

Dexamethasone:

0.75g Dexamethasone raw drug powder from Spectrum chemical (part number DE121, Lot # VC0773) was added to 50.00g with Humco Lipo Heavy (Humco Holding Group, Texarkana, Texas) and levigated with an electronic mortar and pestle, resulting in a final concentration of 1.5% 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.

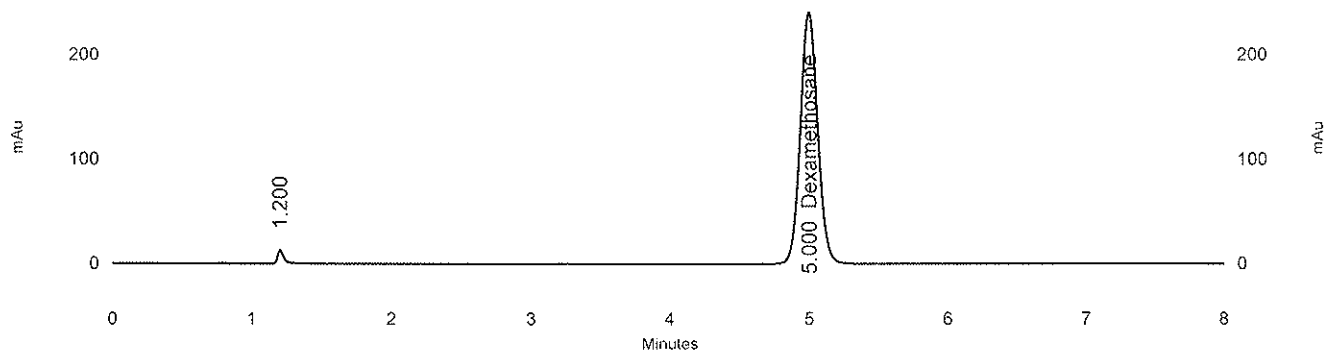
90-Day Summary:

Compounded at 1.5% w/w, stability-indicating HPLC analysis found negligible Dexamethasone loss in Humco Lipo Heavy at 90 days.

Attached are 8 chromatographs of Humco Lipo Heavy 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 QUALITY CONTROL LABORATORY

C:\CLASS-VP\Enterprise\Projects\Default\Data\April-15 Dexamthosane
Precision 101-Rep1
Sample ID: Dexamethosane Standards
C:\CLASS-VP\Sequence\2009\April\HPLC 3\April 15-09 Dexamethasone Precision
.seq
C:\CLASS-VP\Methods\HPLC3\Dexamethosane.met
Vial: 2
Sample amount: 1

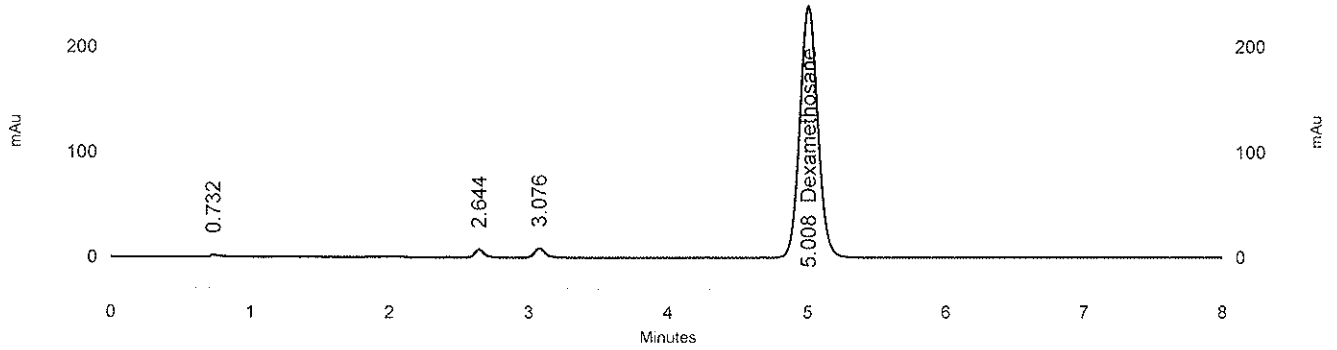


3: 254
nm, 4 nm
Results

Name	Retention Time	Area	%w/w	Asymmetry	Plates / meter (USP)	Resolution (USP)
Dexamethosane	5.000	2062739	0.10 CAL	1.05970	77018.98	24.81013

HUMCO QUALITY CONTROL LABORATORY

C:\CLASS-VP\Enterprise\Projects\Default\Data\April-15 Dexamthosane
Precision 104
Sample ID: Dexamethosane Precision 1
C:\CLASS-VP\Sequence\2009\April\HPLC 3\April 15-09 Dexamethasone Precision
.seq
C:\CLASS-VP\Methods\HPLC3\Dexamethosane.met
Vial: 5
Sample amount: 0.1855



3: 254
nm, 4 nm
Results

Name	Retention Time	Area	%w/w	Asymmetry	Plates / meter (USP)	Resolution (USP)
Dexamethosane	5.008	2112108	1.38	1.07987	72876.27	10.39373

HUMCO QUALITY CONTROL LABORATORY

C:\CLASS-VP\Enterprise\Projects\Default\Data\May-14 Dexamthosane Stability
30 days 01-Rep1

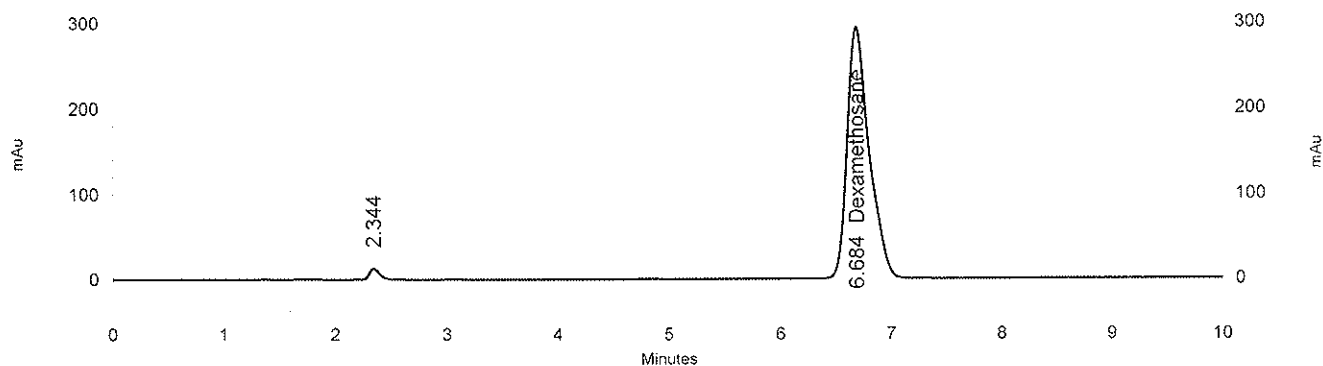
Sample ID: Dexamethosane Standards

C:\CLASS-VP\Sequence\2009\April\HPLC 3\May 14-09 Dexamethasone Stability 30
Days .seq

C:\CLASS-VP\Methods\HPLC3\Dexamethosane.met

Vial: 2

Sample amount: 1



3: 254
nm, 4 nm
Results

Name	Retention Time	Area	%w/w	Asymmetry	Plates / meter (USP)	Resolution (USP)
Dexamethosane	6.684	4016384	0.10 CAL	1.34505	56151.44	16.51814

HUMCO QUALITY CONTROL LABORATORY

C:\CLASS-VP\Enterprise\Projects\Default\Data\May-14 Dexamthosane Stability
30 days 03

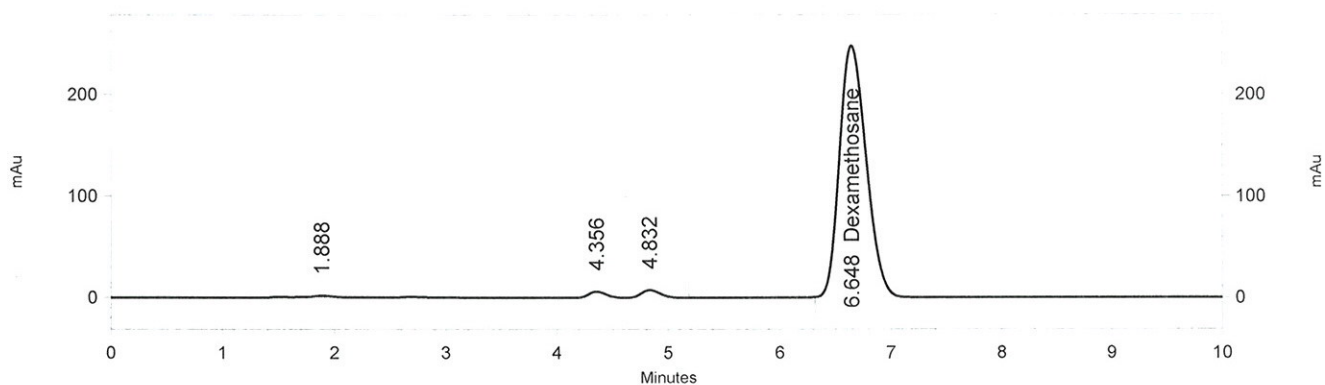
Sample ID: Dexamethosane Precision 1

C:\CLASS-VP\Sequence\2009\April\HPLC 3\May 14-09 Dexamethasone Stability 30
Days .seq

C:\CLASS-VP\Methods\HPLC3\Dexamethosane.met

Vial: 4

Sample amount: 0.3519

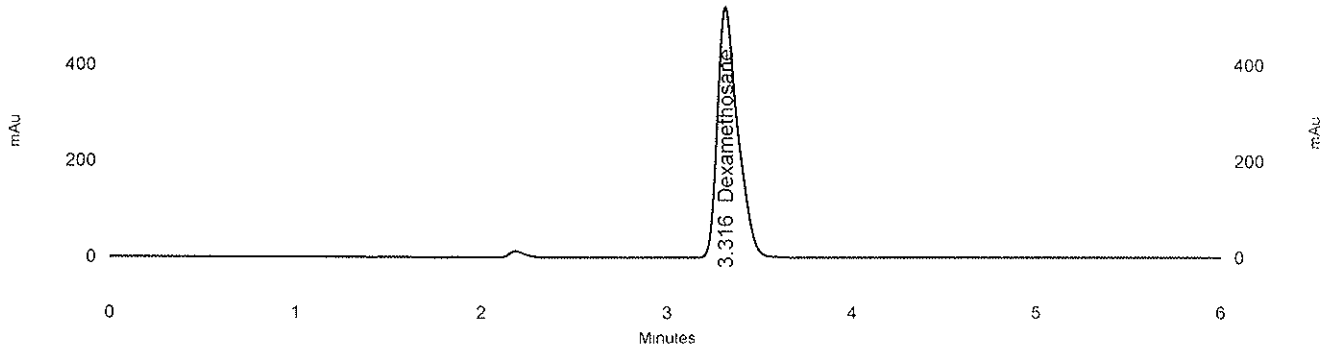


3: 254
nm, 4 nm
Results

Name	Retention Time	Area	%w/w	Asymmetry	Plates / meter (USP)	Resolution (USP)
Dexamethosane	6.648	4107162	1.45	1.17797	35127.41	4.69840

HUMCO QUALITY CONTROL LABORATORY

C:\CLASS-VP\Enterprise\Projects\Default\Data\June 15 09 Dexamethosane
Stability 60 days 01-Rep1
Sample ID: Dexamethosane Standards
C:\CLASS-VP\Sequence\2009\June\HPLC 3\June 15 09 Dexamethosane stability 60
days.seq
C:\CLASS-VP\Methods\HPLC3\Dexamethosane.met
Vial: 2
Sample amount: 1

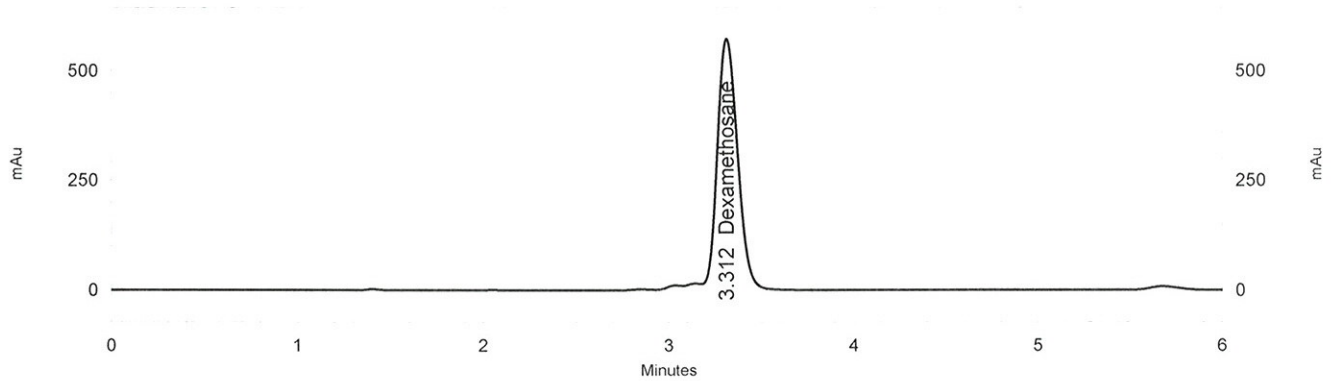


1: 254
nm, 4 nm
Results

Name	Retention Time	Area	%w/w	Asymmetry	Plates / meter (USP)	Resolution (USP)
Dexamethosane	3.316	3912008	0.10 CAL	1.39781	45692.38	0.00000

HUMCO QUALITY CONTROL LABORATORY

C:\CLASS-VP\Enterprise\Projects\Default\Data\June 15 09 Dexamthosane
Stability 60 days 03
Sample ID: Dexamethosane 60 days Stability
C:\CLASS-VP\Sequence\2009\June\HPLC 3\June 15 09 Dexamethosane stability 60
days.seq
C:\CLASS-VP\Methods\HPLC3\Dexamethosane.met
Vial: 4
Sample amount: 0.3903



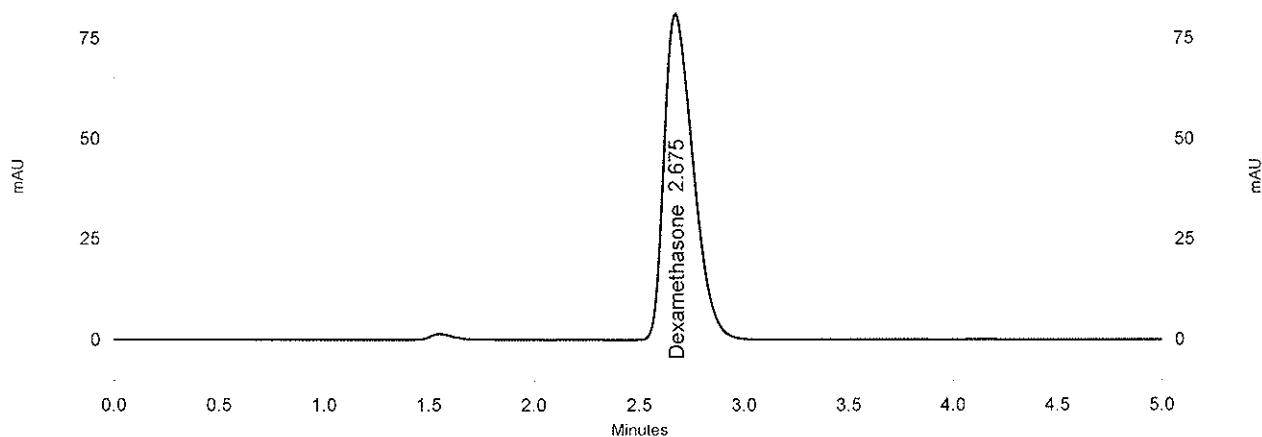
1: 254
nm, 4 nm
Results

Name	Retention Time	Area	%w/w	Asymmetry	Plates / meter (USP)	Resolution (USP)
Dexamethosane	3.312	4440234	1.46	1.16979	44387.38	0.00000

HUMCO QUALITY CONTROL LABORATORY

Sample ID: *Dexamethasone St*

Method Name: C:\CLASS-VP\Methods\HPLC4\Dexamethasone.met
 Sequence: C:\CLASS-VP\Sequence\2009\July\HPLC 4\July 15-09 Dexamethasone Stability 90 Days.seq
 Filename: C:\CLASS-VP\Data\2009\July\HPLC 4\July 15-09 Dexamethasone Stability 90 days 01-Rep1
 Acquired: 7/15/2009 1:57:07 PM
 Printed: 7/15/2009 2:51:53 PM
 Vial: 2



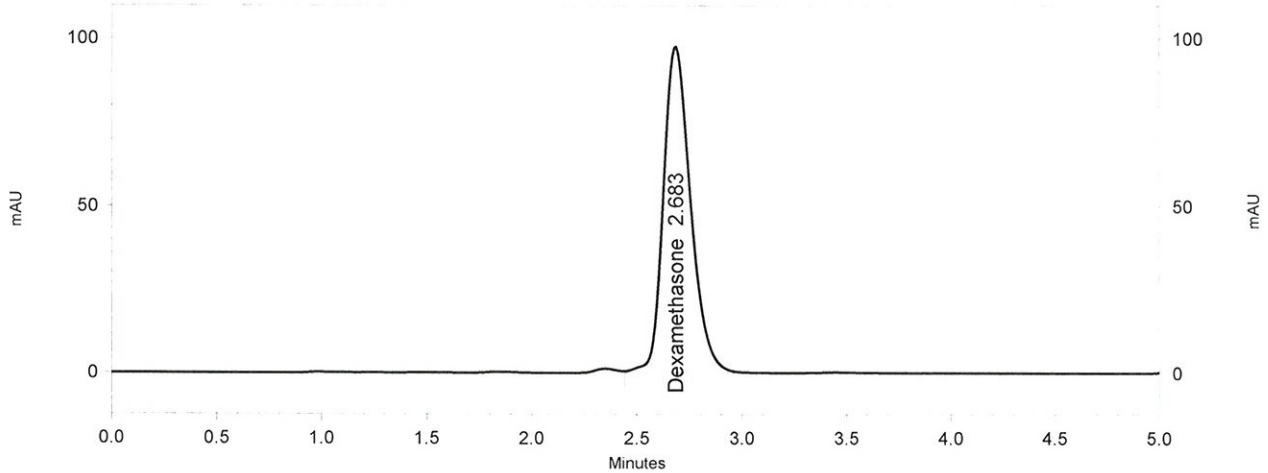
SPD-20AV
 Ch1-254nm
 Results

Name	Retention Time	Area	ESTD concentration	Resolution (USP)	Asymmetry
Dexamethasone	2.675	774650	0.1001 CAL	0.00000	1.40230

HUMCO QUALITY CONTROL LABORATORY

Sample ID: *Dexamethasone 1.5% Stability 90 days*

Method Name: C:\CLASS-VP\Methods\HPLC4\Dexamethasone.met
 Sequence: C:\CLASS-VP\Sequence\2009\July\HPLC 4\July 15-09 Dexamethasone Stability 90 Days.seq
 Filename: C:\CLASS-VP\Data\2009\July\HPLC 4\July 15-09 Dexamethasone Stability 90 days 03
 Acquired: 7/15/2009 2:30:53 PM
 Printed: 7/15/2009 2:51:59 PM
 Vial: 4



SPD-20AV
 Ch1-254nm
 Results

Name	Retention Time	Area	ESTD concentration	Resolution (USP)	Asymmetry
Dexamethasone	2.683	882667	1.5065	0.00000	1.23904