

Cyclobenzaprine Hydrochloride:

1.00g Cyclobenzaprine Hydrochloride raw drug powder from Spectrum chemical (part number C1570, Lot # XG0806) 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 2.0% w/w. This emulsion 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.

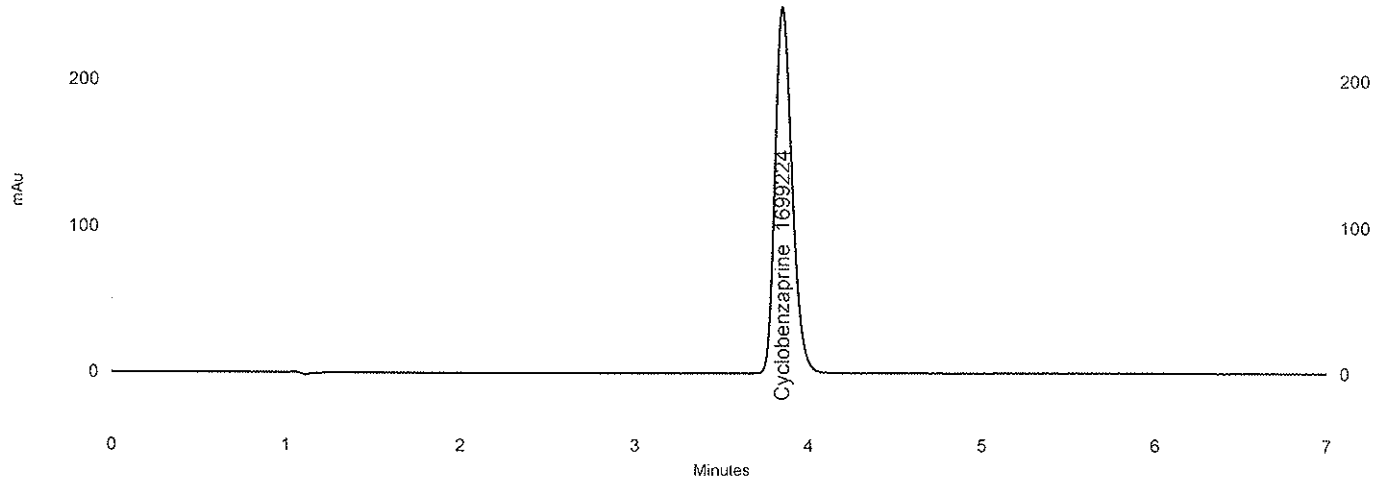
90-Day Summary:

Compounded at 2.0% w/w, stability-indicating HPLC analysis found less than 1% Cyclobenzaprine 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

C:\CLASS-VP\Enterprise\Projects\Default\Data\April-13 Cyclobenzaprine
Linearity 101-Rep1
Sample ID: Cyclobenzaprine Standards
C:\CLASS-VP\Sequence\2009\April\HPLC 3\April 13-09 Cyclobenzaprine
Linearity.seq
C:\CLASS-VP\Enterprise\Projects\Default\Method\Cyclobenzaprine.met
Vial: 2
Sample amount: 1



4: 290
nm, 4 nm
Results

| Name | Retention Time | Area | % W/W | Asymmetry | Resolution (USP) | Theoretical plates (USP) |
|-----------------|----------------|---------|----------|-----------|------------------|--------------------------|
| Cyclobenzaprine | 3.848 | 1699224 | 0.05 CAL | 1.29119 | 0.00000 | 7343 |

HUMCO QUALITY CONTROL LABORATORY

C:\CLASS-VP\Enterprise\Projects\Default\Data\April-19-10 Cyclobenzaprine
Presicion 103

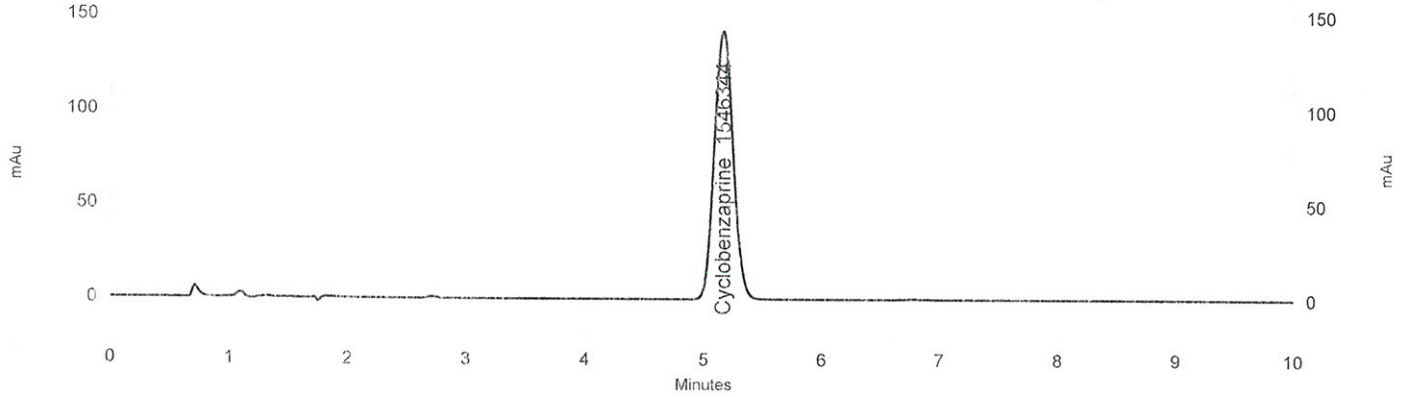
Sample ID: Cyclobenzaprine Presicion 1

C:\CLASS-VP\Sequence\2010\April\HPLC 3\April 19-10 Cyclobenzapirne
Stability time zero.seq

C:\CLASS-VP\Enterprise\Projects\Default\Method\Cyclobenzaprine.met

Vial: 4

Sample amount: 0.2328



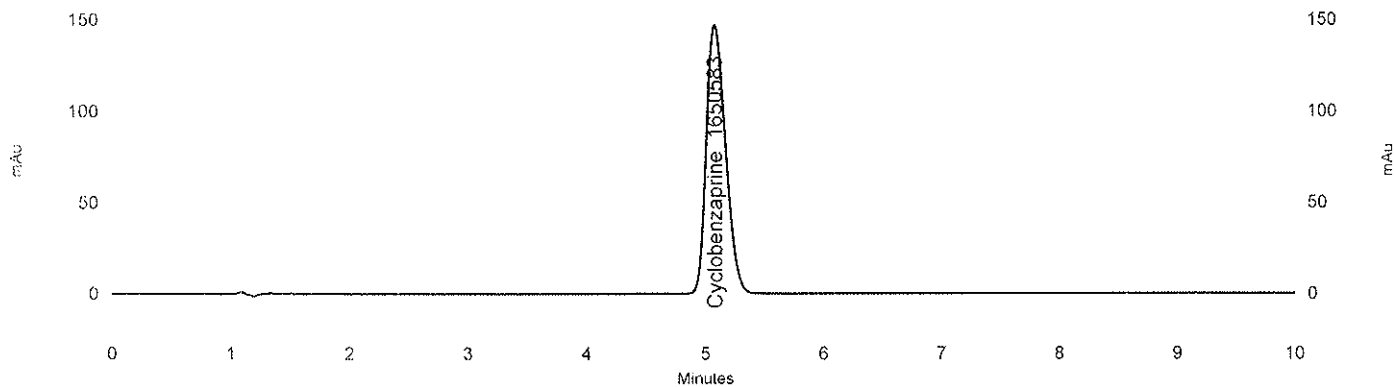
4: 290
nm, 4
nm

Results

| Name | Retention Time | Area | % W/W | Asymmetry | Resolution (USP) | Area Percent | Theoretical plates (USP) |
|-----------------|----------------|---------|-------|-----------|------------------|--------------|--------------------------|
| Cyclobenzaprine | 5.160 | 1546344 | 2.01 | 1.104 | 0.000 | 100.00 | 4988 |
| | | | | | | 0 | |

HUMCO QUALITY CONTROL LABORATORY

C:\CLASS-VP\Enterprise\Projects\Default\Data\May-19-10 Cyclobenzaprine
Stability 30 Days 101-Repl
Sample ID: Cyclobenzaprine Standards
C:\CLASS-VP\Sequence\2010\May\HPLC 3\May 19-10 Cyclobenzaprine 2% 30 days
Stability.seq
C:\CLASS-VP\Enterprise\Projects\Default\Method\Cyclobenzaprine.met
Vial: 2
Sample amount: 1



4: 290
nm, 4
nm
Results

| Name | Retention Time | Area | % W/W | Asymmetry | Resolution (USP) | Area Percent | Theoretical plates (USP) |
|-----------------|----------------|---------|----------|-----------|------------------|--------------|--------------------------|
| Cyclobenzaprine | 5.080 | 1650583 | 0.05 CAL | 1.233 | 0.000 | 100.00 0 | 4509 |

HUMCO QUALITY CONTROL LABORATORY

C:\CLASS-VP\Enterprise\Projects\Default\Data\May-19-10 Cyclobenzaprine
Stability 30 Days 103

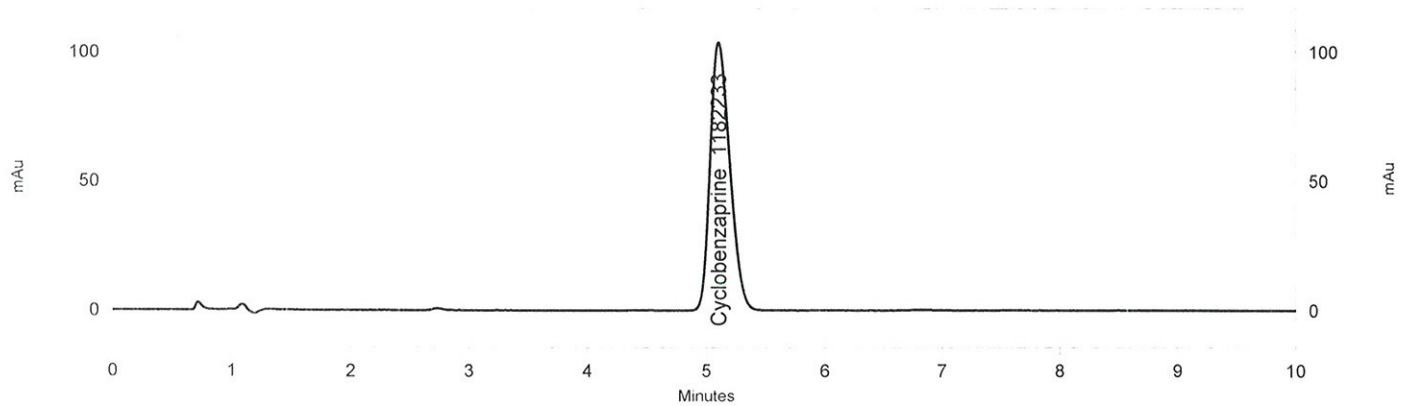
Sample ID: Cyclobenzaprine Presicion 1

C:\CLASS-VP\Sequence\2010\May\HPLC 3\May 19-10 Cyclobenzaprine 2% 30 days
Stability.seq

C:\CLASS-VP\Enterprise\Projects\Default\Method\Cyclobenzaprine.met

Vial: 4

Sample amount: 0.1801



4: 290

nm, 4

nm

Results

| Name | Retention Time | Area | % W/W | Asymmetry | Resolution (USP) | Area Percent | Theoretical plates (USP) |
|-----------------|----------------|---------|-------|-----------|------------------|--------------|--------------------------|
| Cyclobenzaprine | 5.104 | 1182233 | 1.99 | 1.239 | 0.000 | 100.000 | 4385 |

HUMCO QUALITY CONTROL LABORATORY

C:\CLASS-VP\Enterprise\Projects\Default\Data\June-16-10 Cyclobenzaprine
Stability 60 Days 101-Repl

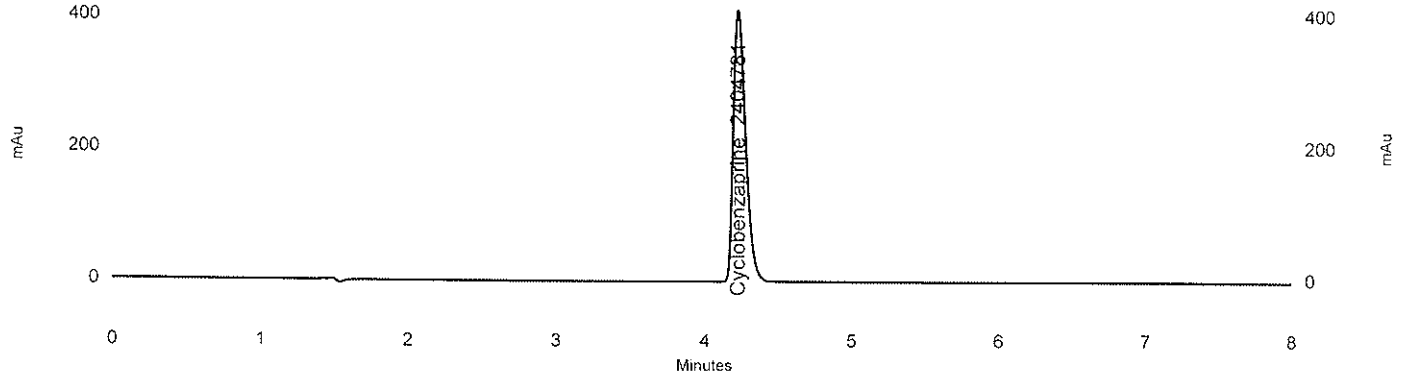
Sample ID: Cyclobenzaprine Standards

C:\CLASS-VP\Sequence\2010\June\HPLC 3\Jun 16 Cyclobenzaprine 60 days
Stability.seq

C:\CLASS-VP\Enterprise\Projects\Default\Method\Cyclobenzaprine.met

Vial: 47

Sample amount: 1



4: 290

nm, 4

nm

Results

| Name | Retention Time | Area | % W/W | Asymmetry | Resolution (USP) | Area Percent | Theoretical plates (USP) |
|-----------------|----------------|---------|----------|-----------|------------------|--------------|--------------------------|
| Cyclobenzaprine | 4.224 | 2404781 | 0.05 CAL | 1.573 | 0.000 | 100.00 | 11871 |
| | | | | | | 0 | |

HUMCO QUALITY CONTROL LABORATORY

C:\CLASS-VP\Enterprise\Projects\Default\Data\June-16-10 Cyclobenzaprine
Stability 60 Days 103

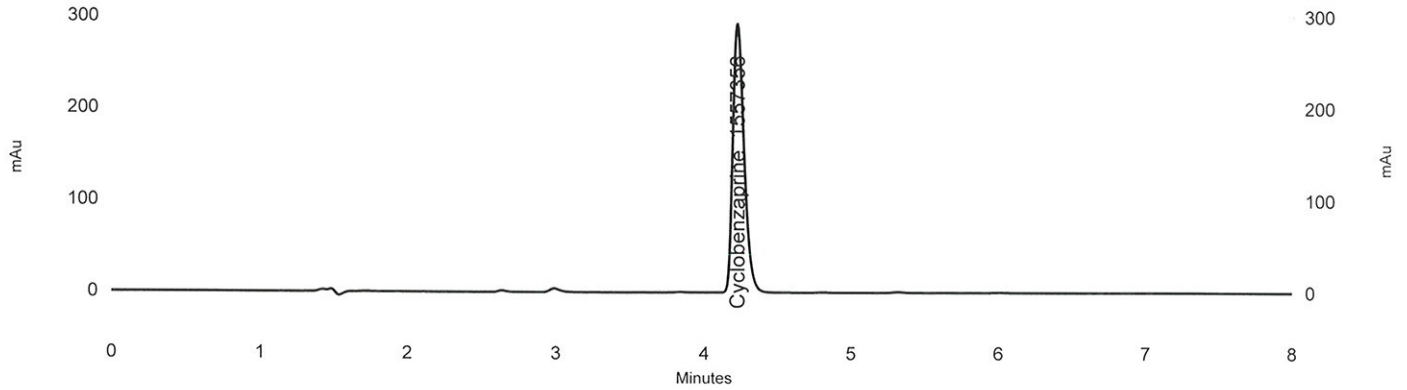
Sample ID: Cyclobenzaprine 60 days Stability

C:\CLASS-VP\Sequence\2010\June\HPLC 3\Jun 16 Cyclobenzaprine 60 days
Stability.seq

C:\CLASS-VP\Enterprise\Projects\Default\Method\Cyclobenzaprine.met

Vial: 49

Sample amount: 0.1651



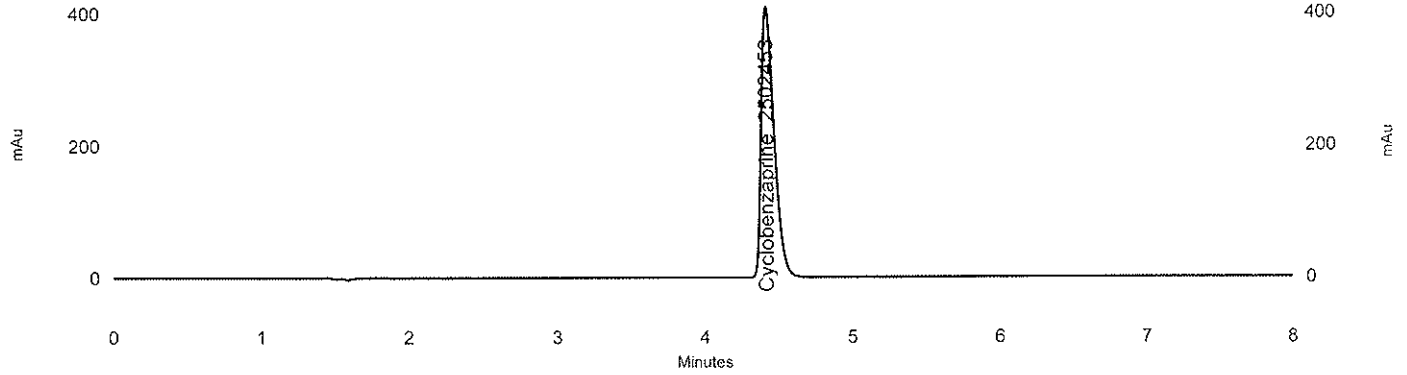
4: 290
nm, 4
nm

Results

| Name | Retention Time | Area | % W/W | Asymmetry | Resolution (USP) | Area Percent | Theoretical plates (USP) |
|-----------------|----------------|---------|-------|-----------|------------------|--------------|--------------------------|
| Cyclobenzaprine | 4.224 | 1557356 | 1.96 | 1.400 | 0.000 | 100.00 0 | 14471 |

HUMCO QUALITY CONTROL LABORATORY

C:\CLASS-VP\Enterprise\Projects\Default\Data\July-19-10 Cyclobenzaprine
Stability 90 Days 101-Repl
Sample ID: Cyclobenzaprine Standards
C:\CLASS-VP\Sequence\2010\July\HPLC 3\July-19-10 Cyclobenzaprine 90 days
Stability.seq
C:\CLASS-VP\Enterprise\Projects\Default\Method\Cyclobenzaprine.met
Vial: 2
Sample amount: 1



4: 290
nm, 4
nm

Results

| Name | Retention Time | Area | % W/W | Asymmetry | Resolution (USP) | Area Percent | Theoretical plates (USP) |
|-----------------|----------------|---------|----------|-----------|------------------|--------------|--------------------------|
| Cyclobenzaprine | 4.416 | 2502453 | 0.05 CAL | 1.604 | 0.000 | 100.00 0 | 11923 |

HUMCO QUALITY CONTROL LABORATORY

C:\CLASS-VP\Enterprise\Projects\Default\Data\July-19-10 Cyclobenzaprine
Stability 90 Days 103

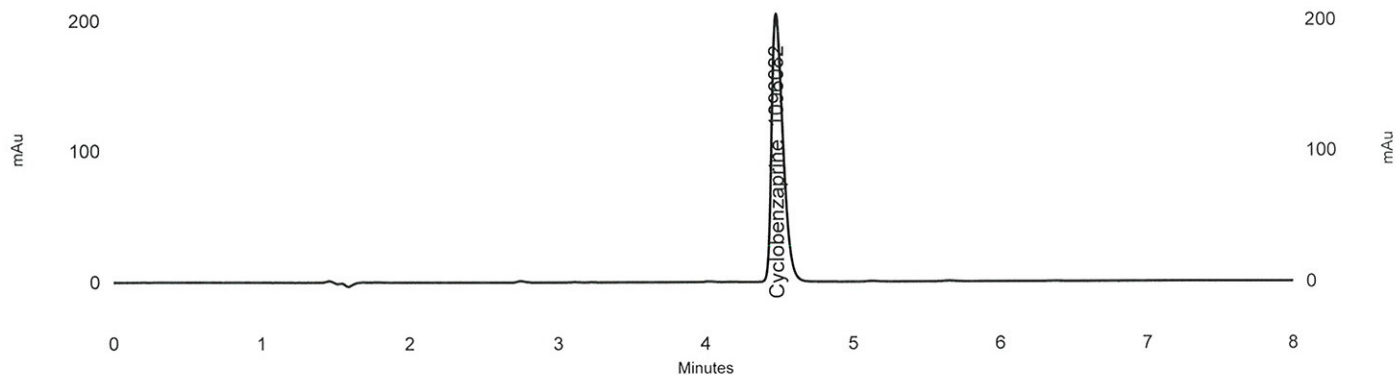
Sample ID: Cyclobenzaprine 90 days Stability

C:\CLASS-VP\Sequence\2010\July\HPLC 3\July-19-10 Cyclobenzaprine 90 days
Stability.seq

C:\CLASS-VP\Enterprise\Projects\Default\Method\Cyclobenzaprine.met

Vial: 4

Sample amount: 0.1102



4: 290
nm, 4
nm

Results

| Name | Retention Time | Area | % W/W | Asymmetry | Resolution (USP) | Area Percent | Theoretical plates (USP) |
|-----------------|----------------|---------|-------|-----------|------------------|--------------|--------------------------|
| Cyclobenzaprine | 4.484 | 1096082 | 1.99 | 1.376 | 0.000 | 100.00 0 | 16361 |