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

Project ID: EL20151326

Report Date: 1/12/2016

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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	24
STD A	408705	742203	8.670	28
STD A	408705	742204	8.670	29
STD A	408705	742205	8.670	30
STD A	408705	742206	8.669	31
STD B	408706	742207	8.669	32
Blank	408677	742208	---	33
STD A	408705	742215	8.673	34
STD A	408705	742222	8.676	35
STD A	408705	742229	8.677	36
STD A	408705	742235	8.681	37
STD A	408705	742242	8.682	38
STD A	408705	742249	8.684	39
STD A	408705	742256	8.690	40
STD A	408705	742262	8.691	41
240031	403478	742263	8.670	42
240031	403479	742264	8.670	43
240031	403480	742265	8.670	44
240031	403481	742266	8.673	45
240031	403482	742267	8.671	46
240031	403483	742268	8.672	47
STD A	408705	742269	8.694	48
240031	403484	742272	8.676	49
240031	403485	742273	8.676	50
240031	403487	742274	8.678	51
240031	403488	742275	8.680	52
STD A	408705	742276	8.701	53

II. CHROMATOGRAMS

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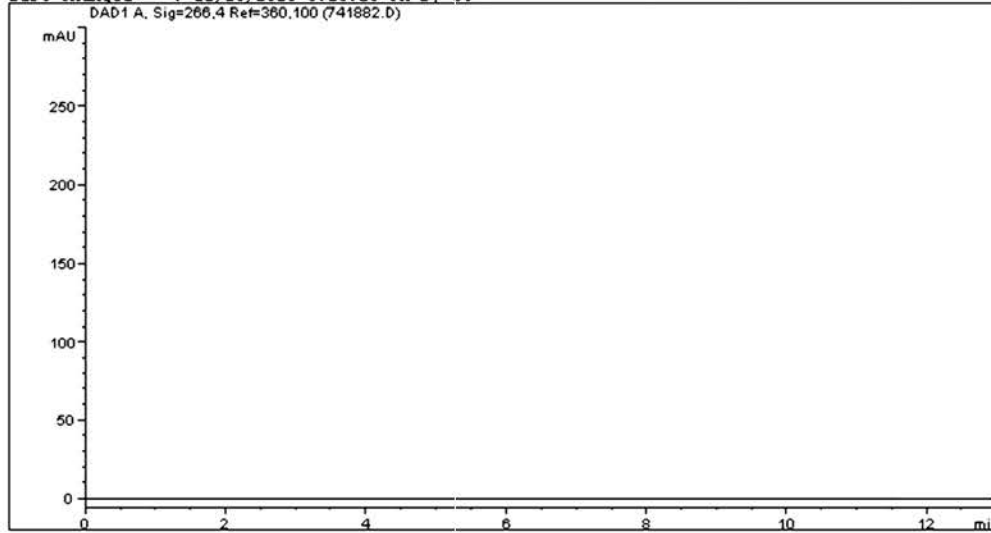
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```

=====
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

```

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

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