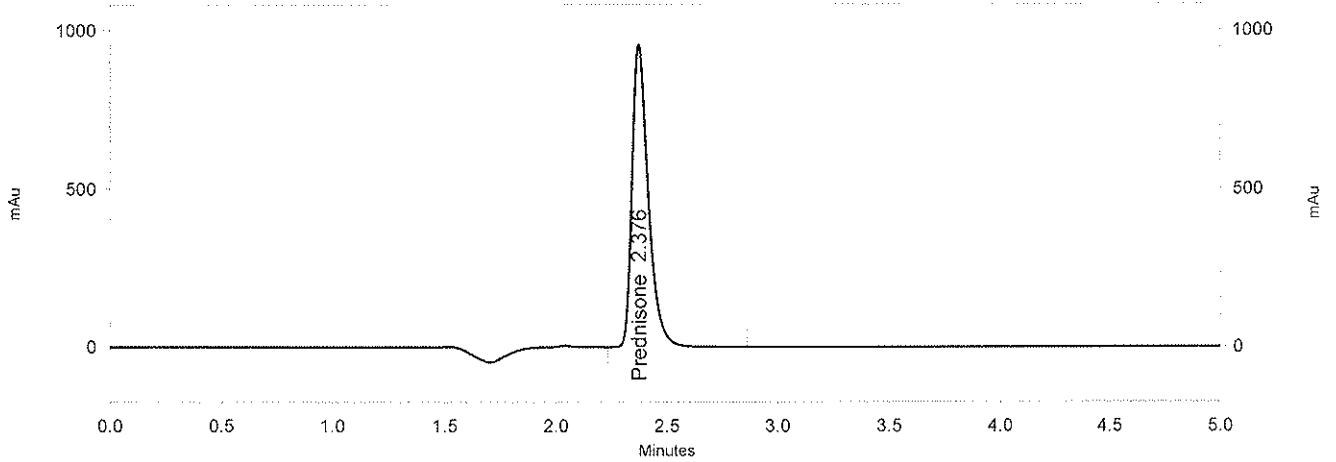
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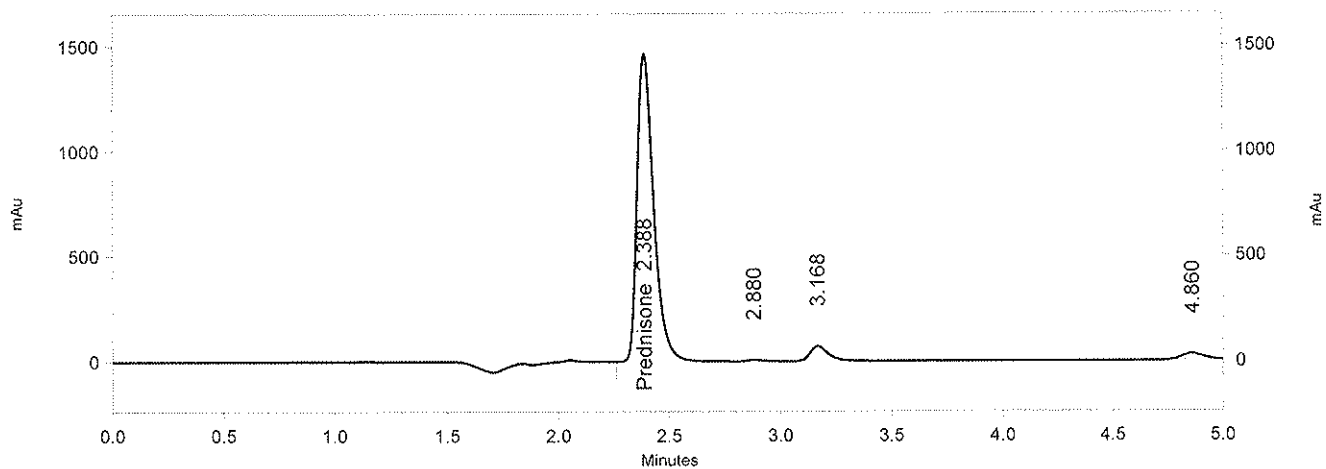
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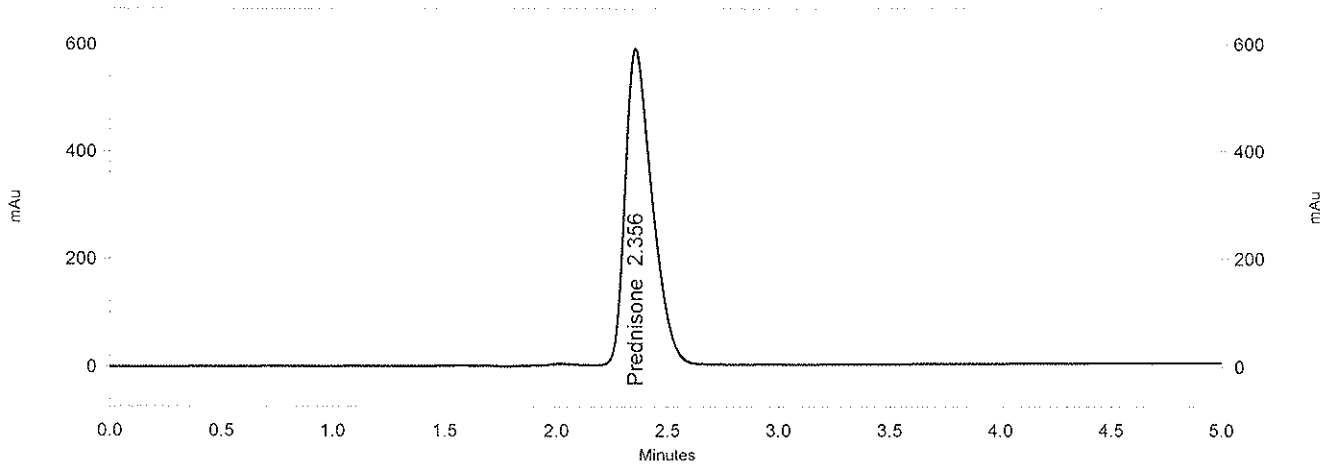
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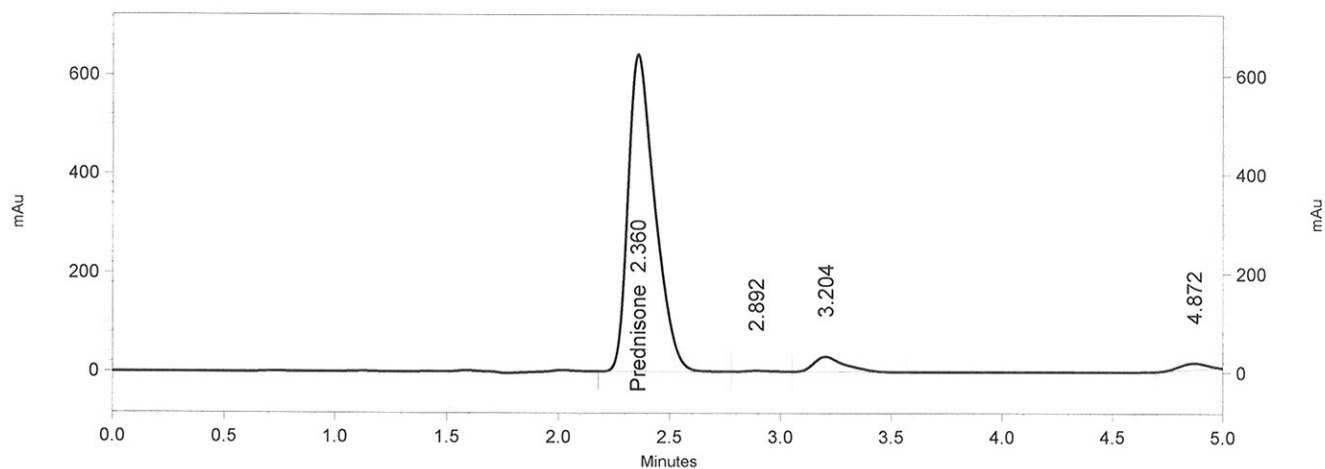
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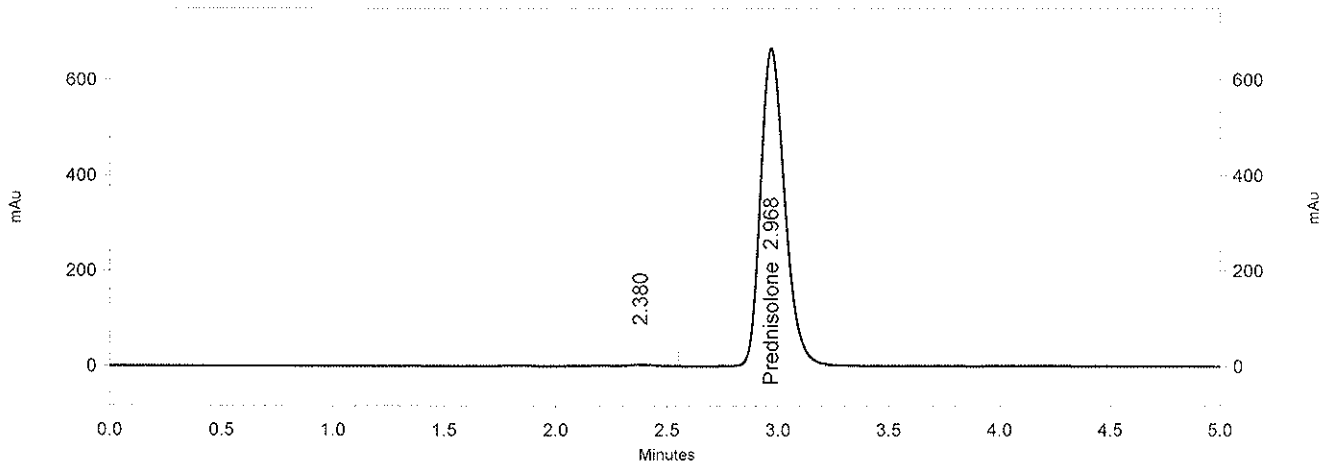
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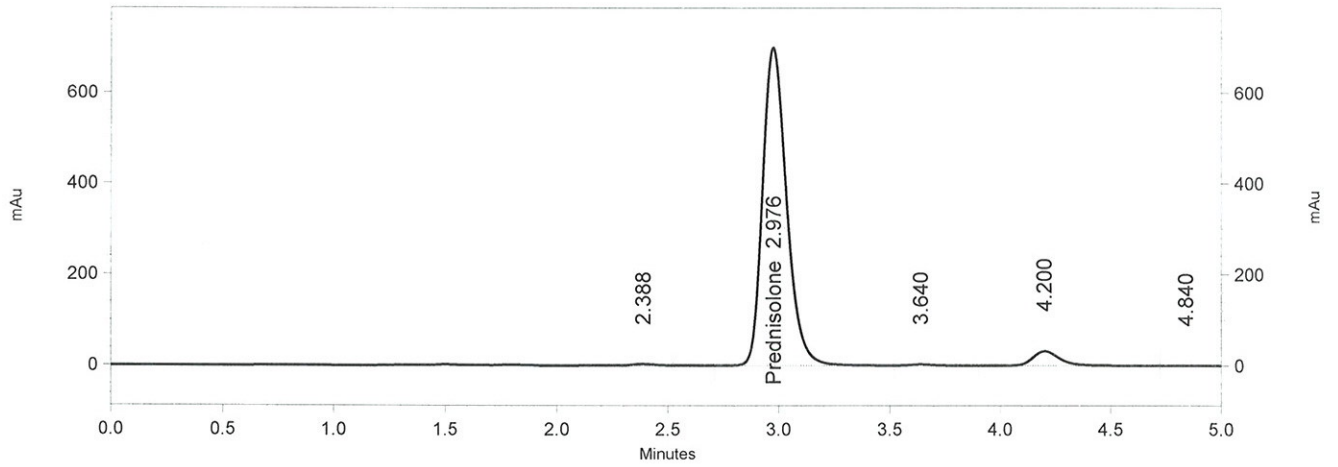
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