

Haloperidol:

1.00g Haloperidol raw drug powder from Spectrum chemical (part number HA103, Lot # VJ0877) was added to 50.00g Humco PLO 20 Flowable (Humco Holding Group, Texarkana, Texas) and levigated with an electronic mortar and pestle, resulting in a final concentration of 2.0% w/w. This gel was then stored at room temperature in the same 50/70 mL Unguator container.

Similar steps were used in preparing samples in Humco LipoBase Heavy (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 2.0% w/w, stability-indicating HPLC analysis found negligible Haloperidol loss in Humco PLO 20 Flowable at 90 days.

Compounded at 0.1% w/w, stability-indicating HPLC analysis found less than 1% Haloperidol loss in Humco LipoBase Heavy at 90 days.

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.

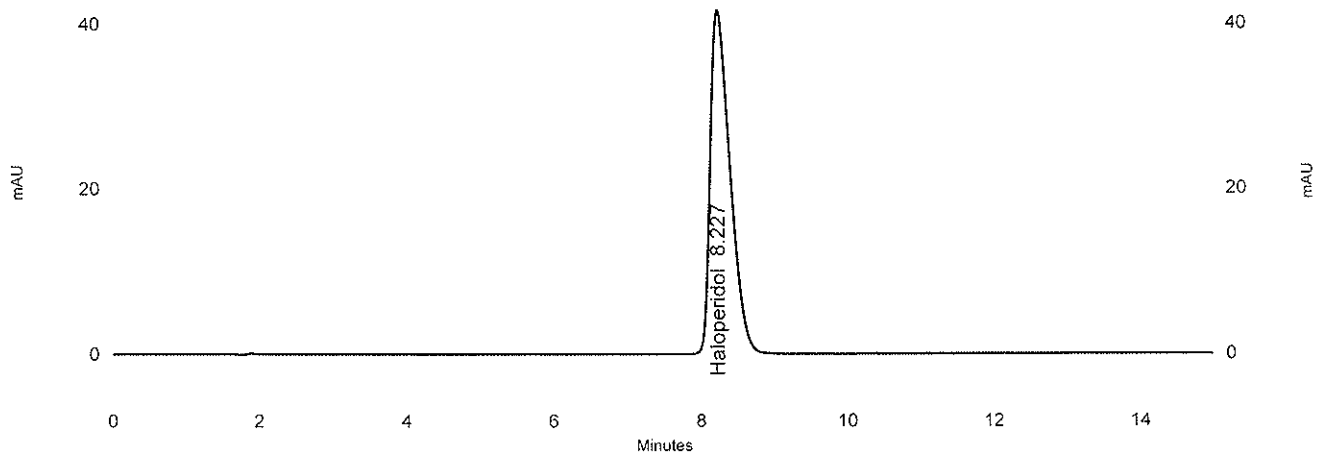
Attached are 8 chromatographs of Humco LipoBase Heavy showing in order: Initial Standard, Initial Sample, 30-Day Standard, 30-Day Sample, 60-Day Standard, 60-Day Sample, 90-Day Standard, and 90-Day Sample.

HUMCO QUALITY CONTROL LABORATORY

Sample ID:

Standard

Method Name: C:\CLASS-VP\Methods\HPLC4\Haloperidol stability.met
Sequence: C:\CLASS-VP\Sequence\2010\August\HPLC 4\August 18-10 Haloperidol stability Zero day.seq
Filename: C:\CLASS-VP\Data\2010\August\HPLC 4\August 18-10 Haloperidol stability 01-Rep1
Acquired: 8/18/2010 1:51:02 PM
Printed: 8/18/2010 5:07:54 PM
Vial: 2



SPD-20AV
Ch1-245nm
Results

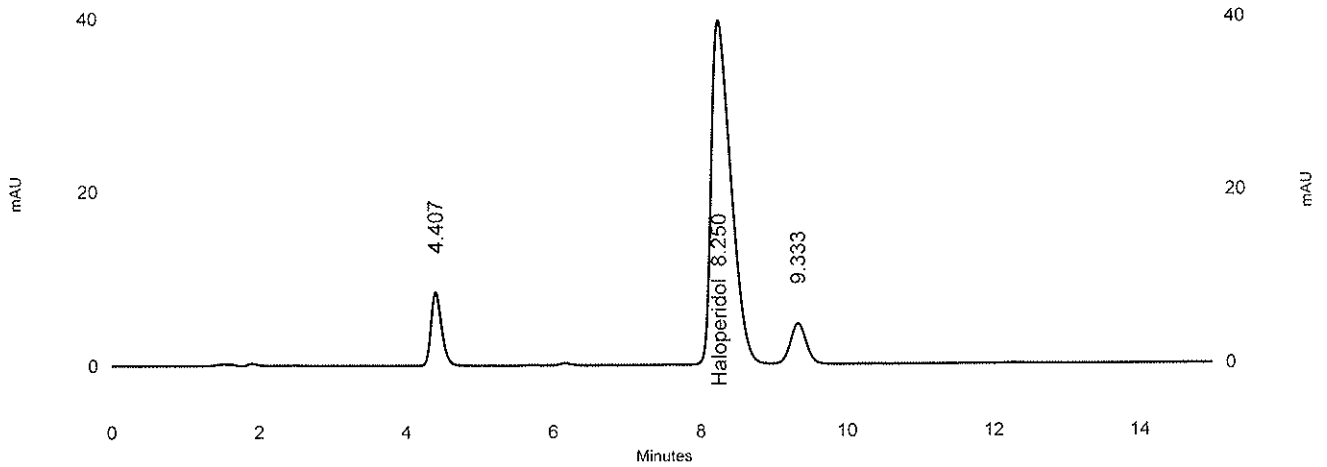
Name	Retention Time	Height	Area	ESTD concentration	Asymmetry
Haloperido 1	8.227	41652	789843	0.101 CAL	1.58552

HUMCO QUALITY CONTROL LABORATORY

Sample ID:
sample

Haloperidol

Method Name: C:\CLASS-VP\Methods\HPLC4\Haloperidol stability.met
Sequence: C:\CLASS-VP\Sequence\2010\August\HPLC 4\August 18-10 Haloperidol stability Zero day.seq
Filename: C:\CLASS-VP\Data\2010\August\HPLC 4\August 18-10 Haloperidol stability 03
Acquired: 8/18/2010 3:24:51 PM
Printed: 8/18/2010 5:08:01 PM
Vial: 4



SPD-20AV
Ch1-245nm
Results

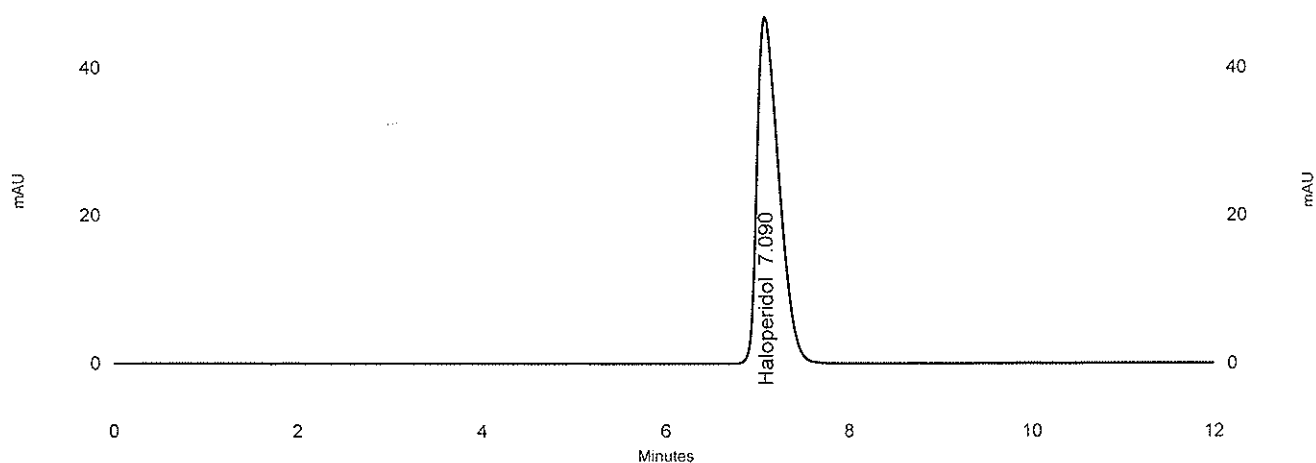
Name	Retention Time	Height	Area	ESTD concentration	Asymmetry
	4.407	8443	83626	0.000	1.24484
Haloperidol	8.250	39657	736222	1.861	1.56971
	9.333	4640	69010	0.000	1.05109

HUMCO QUALITY CONTROL LABORATORY

Sample ID:

Standard

Method Name: C:\CLASS-VP\Methods\HPLC4\Haloperidol stability.met
Sequence: C:\CLASS-VP\Sequence\2010\September\HPLC 4\2% haloperidol 30days stability 9-20-10.seq
Filename: C:\CLASS-VP\Data\2010\September\HPLC 4\Sept 20-10 Haloperidol 001-Rep1
Acquired: 9/20/2010 9:56:33 AM
Printed: 9/20/2010 3:32:08 PM
Vial: 2



SPD-20AV
Ch1-245nm
Results

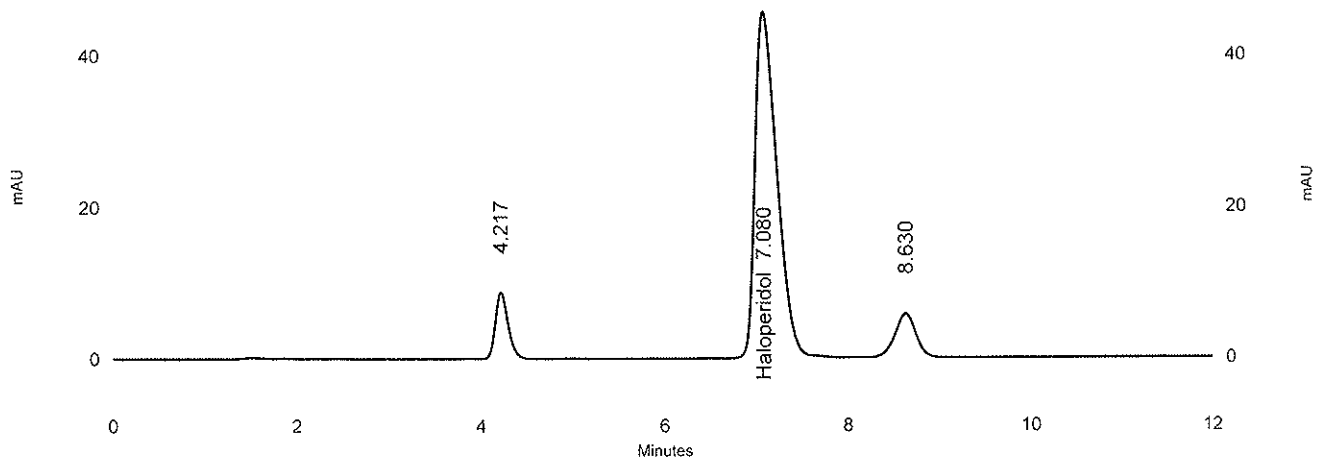
Name	Retention Time	Height	Area	ESTD concentration	Asymmetry
Haloperido 1	7.090	46785	779885	0.101 CAL	1.50907

HUMCO QUALITY CONTROL LABORATORY

Sample ID:
sample

30 days stability

Method Name: C:\CLASS-VP\Methods\HPLC4\Haloperidol stability.met
 Sequence: C:\CLASS-VP\Sequence\2010\September\HPLC 4\2% haloperidol 30days stability 9-20-10.seq
 Filename: C:\CLASS-VP\Data\2010\September\HPLC 4\Sept 20-10 Haloperidol 003
 Acquired: 9/20/2010 11:12:20 AM
 Printed: 9/20/2010 3:32:29 PM
 Vial: 4



SPD-20AV
Ch1-245nm
Results

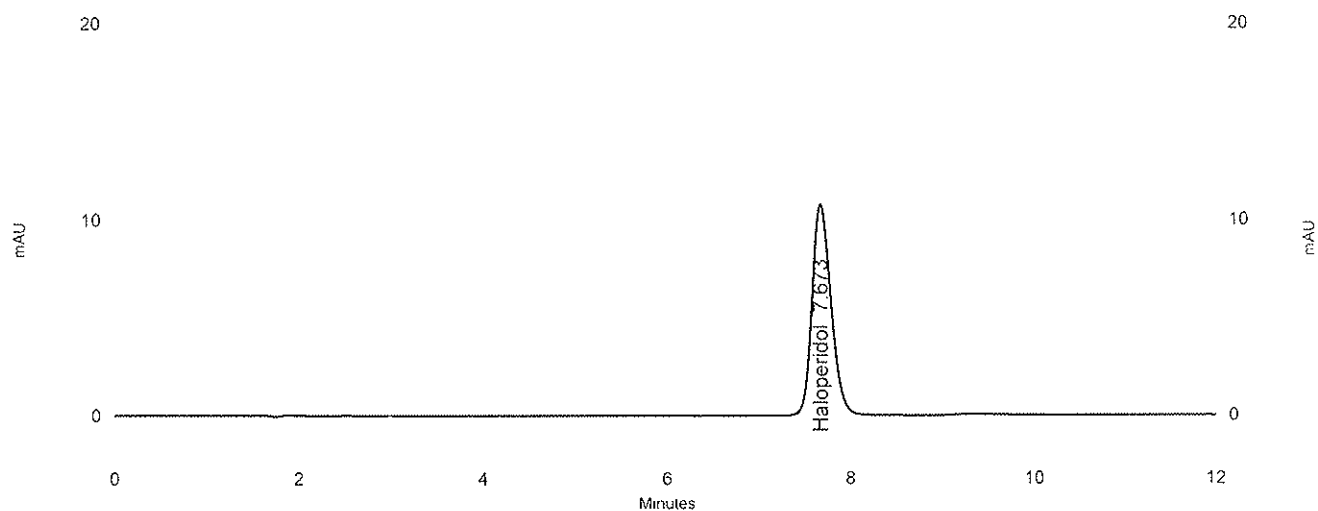
Name	Retention Time	Height	Area	ESTD concentration	Asymmetry
	4.217	8740	86608	0.000	1.26038
Haloperidol	7.080	45683	758173	1.948	1.51312
1	8.630	5785	91628	0.000	0.97352

HUMCO QUALITY CONTROL LABORATORY

Sample ID:

Standard

Method Name: C:\CLASS-VP\Methods\Methods\HPLC4\Haloperidol stability.met
Sequence: C:\CLASS-VP\Sequence\Sequence\2010\October\HPLC 4\Haloperidol 60days 2%stability studie 10-20-10
.seq
Filename: C:\CLASS-VP\Methods\Methods\HPLC4\Oct 20-10 Haloperidol 2% 01-Rep1
Acquired: 10/20/2010 4:04:23 PM
Printed: 10/21/2010 9:09:41 AM
Vial: 2



SPD-20AV
Ch1-245nm

Results

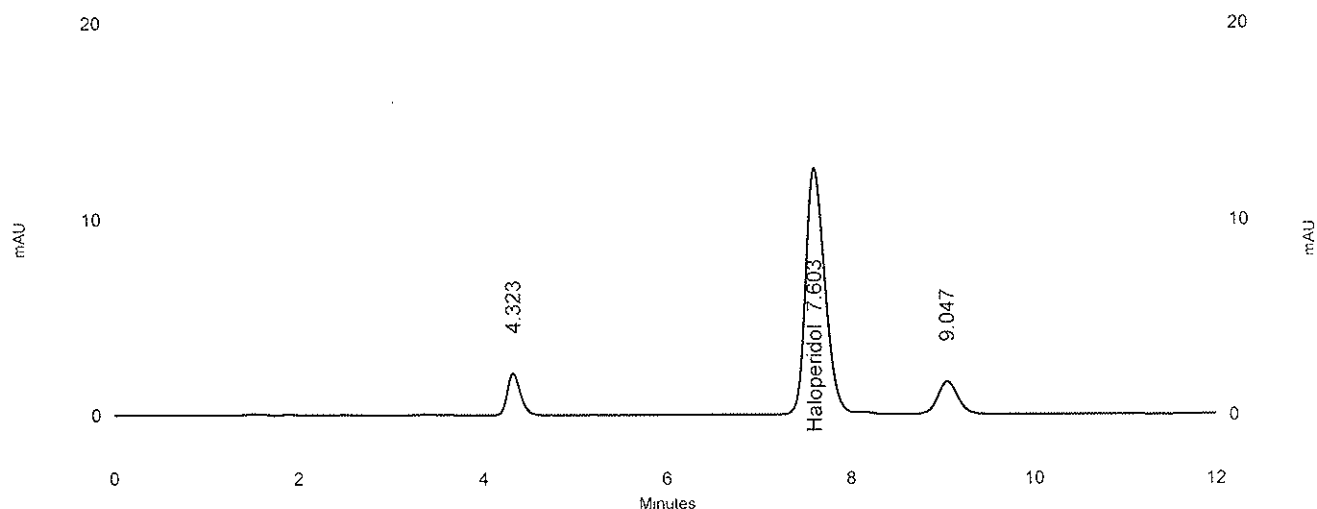
Name	Retention Time	Height	Area	ESTD concentration	Asymmetry
Haloperido l	7.673	10755	154629	0.020 CAL	1.21047

HUMCO QUALITY CONTROL LABORATORY

Sample ID:
days stability sample

Haloperidol 60

Method Name: C:\CLASS-VP\Methods\Methods\HPLC4\Haloperidol stability.met
 Sequence: C:\CLASS-VP\Sequence\Sequence\2010\October\HPLC 4\Haloperidol 60days 2%stability studie 10-20-10
 .seq
 Filename: C:\CLASS-VP\Methods\Methods\HPLC4\Oct 20-10 Haloperidol 2% 03
 Acquired: 10/20/2010 5:20:09 PM
 Printed: 10/21/2010 9:10:11 AM
 Vial: 4



SPD-20AV
Ch1-245nm
Results

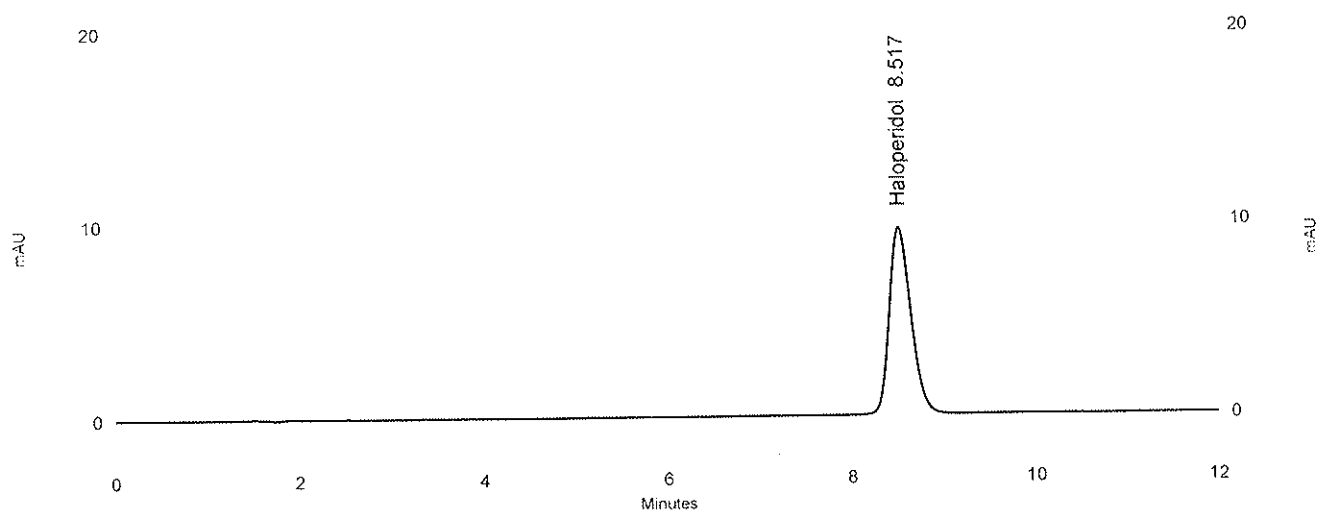
Name	Retention Time	Height	Area	ESTD concentration	Asymmetry
	4.323	2135	20845	0.000	1.24488
Haloperidol	7.603	12533	180309	2.010	1.21328
	9.047	1639	24458	0.000	1.10881

HUMCO QUALITY CONTROL LABORATORY

Sample ID:

Standard

Method Name: C:\CLASS-VP\Methods\Methods\HPLC4\Haloperidol stability.met
 Sequence: C:\CLASS-VP\Sequence\Sequence\2010\November\HPLC 4\Haloperidol 90days 2%stability studie
 11-30-10 .seq
 Filename: C:\CLASS-VP\Methods\Methods\HPLC4\Nov 30-10 Haloperidol 2% 101-Rep1
 Acquired: 11/30/2010 5:26:12 PM
 Printed: 12/1/2010 10:04:57 AM
 Vial: 5



SFD-20AV
 Ch1-245nm

Results

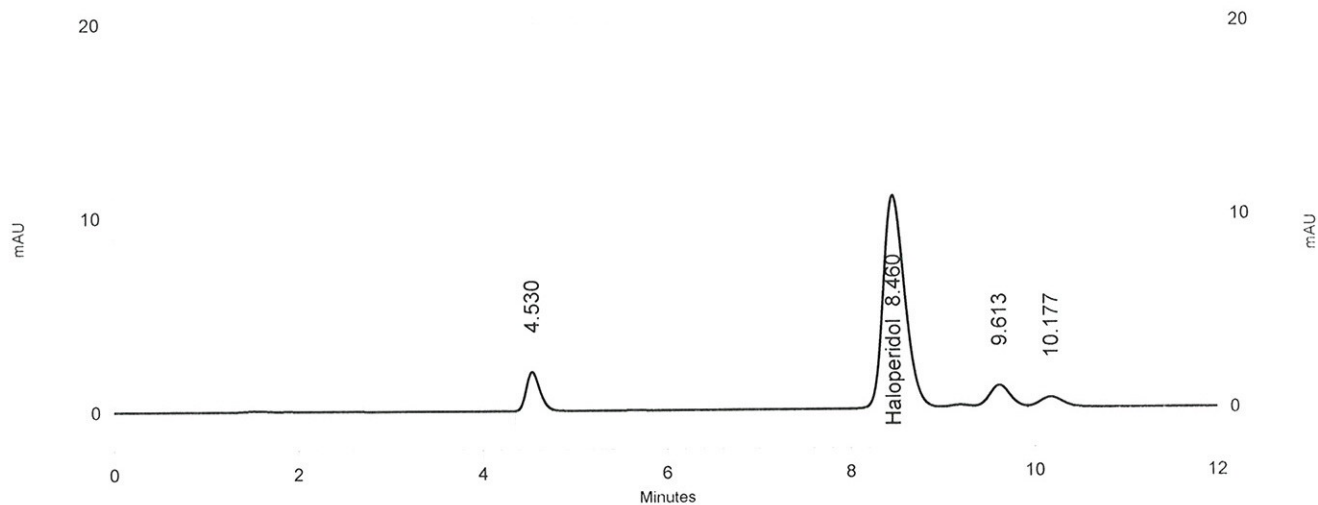
Name	Retention Time	Height	Area	ESTD concentration	Asymmetry
Haloperido 1	8.517	9626	156659	0.020 CAL	1.22805

HUMCO QUALITY CONTROL LABORATORY

Sample ID:
days stability sample

Haloperidol 60

Method Name: C:\CLASS-VP\Methods\Methods\HPLC4\Haloperidol stability.met
 Sequence: C:\CLASS-VP\Sequence\Sequence\2010\November\HPLC 4\Haloperidol 90days 2%stability studie
 11-30-10 .seq
 Filename: C:\CLASS-VP\Methods\Methods\HPLC4\Nov 30-10 Haloperidol 2% 103
 Acquired: 11/30/2010 6:41:48 PM
 Printed: 12/1/2010 10:05:28 AM
 Vial: 7



SPD-20AV
Ch1-245nm
Results

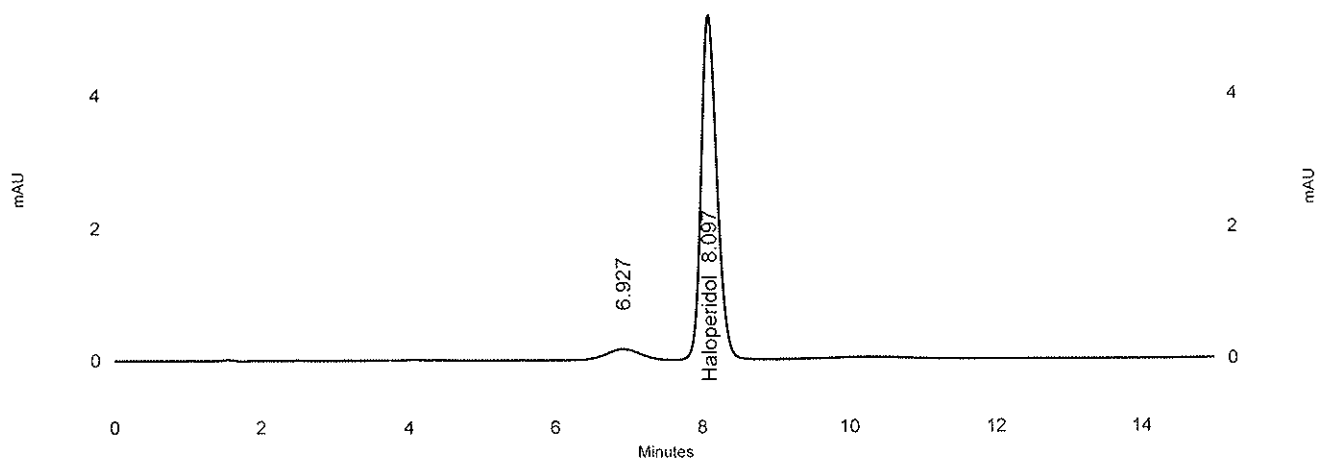
Name	Retention Time	Height	Area	ESTD concentration	Asymmetry
Haloperido 1	8.460	10971	178216	1.970	1.23256

HUMCO QUALITY CONTROL LABORATORY

Sample ID:

Standard

Method Name: C:\CLASS-VP\Methods\HPLC4\Haloperidol stability.met
 Sequence: C:\CLASS-VP\Sequence\2010\August\HPLC 4\August 19-10-2 Haloperidol stability Zero day.seq
 Filename: C:\CLASS-VP\Data\2010\August\HPLC 4\August 19-10-2 Haloperidol lipo stability 02-Rep1
 Acquired: 8/19/2010 6:11:29 PM
 Printed: 8/20/2010 8:06:43 AM
 Vial: 3



SPD-20AV
 Ch1-245nm
 Results

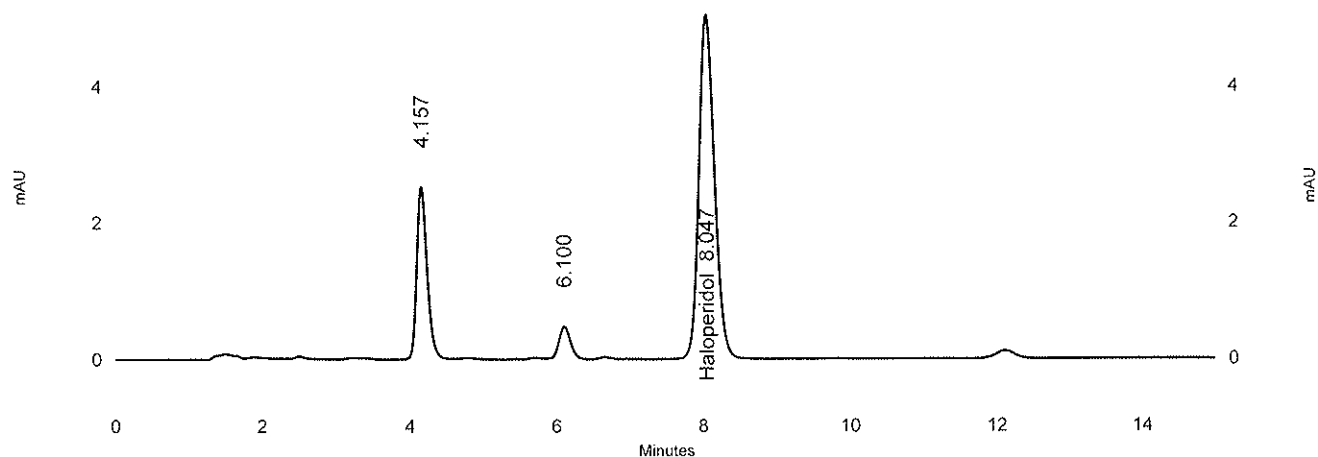
Name	Retention Time	Height	Area	ESTD concentration	Asymmetry
	6.927	162	5135	0.000	1.03371
Haloperidol 1	8.097	5191	77134	0.010 CAL	1.12309

HUMCO QUALITY CONTROL LABORATORY

Sample ID:
sample

Haloperidol

Method Name: C:\CLASS-VP\Methods\HPLC4\Haloperidol stability.met
 Sequence: C:\CLASS-VP\Sequence\2010\August\HPLC 4\August 19-10-2 Haloperidol stability Zero day.seq
 Filename: C:\CLASS-VP\Data\2010\August\HPLC 4\August 19-10-2 Haloperidol lipo stability 04
 Acquired: 8/19/2010 7:45:15 PM
 Printed: 8/20/2010 8:07:31 AM
 Via: 5



SPD-20AV
Ch1-245nm
Results

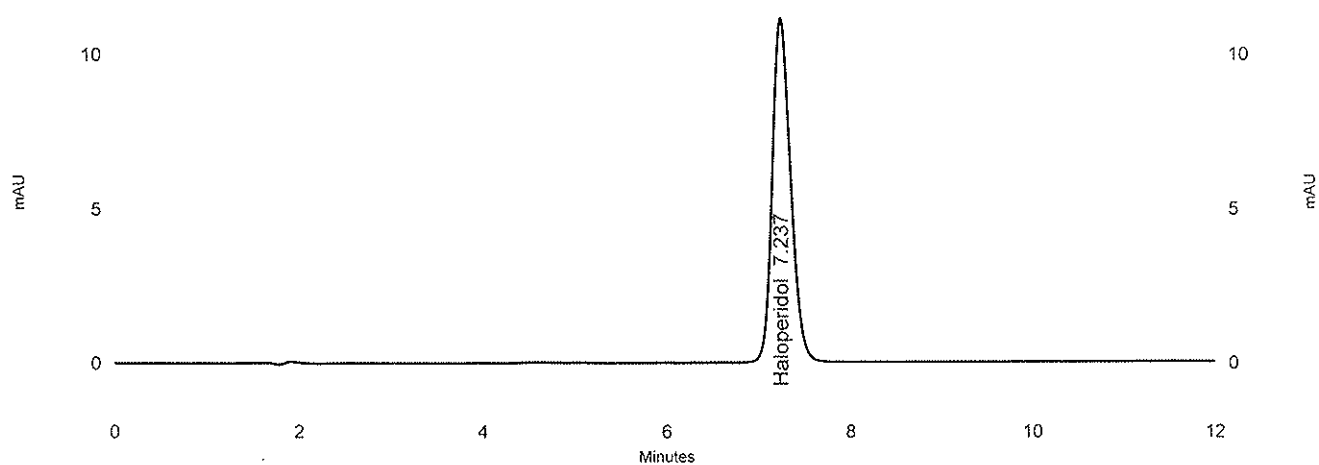
Name	Retention Time	Height	Area	ESTD concentration	Asymmetry
	4.157	2525	24791	0.000	1.25301
	6.100	478	5285	0.000	1.14399
Haloperido 1	8.047	5046	74451	0.095	1.12020

HUMCO QUALITY CONTROL LABORATORY

Sample ID:

Standard

Method Name: C:\CLASS-VP\Methods\HPLC4\Haloperidol stability.met
Sequence: C:\CLASS-VP\Sequence\2010\September\HPLC 4\Sept 20-10 0.1%Haloperidol stability 30days.seq
Filename: C:\CLASS-VP\Data\2010\August\HPLC 4\Sept 20-10 0-Rep1.1% Haloperidol 30days stability 01
Acquired: 9/17/2010 8:44:38 AM
Printed: 9/17/2010 10:47:33 AM
Vial: 2



SPD-20AV
Ch1-245nm
Results

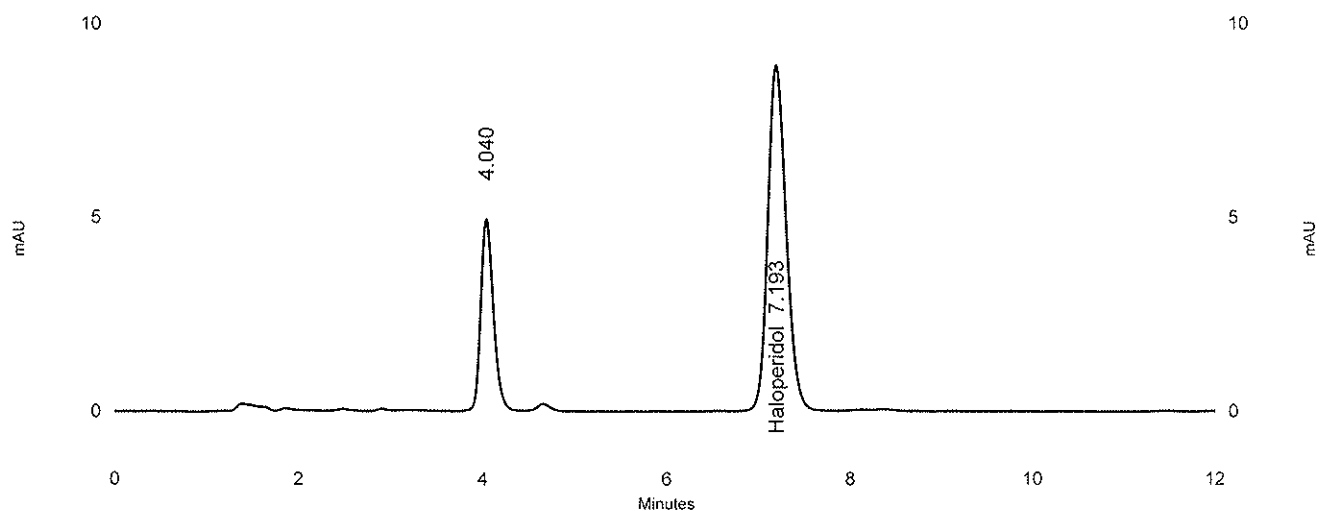
Name	Retention Time	Height	Area	ESTD concentration	Asymmetry
Haloperido 1	7.237	11136	155160	0.020 CAL	1.18878

HUMCO QUALITY CONTROL LABORATORY

Sample ID:
sample

Haloperidol

Method Name: C:\CLASS-VP\Methods\HPLC4\Haloperidol stability.met
 Sequence: C:\CLASS-VP\Sequence\2010\September\HPLC 4\Sept 20-10 0.1%Haloperidol stability 30days.seq
 Filename: C:\CLASS-VP\Data\2010\August\HPLC 4\Sept 20-10 0.1% Haloperidol 30days stability 03
 Acquired: 9/17/2010 10:00:24 AM
 Printed: 9/17/2010 10:48:19 AM
 Vial: 4



SPD-20AV
Ch1-245nm
Results

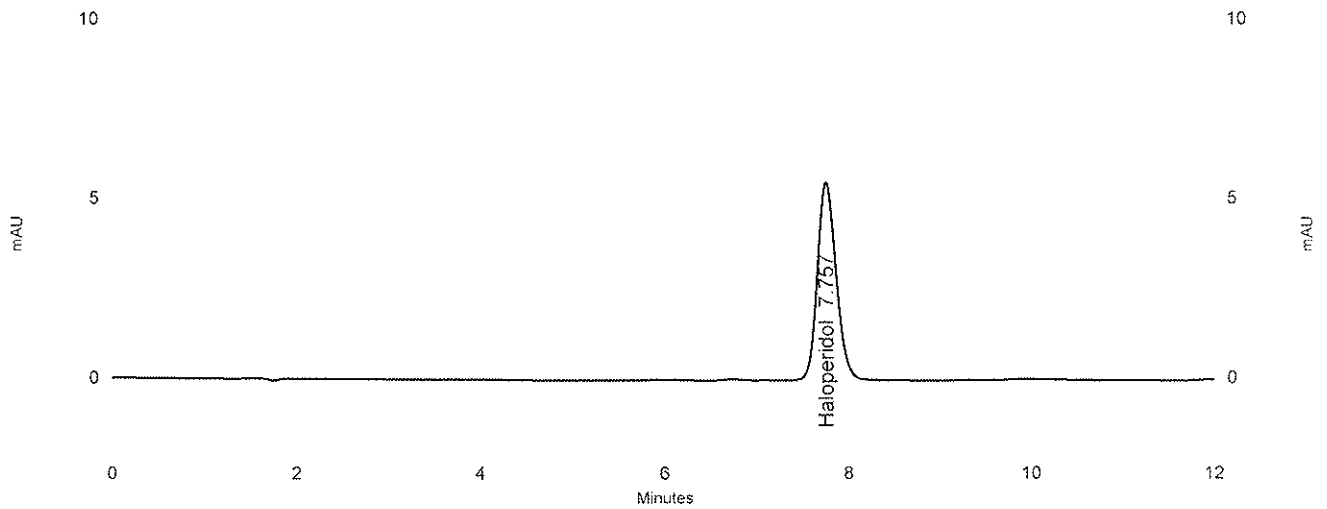
Name	Retention Time	Height	Area	ESTD concentration	Asymmetry
	4.040	4932	47901	0.000	1.26888
Haloperidol	7.193	8901	122856	0.079	1.17173

HUMCO QUALITY CONTROL LABORATORY

Sample ID:

Standard

Method Name: C:\CLASS-VP\Methods\Methods\HPLC4\Haloperidol stability.met
Sequence: C:\CLASS-VP\Sequence\Sequence\2010\October\HPLC 4\Haloperidol 60days stability studie .seq
Filename: C:\CLASS-VP\Methods\Methods\HPLC4\Oct 20-10 Haloperidol 01-Rep1
Acquired: 10/20/2010 1:38:48 PM
Printed: 10/20/2010 3:35:12 PM
Vial: 2



SPD-20AV
Ch1-245nm
Results

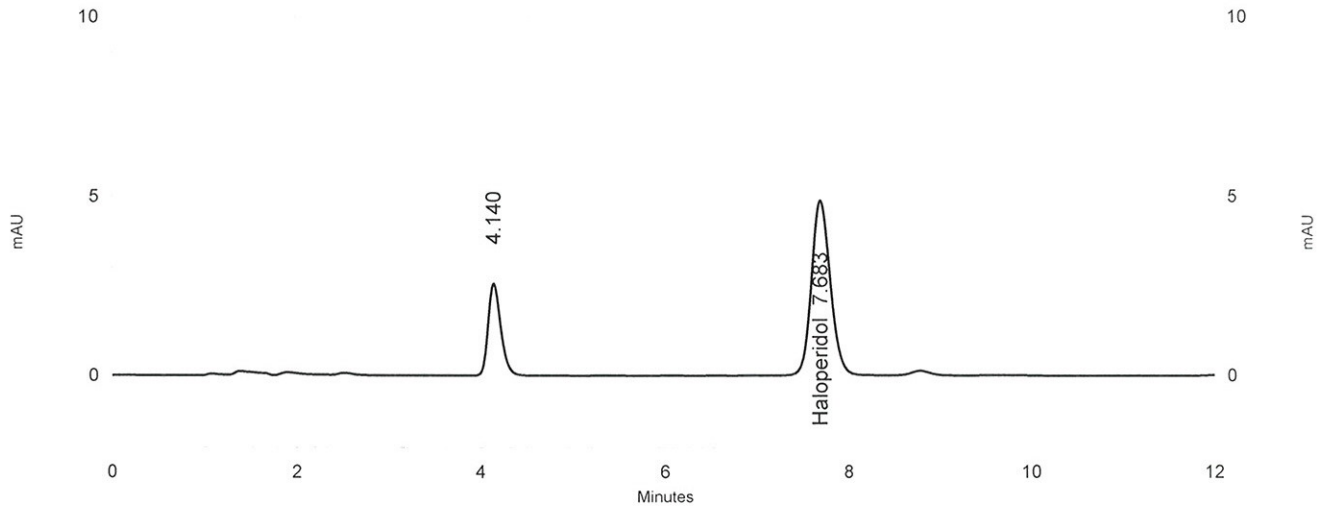
Name	Retention Time	Height	Area	ESTD concentration	Asymmetry
Haloperido 1	7.757	5494	77968	0.010 CAL	1.14549

HUMCO QUALITY CONTROL LABORATORY

Sample ID:
days stability sample

Haloperidol 60

Method Name: C:\CLASS-VP\Methods\Methods\HPLC4\Haloperidol stability.met
 Sequence: C:\CLASS-VP\Sequence\Sequence\2010\October\HPLC 4\Haloperidol 60days stability studie .seq
 Filename: C:\CLASS-VP\Methods\Methods\HPLC4\Oct 20-10 Haloperidol 03
 Acquired: 10/20/2010 2:54:31 PM
 Printed: 10/20/2010 3:35:41 PM
 Vial: 4



SPD-20AV
Ch1-245nm
Results

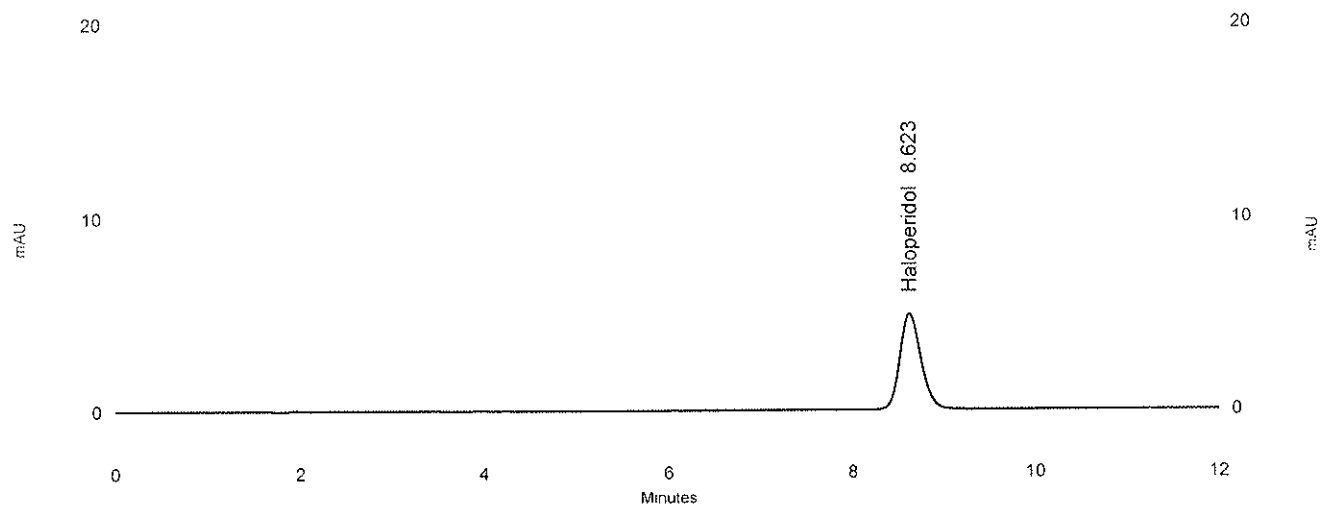
Name	Retention Time	Height	Area	ESTD concentration	Asymmetry
	4.140	2550	24564	0.000	1.28304
Haloperidol 1	7.683	4858	68738	0.086	1.14510

HUMCO QUALITY CONTROL LABORATORY

Sample ID:

Standard

Method Name: C:\CLASS-VP\Methods\Methods\HPLC4\Haloperidol stability.met
Sequence: C:\CLASS-VP\Sequence\Sequence\2010\October\HPLC 4\Haloperidol 0.1% 90days stability studie .seq
Filename: C:\CLASS-VP\Methods\Methods\HPLC4\Nov 30-10 Haloperidol 01-Rep1
Acquired: 11/30/2010 3:32:27 PM
Printed: 12/1/2010 10:10:13 AM
Vial: 2



SPD-20AV
Ch1-245nm

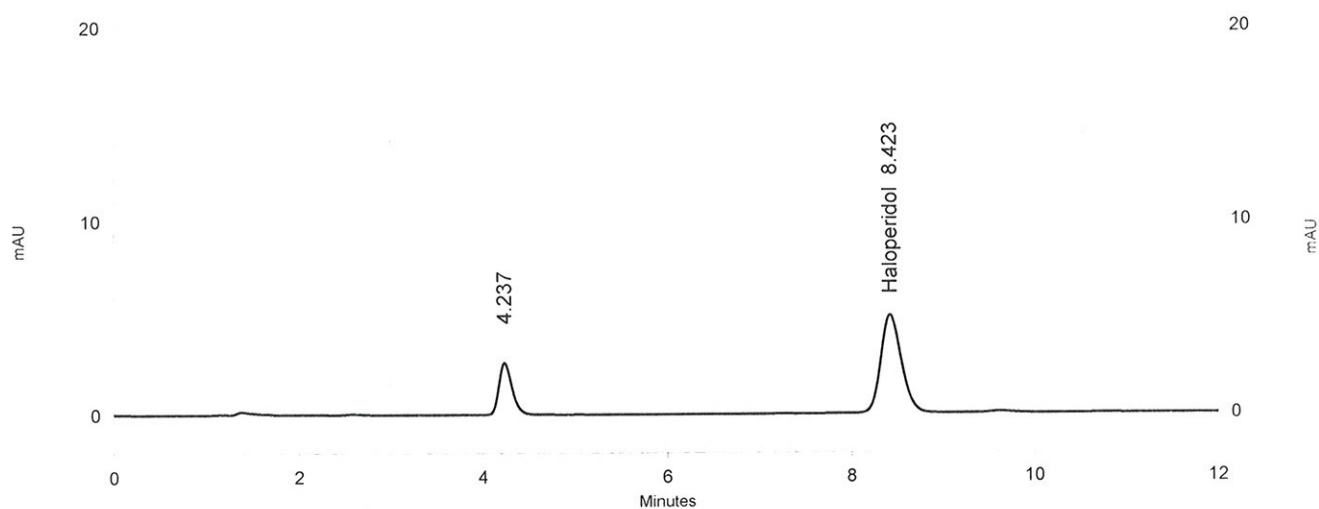
Results Name	Retention Time	Height	Area	ESTD concentration	Asymmetry
Haloperido 1	8.623	4966	78889	0.010 CAL	1.17528

HUMCO QUALITY CONTROL LABORATORY

Sample ID:
days stability sample

Haloperidol 60

Method Name: C:\CLASS-VP\Methods\Methods\HPLC4\Haloperidol stability.met
Sequence: C:\CLASS-VP\Sequence\Sequence\2010\October\HPLC 4\Haloperidol 0.1% 90days stability studie .seq
Filename: C:\CLASS-VP\Methods\Methods\HPLC4\Nov 30-10 Haloperidol 03
Acquired: 11/30/2010 4:48:16 PM
Printed: 12/1/2010 10:10:23 AM
Vial: 4



SPD-20AV
Ch1-245nm
Results

Name	Retention Time	Height	Area	ESTD concentration	Asymmetry
Haloperidol 1	8.423	5051	79019	0.094	1.16807