

## Diphenhydramine Hydrochloride:

5.00g Diphenhydramine Hydrochloride raw drug powder from Spectrum chemical (part number DI160, Lot # WN0253) was added to 50.00g Humco Salt-Stable LO (Humco Holding Group, Texarkana, Texas) and levigated with an electronic mortar and pestle, resulting in a final concentration of 10.0% 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 10.0% w/w, stability-indicating HPLC analysis found negligible Diphenhydramine Hydrochloride loss in Humco Salt-Stable LO at 90 days.

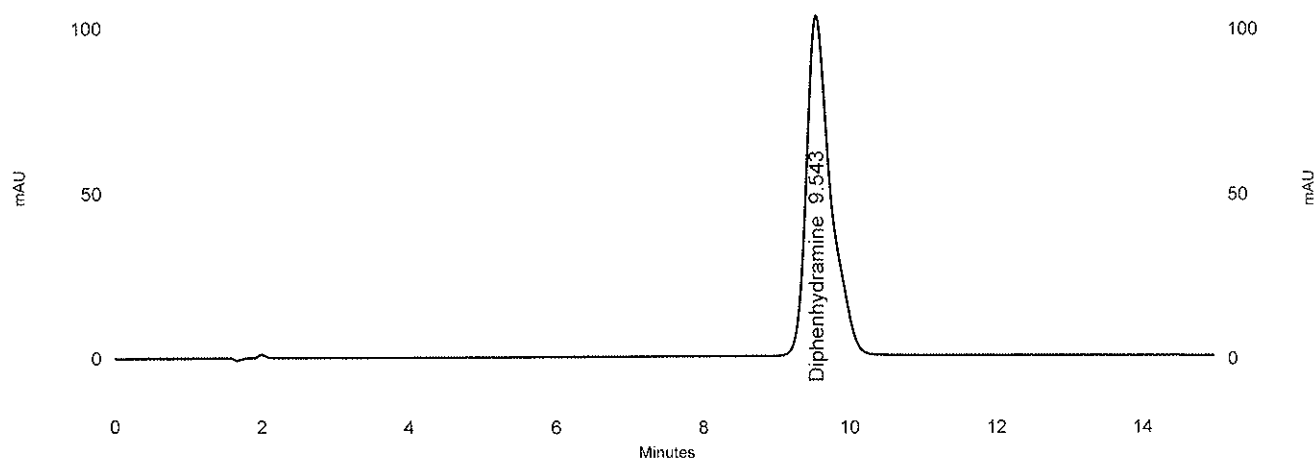
Attached are 8 chromatographs of Humco Salt-Stable LO showing in order: Initial Standard, Initial Sample, 30-Day Standard, 30-Day Sample, 60-Day Standard, 60-Day Sample, 90-Day Standard, and 90-Day Sample.

# HUMCO QUALITY CONTROL LABORATORY

Sample ID:

Standard

Method Name: C:\CLASS-VP\Enterprise\Projects\Default\Method\Diphenhydramine HCl method.met  
Sequence: C:\CLASS-VP\Sequence\2010\August\HPLC 4\August 26-10 Diphenhydramine HCl Validation.seq  
Filename: C:\CLASS-VP\Data\2010\August\HPLC 4\August 26-10 Diphenhydramine validation 02-Rep1  
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Printed: 8/26/2010 5:03:03 PM  
Vial: 3



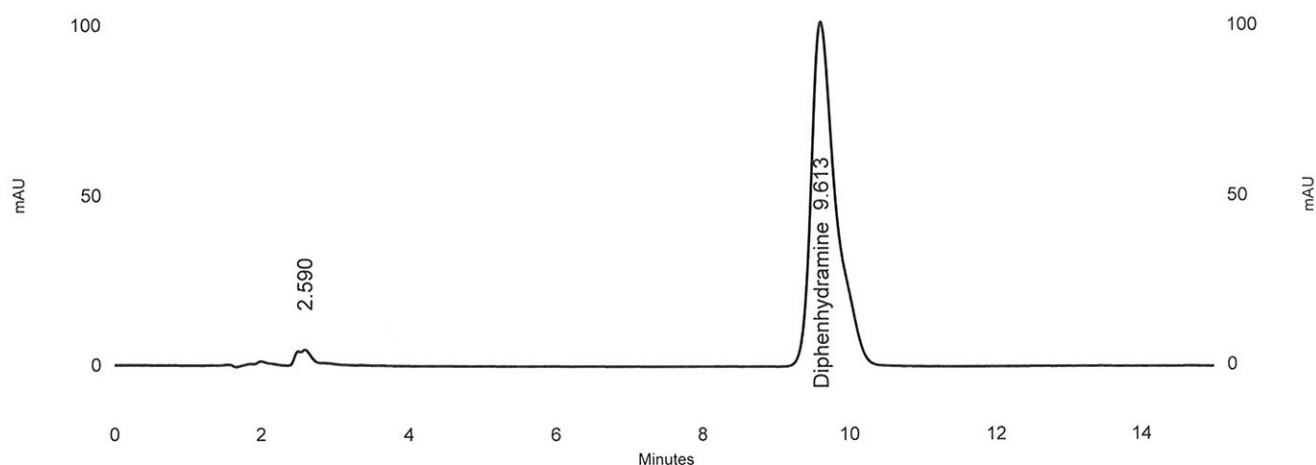
SPD-20AV  
Ch1-210nm  
Results

Name	Retention Time	Height	Area	ESTD concentration	Asymmetry
Diphenhydr amine	9.543	103129	2394858	0.501 CAL	1.42627

# HUMCO QUALITY CONTROL LABORATORY

Sample ID:  
Diphenhydramine HCl -1

Method Name: C:\CLASS-VP\Enterprise\Projects\Default\Method\Diphenhydramine HCl method.met  
 Sequence: C:\CLASS-VP\Sequence\2010\August\HPLC 4\August 26-10 Diphenhydramine HCl Validation.seq  
 Filename: C:\CLASS-VP\Data\2010\August\HPLC 4\August 26-10 Diphenhydramine validation 04  
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 Printed: 8/26/2010 5:03:35 PM  
 Vial: 5



SPD-20AV  
Ch1-210nm  
Results

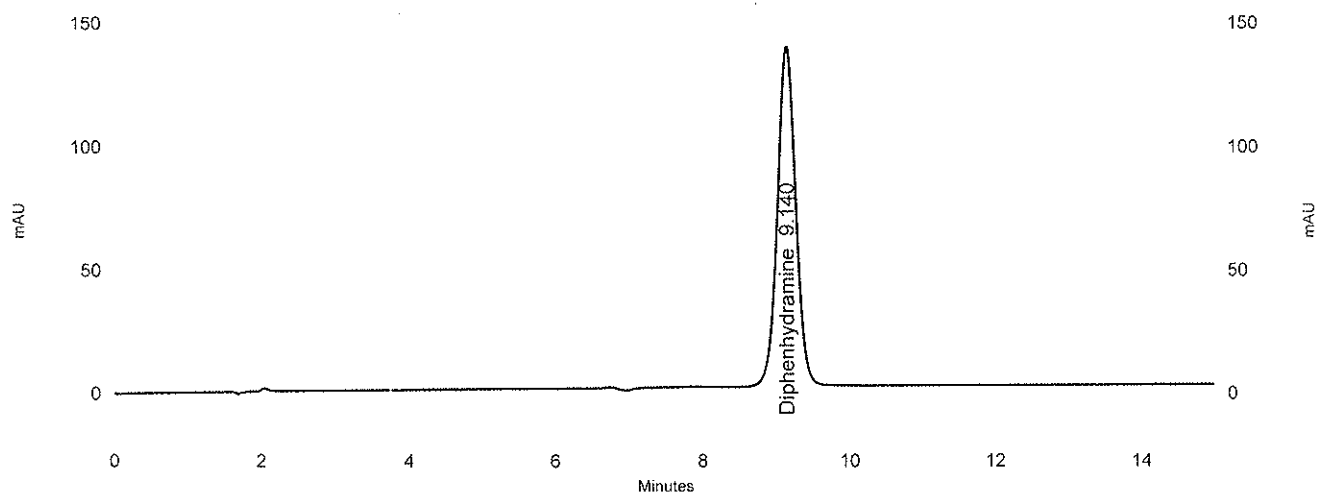
Name	Retention Time	Height	Area	ESTD concentration	Asymmetry
	2.590	4566	76175	0.000	1.73818
Diphenhydramine	9.613	101502	2381658	9.929	1.47071

# HUMCO QUALITY CONTROL LABORATORY

Sample ID:

Standard

Method Name: C:\CLASS-VP\Enterprise\Projects\Default\Method\Diphenhydramine HCl method.met  
 Sequence: C:\CLASS-VP\Sequence\2010\September\HPLC 4\Diphenhydramine 10% 30days stability 9-29-10.seq  
 Filename: C:\CLASS-VP\Data\2010\August\HPLC 4\Sept 29-10 Diphenhydramine 30days 02-Rep1  
 Acquired: 9/29/2010 2:05:11 PM  
 Printed: 9/29/2010 4:36:43 PM  
 Vial: 2



SPD-20AV  
 Ch1-210nm  
 Results

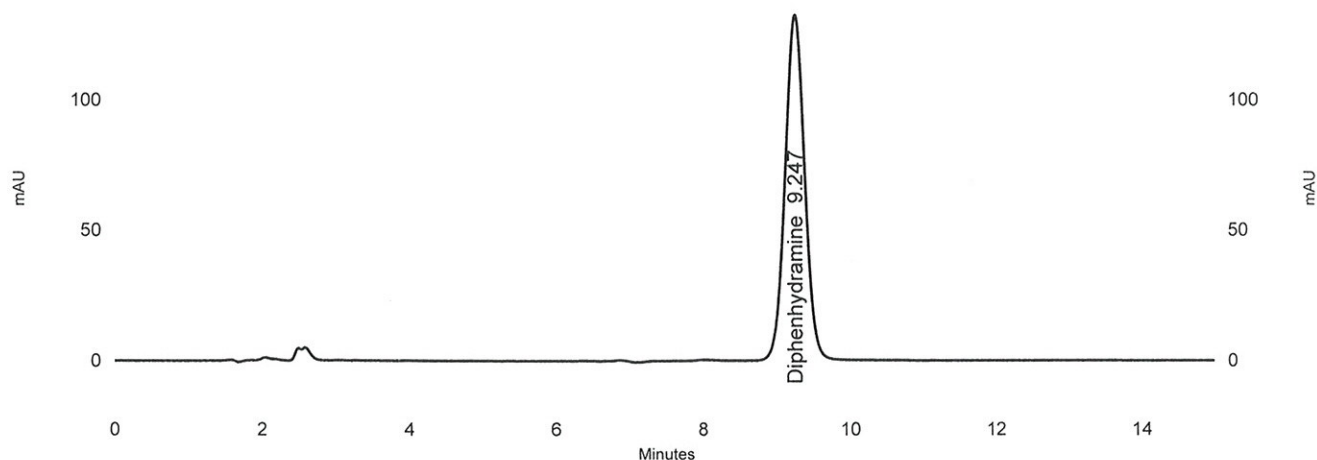
Name	Retention Time	Height	Area	ESTD concentration	Asymmetry
Diphenhydr amine	9.140	137482	2381461	0.501 CAL	1.00912

# HUMCO QUALITY CONTROL LABORATORY

Sample ID:  
stability

Sample 30days

Method Name: C:\CLASS-VP\Enterprise\Projects\Default\Method\Diphenhydramine HCl method.met  
Sequence: C:\CLASS-VP\Sequence\2010\September\HPLC 4\Diphenhydramine 10% 30days stability 9-29-10.seq  
Filename: C:\CLASS-VP\Data\2010\August\HPLC 4\Sept 29-10 Diphenhydramine 30days 04  
Acquired: 9/29/2010 3:38:58 PM  
Printed: 9/29/2010 4:36:51 PM  
Vial: 4



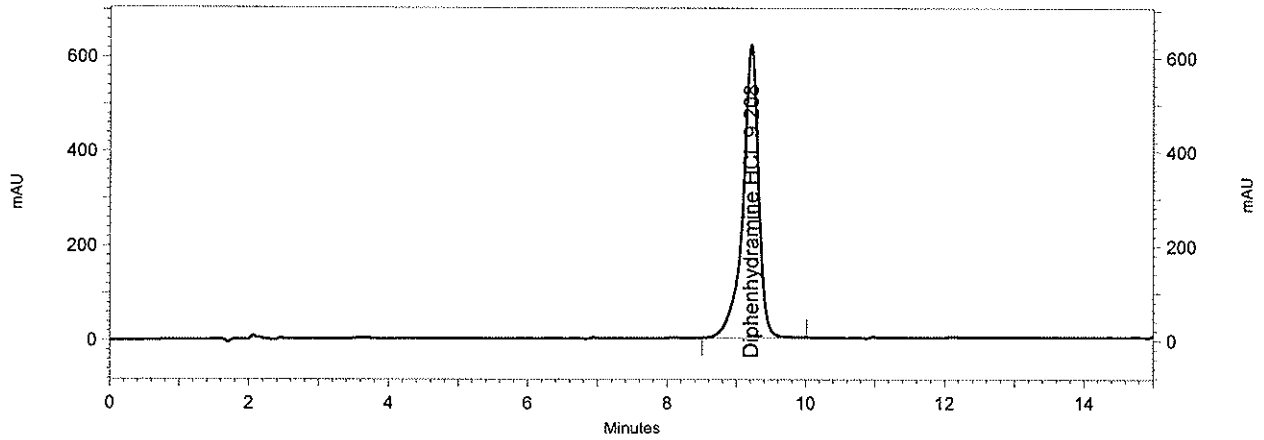
SPD-20AV  
Ch1-210nm  
Results

Name	Retention Time	Height	Area	ESTD concentration	Asymmetry
Diphenhydramine	9.247	132498	2434613	10.090	1.01582

# HUMCO QUALITY CONTROL LABORATORY

Sample ID: Standard

Method Name: C:\CLASS-VP\Methods\Methods\HPLC4\Diphenhydramine HCl Met.met  
Sequence: C:\CLASS-VP\Sequence\Sequence\2010\August\HPLC 4\Diphenhydramine stability 60days 11-3-10.seq  
Filename: C:\CLASS-VP\Sequence\Sequence\2010\August\HPLC 4\Nov 3-10 Diphenhydramine validation 01-Rep1  
Acquired: 11/3/2010 4:19:23 PM  
Printed: 11/4/2010 8:13:37 AM  
Vial: 2



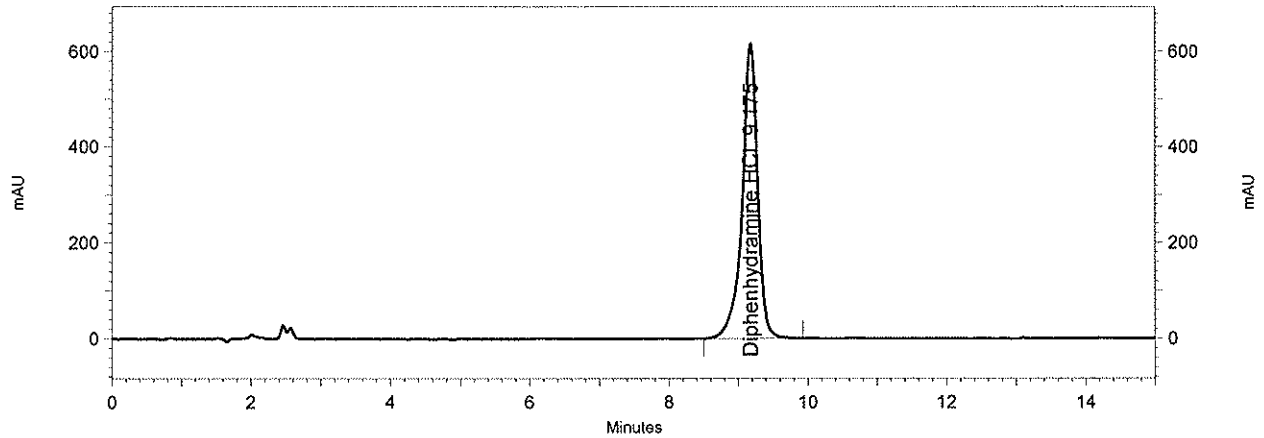
SPD-20AV  
Ch1-210nm  
Results

Name	Retention Time	Height	Area	ESTD concentration	Asymmetry
Diphenhydramine HCl	9.208	620233	9720321	0.50 CAL	0.84

# HUMCO QUALITY CONTROL LABORATORY

Sample ID: Diphenhydramine HCl

Method Name: C:\CLASS-VP\Methods\Methods\HPLC4\Diphenhydramine HCl Met.met  
Sequence: C:\CLASS-VP\Sequence\Sequence\2010\August\HPLC 4\Diphenhydramine stability 60days 11-3-10.seq  
Filename: C:\CLASS-VP\Sequence\Sequence\2010\August\HPLC 4\Nov 3-10 Diphenhydramine validation 03  
Acquired: 11/3/2010 5:53:09 PM  
Printed: 11/4/2010 8:13:53 AM  
Vial: 4



SPD-20AV  
Ch1-210nm

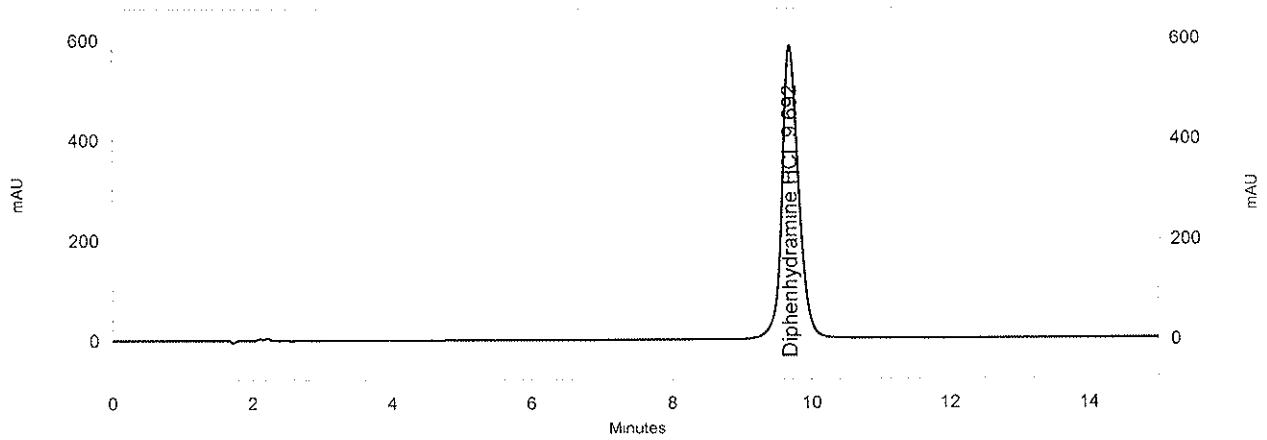
Results

Name	Retention Time	Height	Area	ESTD concentration	Asymmetry
Diphenhydramine HCl	9.175	616068	9570603	9.87	0.86

# HUMCO QUALITY CONTROL LABORATORY

Sample ID: Standard

Method Name: C:\CLASS-VP\Methods\Methods\HPLC4\Diphenhydramine HCl Met.met  
Sequence: C:\CLASS-VP\Sequence\Sequence\2010\December\HPLC 4\Dec 6-10 Diphenhydramine 90days stability.seq  
Filename: C:\CLASS-VP\Sequence\Sequence\2010\August\HPLC 4\Dec 6-10 Diphenhydramine 01-Rep1  
Acquired: 12/6/2010 4:55:15 PM  
Printed: 12/7/2010 9:32:24 AM  
Vial: 1



SPD-20AV  
Ch1-210nm  
Results

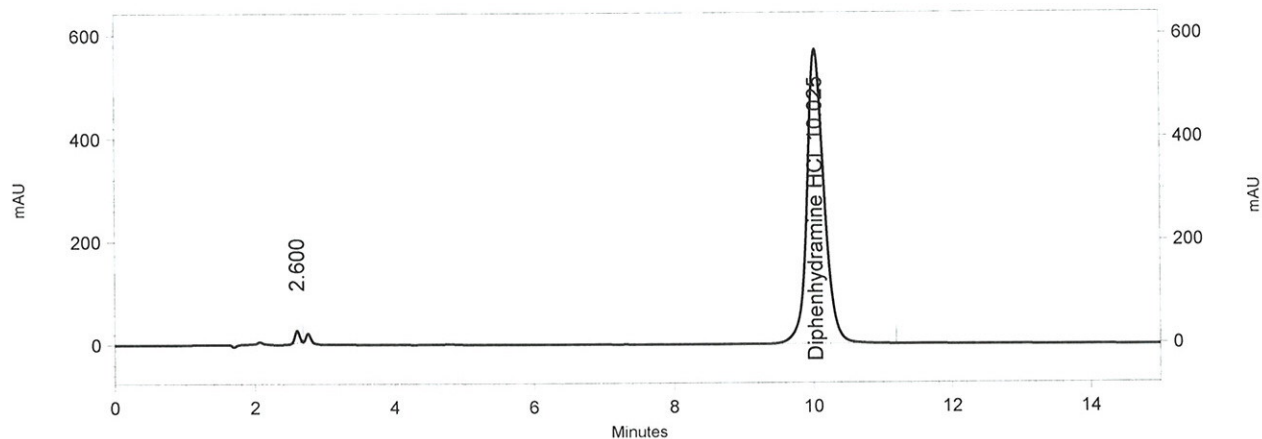
Name	Retention Time	Height	Area	ESTD concentration	Asymmetry
Diphenhydramine HCl	9.692	584257	9669088	0.50 CAL	1.09



# HUMCO QUALITY CONTROL LABORATORY

Sample ID: *Diphenhydramine HCl*

Method Name: C:\CLASS-VP\Methods\Methods\HPLC4\Diphenhydramine HCl Met.met  
Sequence: C:\CLASS-VP\Sequence\Sequence\2010\December\HPLC 4\Dec 6-10 Diphenhydramine 90days stability.seq  
Filename: C:\CLASS-VP\Sequence\Sequence\2010\August\HPLC 4\Dec 6-10 Diphenhydramine 03  
Acquired: 12/6/2010 6:29:03 PM  
Printed: 12/7/2010 9:35:11 AM  
Vial: 3



SPD-20AV  
Ch1-210nm

Results

Name	Retention Time	Height	Area	ESTD concentration	Asymmetry
Diphenhydramine HCl	10.025	570638	9747644	10.01	1.10