Chromatographic Data for the Placebo of the Bromfenac Sodium Drug Product

Project ID: EL20151326
Report Date: 2/8/2016

I. SUMMARY

This document contains chromatographic data obtained from the injection of a prepared placebo sample of the Bromfenac sodium ophthalmic solution drug product. The sample was prepared at SSCI from commercially sourced materials.

Table 1. Summary of HPLC Data, Placebo Sample

Sample Description	Sample ID	LIMS	LC Filename	RT	Area(mAU*s)	Page
Placebo	6294-04-01	407751	740025	---	---	4

II. CHROMATOGRAMS

E x t e n d e d   P e r f o r m a n c e   R e p o r t

Instrument: Instrument 1

Module	Firmware revision	Serial number
1100 Quaternary Pump	A.05.11 [013]	US70201400
1100 Autosampler	A.05.11 [013]	US70201352
1100 Diode Array Detector	A.05.11 [013]	US64400691
1100 Column Thermostat	A.05.11 [013]	DE63064158

Software Revision: Rev. A.10.02 [1757] Copyright © Agilent Technologies

```
Column Description :   C18 Symmetry
Product#           :   WAT045905        Batch#:   027132284
Serial#            :   0271322842381
Diameter           :   4.6 mm           Length :   150.0 mm
Particle size      :   5.0 µm       Void volume :    68.0 %
Maximum Pressure   :   400 bar       Maximum pH :       0
Maximum Temperature:     0 °C
Comment            :
```

Analysis method: C:\HPCHEM\1\METHODS\62940202.M

Sample information for Location: Vial 1

```
   Sample Name:     407751              Multiplier:        1.00
   Injection#:      1                   Dilution:          1.00
   Injection volume: 5 µl
```
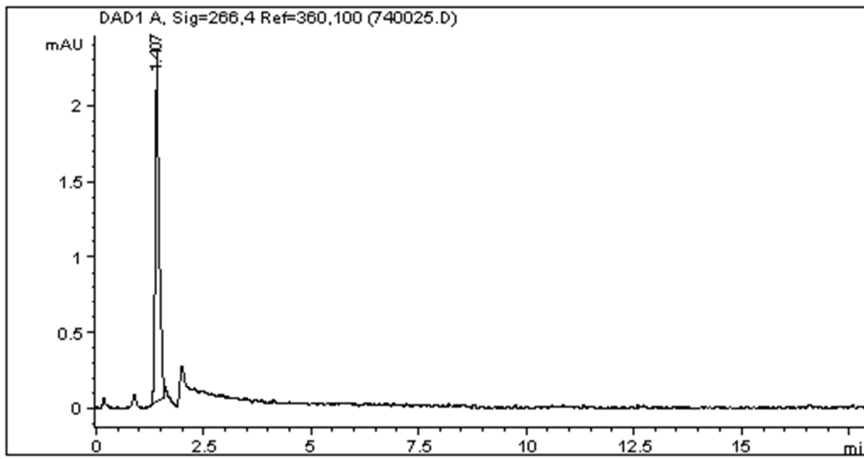
Acquisition information:

```
   Operator:        GT
   Date/Time:       11/3/2015 6:19:37 PM
   Data file name:  D:\LIMSDATA\740025.D
   Method file name: C:\HPCHEM\1\METHODS\62940202.M
```

```
   Flow:            1.000   ml/min
   Pressure at start:    78   bar      Pressure at end:        79 bar
   Left Temp. at start:  25.0°C        Left Temp. at end:     25.3 °C
   Right Temp. at start: 25.0°C        Right Temp. at end:    25.0 °C
```

```
   Solvents:             PMP1, Solvent A 6294-02-01 (exp 11/13/15)
                         PMP1, Solvent B
                         PMP1, Solvent C
                         PMP1, Solvent D
```

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

DAD1 A, Sig=266,4 Ref=360,100 (740025.D)

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