



SSCITM

A Division of Albany Molecular Research Inc.

3065 Kent Avenue
West Lafayette, IN 47906-1076
Phone: (765) 463-0112
Fax: (765) 463-4722
E-mail: info@ssci-inc.com
Web: www.ssci-inc.com

Chromatographic Data from the Stability Evaluation of Bromfenac Sodium Drug Product Samples for Potency

Project ID: EL20151326
Report Date: 1/12/2016

CONFIDENTIAL

BBOL0227648

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I. SUMMARY

This document contains chromatographic stability data from the analysis of Bromfenac sodium ophthalmic solution drug product for potency. Samples were sourced from Senju.

Table 1. Summary of HPLC Data, Sequence 741881

| Sample Description | LIMS LC Filename | RT | Area(mAU*s) | Page |
|--------------------|------------------|-------|-------------|------|
| Blank | 408677 741882 | --- | --- | 5 |
| Blank | 408677 741883 | --- | --- | 6 |
| STD A | 408705 741884 | 8.667 | 4012.66 | 7 |
| STD A | 408705 741885 | 8.668 | 4015.13 | 11 |
| STD A | 408705 741886 | 8.666 | 4016.96 | 12 |
| STD A | 408705 741887 | 8.666 | 4016.04 | 13 |
| STD A | 408705 741888 | 8.666 | 4018.79 | 14 |
| STD B | 408706 741889 | 8.665 | 4038.45 | 15 |
| Blank | 408677 741890 | --- | --- | 16 |
| STD A | 408705 741897 | 8.666 | 4019.73 | 17 |
| 240031 | 403486 741898 | 8.646 | 4556.16 | 18 |
| 240031 | 403489 741899 | 8.648 | 4548.27 | 19 |
| 240031 | 403490 741900 | 8.647 | 4547.03 | 20 |
| STD A | 408705 741901 | 8.663 | 4016.40 | 21 |

Table 2. Summary of HPLC Data, Sequence

| Sample Description | LIMS LC Filename | RT | Area(mAU*s) | Page |
|--------------------|------------------|-------|-------------|------|
| Blank | 408677 742200 | --- | --- | 22 |
| Blank | 408677 742201 | --- | --- | 23 |
| STD A | 408705 742202 | 8.669 | 4011.82 | 24 |
| STD A | 408705 742203 | 8.670 | 4013.03 | 28 |
| STD A | 408705 742204 | 8.670 | 4010.89 | 29 |
| STD A | 408705 742205 | 8.670 | 4010.87 | 30 |
| STD A | 408705 742206 | 8.669 | 4015.36 | 31 |
| STD B | 408706 742207 | 8.669 | 4055.66 | 32 |
| Blank | 408677 742208 | --- | --- | 33 |
| STD A | 408705 742215 | 8.673 | 4015.87 | 34 |
| STD A | 408705 742222 | 8.676 | 4019.08 | 35 |
| STD A | 408705 742229 | 8.677 | 4018.56 | 36 |
| STD A | 408705 742235 | 8.681 | 4017.59 | 37 |
| STD A | 408705 742242 | 8.682 | 4019.84 | 38 |
| STD A | 408705 742249 | 8.684 | 4017.62 | 39 |
| STD A | 408705 742256 | 8.690 | 4017.27 | 40 |
| STD A | 408705 742262 | 8.691 | 4023.48 | 41 |
| 240031 | 403478 742263 | 8.670 | 4537.86 | 42 |
| 240031 | 403479 742264 | 8.670 | 4545.41 | 43 |
| 240031 | 403480 742265 | 8.670 | 4541.65 | 44 |
| 240031 | 403481 742266 | 8.673 | 4522.94 | 45 |
| 240031 | 403482 742267 | 8.671 | 4555.21 | 46 |
| 240031 | 403483 742268 | 8.672 | 4556.05 | 47 |
| STD A | 408705 742269 | 8.694 | 4024.68 | 48 |
| 240031 | 403484 742272 | 8.676 | 4541.95 | 49 |
| 240031 | 403485 742273 | 8.676 | 4541.17 | 50 |
| 240031 | 403487 742274 | 8.678 | 4524.65 | 51 |
| 240031 | 403488 742275 | 8.680 | 4523.19 | 52 |
| STD A | 408705 742276 | 8.701 | 4024.02 | 53 |

II. CHROMATOGRAMS

Chromatographic Data from the Stability Evaluation of Bromfenac Sodium Drug Product Samples for Potency, 1/12/2016,
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BBOL0227654

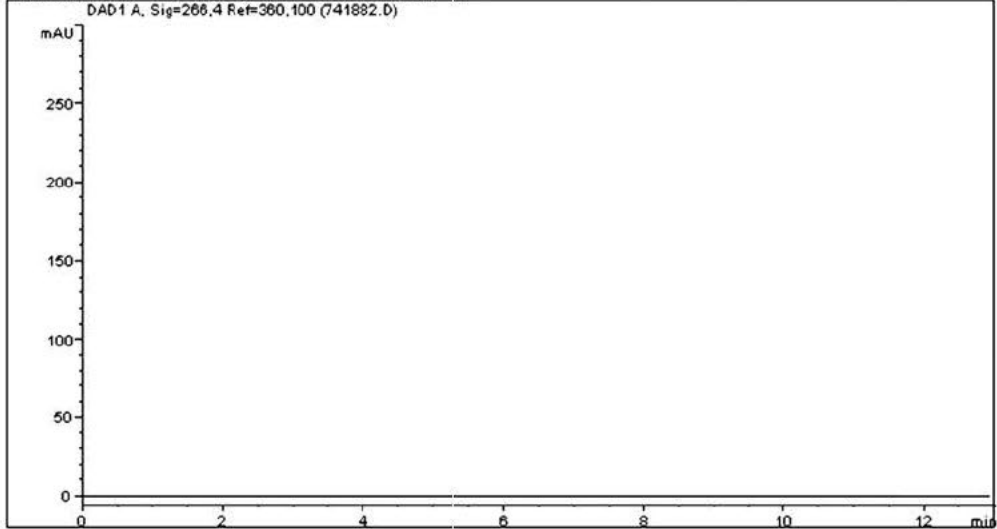
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```

=====
Injection Date : 11/16/2015 5:01:26 PM      Seq. Line : 1
Sample Name    : 408677                    Location  : Vial 1
Acq. Operator  : GT                       Inj      : 1
Acq. Instrument : Instrument 1             Inj Volume : 5 µl
Sequence File  : D:\LIMSDATA\741881.S
Method         : C:\HPCHEM\1\METHODS\62940502.M
Last changed   : 11/16/2015 3:25:25 PM by GT
=====

```



```

=====
                          Area Percent Report
=====

```

```

Sorted By      :      Signal
Calib. Data Modified : 11/16/2015 2:21:49 PM
Multiplier     :      1.0000
Dilution       :      1.0000
Use Multiplier & Dilution Factor with ISTDs

```

Signal 1: DAD1 A, Sig=266,4 Ref=360,100

| Peak # | RetTime [min] | Type | Width [min] | Area [mAU*s] | Area % | Name |
|--------|---------------|------|-------------|--------------|--------|-----------|
| 1 | 8.100 | | 0.0000 | 0.00000 | 0.0000 | Bromfenac |

Totals : 0.00000

Results obtained with enhanced integrator!
 1 Warnings or Errors :

Warning : Calibrated compound(s) not found

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=====
*** End of Report ***
=====

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