

Dehydroepiandrosterone:

0.625g Dehydroepiandrosterone raw drug powder from Spectrum chemical (part number D1225, Lot # VH1454) was added to 50.00g Humco LipoBase Regular (Humco Holding Group, Texarkana, Texas) and levigated with an electronic mortar and pestle, resulting in a final concentration of 1.25% w/w. This gel 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.

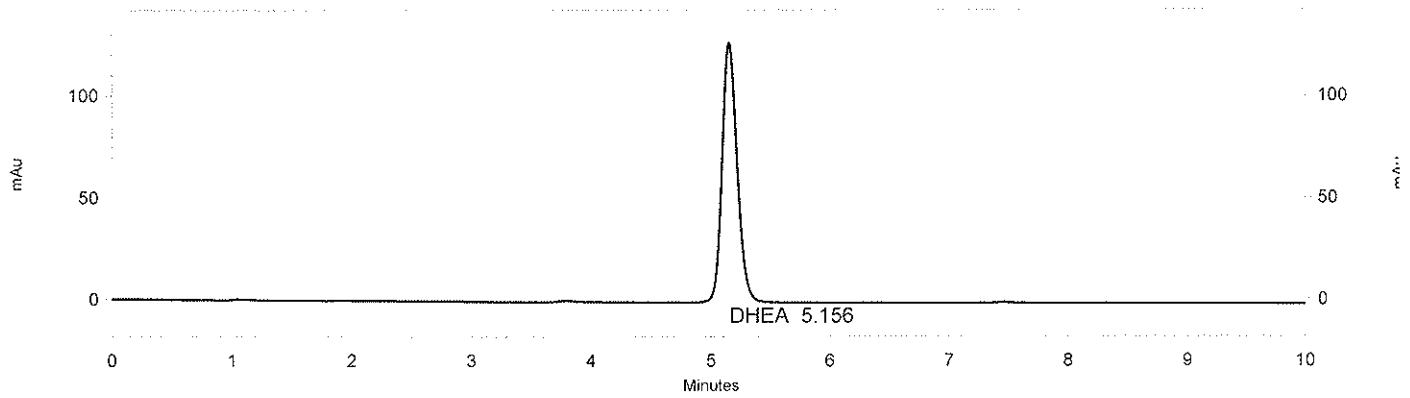
Results were compared and samples were analyzed each 14 day interval. The limits of acceptance of results were to be < 90% theoretical concentration of initial prepared sample. The results were tabulated for each 14 day interval and examples of chromatography are attached which show standard preparations, initial interval, and latest passing interval to illustrate no co-elution or baseline interference, as well as degradation products.

90-Day Summary:

Compounded at 1.25% w/w, stability-indicating HPLC analysis found less than 4% Dehydroepiandrosterone loss in Humco LipoBase Regular at 90 days.

Attached are 8 chromatographs of Humco LipoBase Regular 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.

HUMCO HOLDING GROUP
 Sample: DHEA Standards
 Method: C:\CLASS-VP\Methods\HPLC3\Dehydroepiandrosterone (DHEA).met
 Integration Method: C:\CLASS-VP\Methods\HPLC3\Dehydroepiandrosterone (DHEA).met
 Vial: #2



1: 210 nm,
 4 nm

Results

Name	Retention Time	Area	ESTD concentration	Resolution (USP)	Asymmetry
DHEA	5.156	1125604	0.125 CAL	0.00000	1.13983

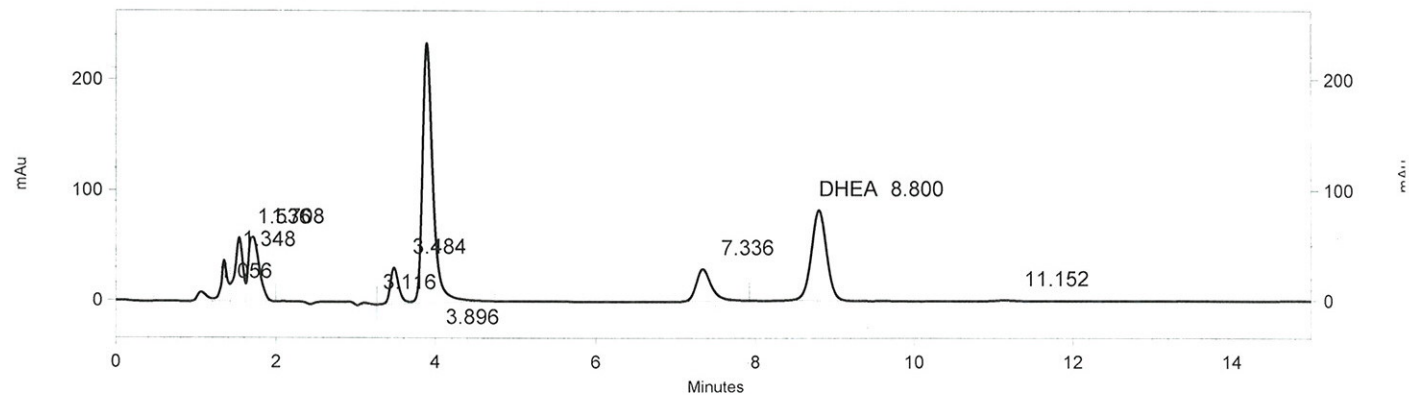
HUMCO HOLDING GROUP

Sample: Precision-1

Method: C:\CLASS-VP\Methods\HPLC3\Dehydroepiandrosterone (DHEA).met

Integration Method: C:\CLASS-VP\Methods\HPLC3\Dehydroepiandrosterone (DHEA).met

Vial: #5



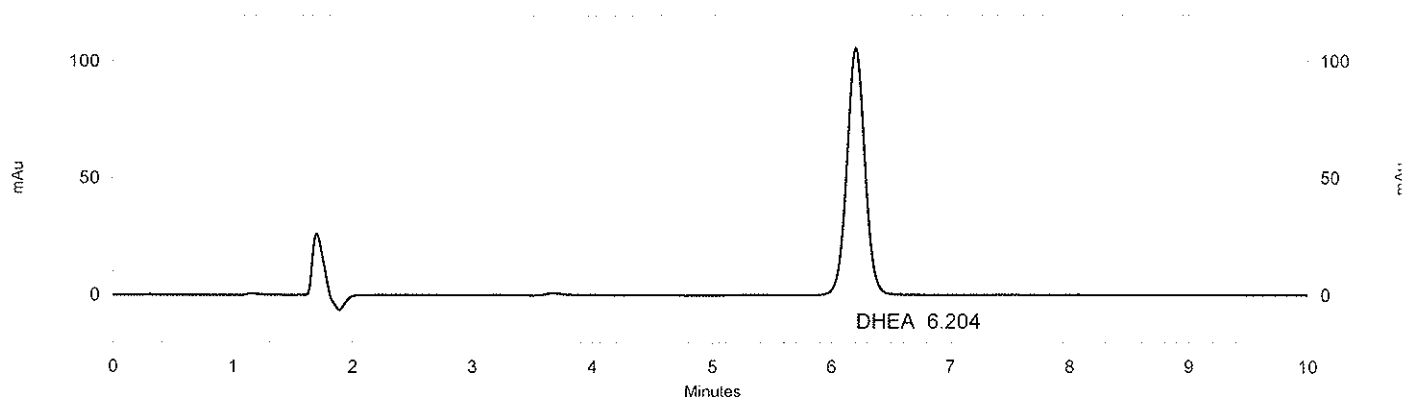
1: 210 nm,

4 nm

Results

Name	Retention Time	Area	ESTD concentration	Resolution (USP)	Asymmetry
DHEA	8.800	1098207	1.269	4.21801	1.01871

HUMCO HOLDING GROUP
 Sample: DHEA Standards
 Method: C:\CLASS-VP\Methods\HPLC3\Dehydroepiandrosterone (DHEA).met
 Integration Method: C:\CLASS-VP\Methods\HPLC3\Dehydroepiandrosterone (DHEA).met
 Vial: #2



1: 210 nm,
 4 nm

Results

Name	Retention Time	Area	ESTD concentration	Resolution (USP)	Asymmetry
DHEA	6.204	1101694	0.125 CAL	0.00000	1.02792

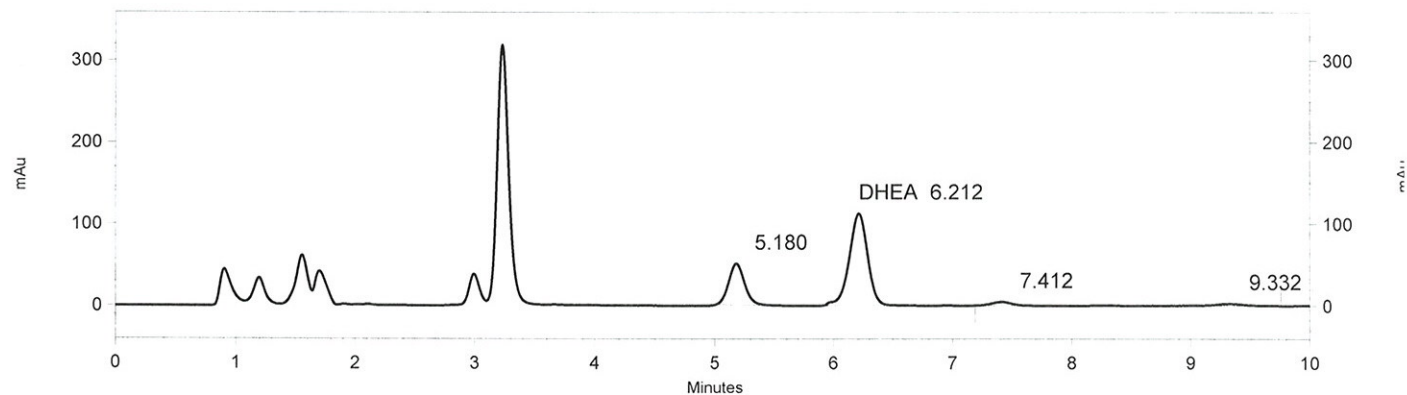
HUMCO HOLDING GROUP

Sample: DHEA Stability 30 days

Method: C:\CLASS-VP\Methods\HPLC3\Dehydroepiandrosterone (DHEA).met

Integration Method: C:\CLASS-VP\Methods\HPLC3\Dehydroepiandrosterone (DHEA).met

Vial: #4



1: 210 nm,

4 nm

Results

Name	Retention Time	Area	ESTD concentration	Resolution (USP)	Asymmetry
DHEA	6.212	1204552	1.307	3.92977	0.93843

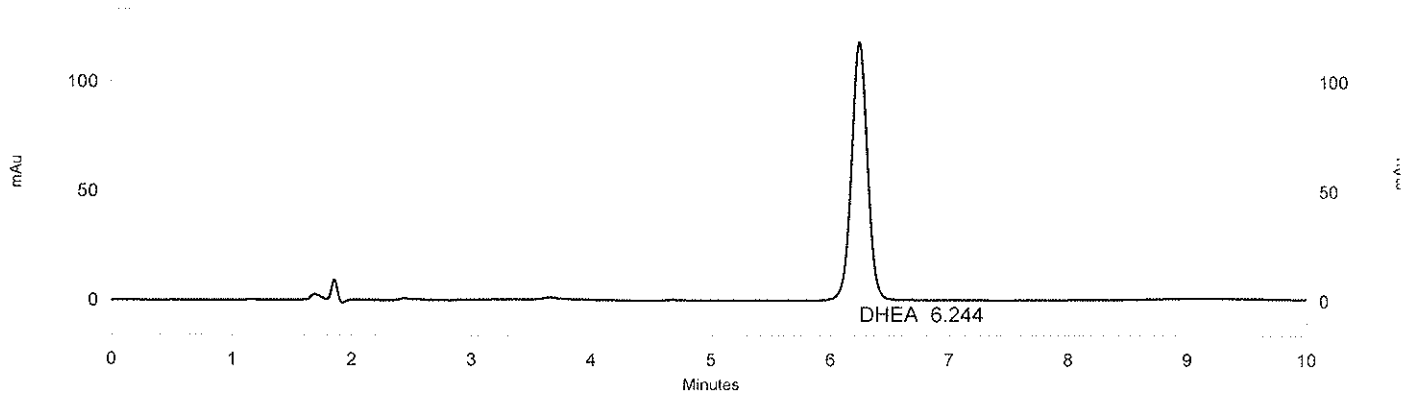
HUMCO HOLDING GROUP

Sample: DHEA Standards

Method: C:\CLASS-VP\Methods\HPLC3\Dehydroepiandrosterone (DHEA).met

Integration Method: C:\CLASS-VP\Methods\HPLC3\Dehydroepiandrosterone (DHEA).met

Vial: #2



1: 210 nm,
4 nm

Results

Name	Retention Time	Area	ESTD concentration	Resolution (USP)	Asymmetry
DHEA	6.244	1104808	0.125 CAL	0.00000	1.02481

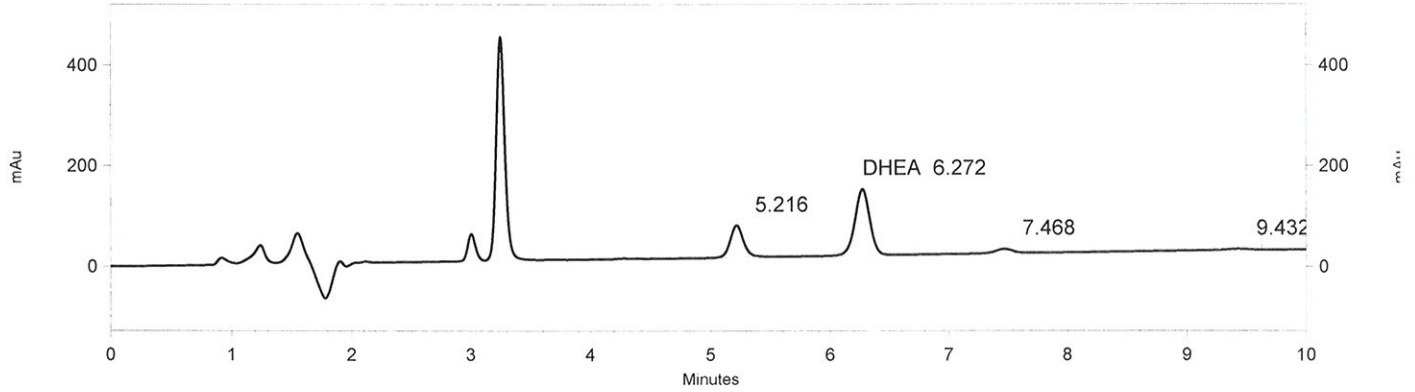
HUMCO HOLDING GROUP

Sample: DHEA Stability 60 days

Method: C:\CLASS-VP\Methods\HPLC3\Dehydroepiandrosterone (DHEA).met

Integration Method: C:\CLASS-VP\Methods\HPLC3\Dehydroepiandrosterone (DHEA).met

Vial: #4



1: 210 nm,

4 nm

Results

Name	Retention Time	Area	ESTD concentration	Resolution (USP)	Asymmetry
DHEA	6.272	1130716	1.218	4.96006	0.97522

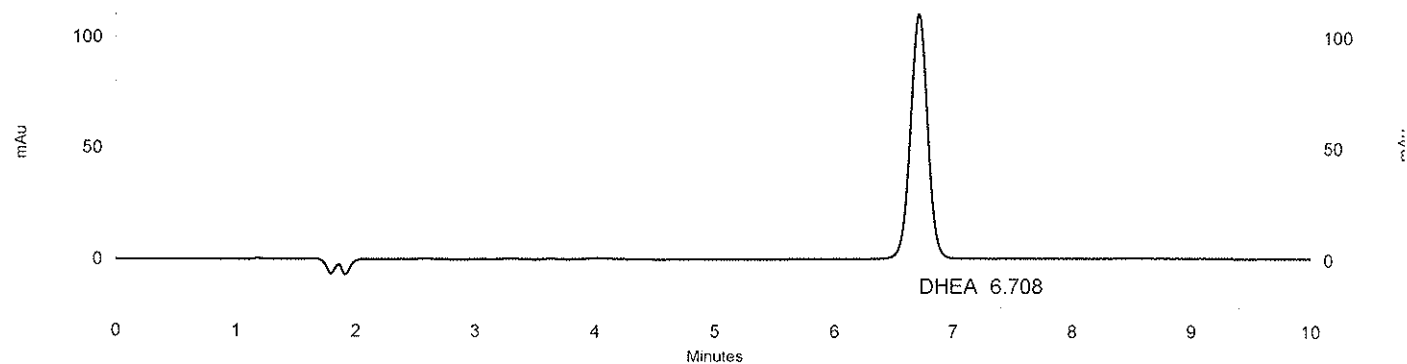
HUMCO HOLDING GROUP

Sample: DHEA Standard

Method: C:\CLASS-VP\Methods\HPLC3\Dehydroepiandrosterone (DHEA).met

Integration Method: C:\CLASS-VP\Methods\HPLC3\Dehydroepiandrosterone (DHEA).met

Vial: #2



1: 210 nm,

4 nm

Results

Name	Retention Time	Area	ESTD concentration	Resolution (USP)	Asymmetry
DHEA	6.708	1103432	0.125 CAL	0.00000	1.02948

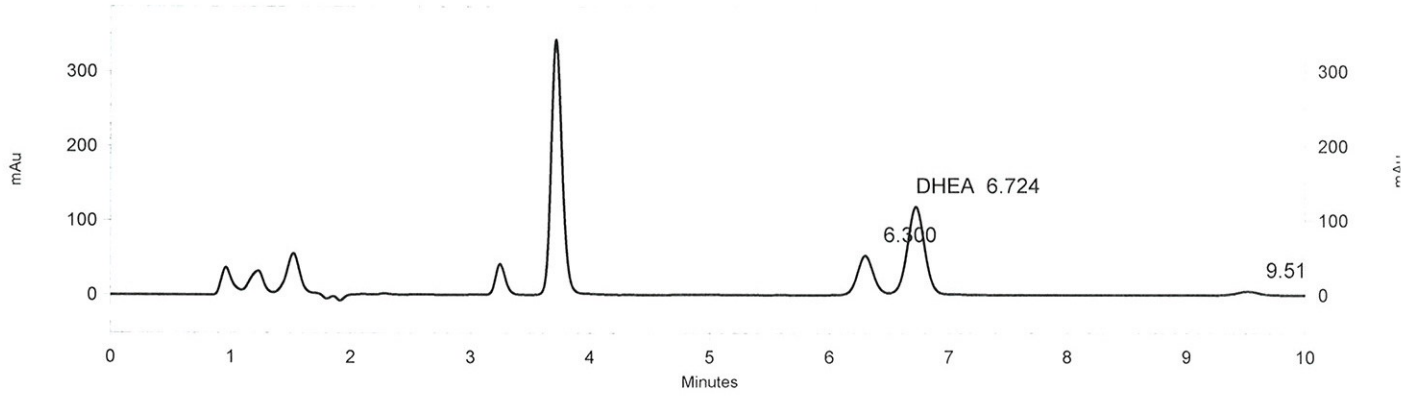
HUMCO HOLDING GROUP

Sample: DHEA Stability 90 days

Method: C:\CLASS-VP\Methods\HPLC3\Dehydroepiandrosterone (DHEA).met

Integration Method: C:\CLASS-VP\Methods\HPLC3\Dehydroepiandrosterone (DHEA).met

Vial: #4



55000

1: 210 nm,

4 nm

Results

Name	Retention Time	Area	ESTD concentration	Resolution (USP)	Asymmetry
DHEA	6.724	1184490	1.220	1.65068	1.00780