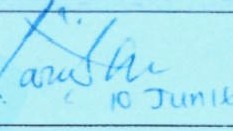


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| Effective Date:  1 3 \_ \_N 2016 | **O PT.**Merck Sharp Dohme Pharma Tbk | | | Datasheet No:  C 1 7 u 7 | |
| Superseded No: QC-01-011.03 | Data Sheet  Check List Variable Database Empower for  Anal sis with HPLC and GC Method | | | Documen t No: QC-01-011.04 | |
| Prepared by: | | Reviewed by:  IO J'\J t'\ t b | Approved by: | |  |

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**SECTION 1:** Analist melakukan pengecekan ulang terhadap raw data yang dimasukkan ke dalam variable database Empower

c. B erat Sample/ Volum e Sample

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Yes e5 Yes e,-

Yes (9"

**Yes** O

Yes @"

No Q No Q N o Q No Q No e

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Keterangan:

/ -

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a. B era t Standard

b. Standard Diluti on

d. Sampl e Dilution

e. AUW (Tablet Only)

f. Label Claim

g. Standard Potenc y

**Yes** 0'

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h. Sample Set Pre Run

**Yes**

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| **Verified** by & **Date** | k, ..., | I | *6'* | A | p | r- | \ | *·r* |

**SECTION 2:** Lab Supervisor melakukan pengecekan terhadap raw data yang dimasukkan Analist ke dalam variable database Emoower

**Yes** *(St* No Q

**Yes** G No Q

**Yes** g- No Q

**Yes** O No (9 **Yes** *(5* - No Q **Yes** 0 **NoQ**

**a. Berat Standard**

**Yes**

No Q

1. **Standard** Dilution
2. **Berat Sample/ Volume Sample**
3. **Sample** Dilution

**e. AUW (Tablet Only)**

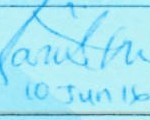
f. **Label Claim**

g. **Standard** Potency

j **Review ed by** & **Dat e** c I I *9* A Ir I *r* I l '.t-- 1

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| **His** | **tory** | **:** |  |  |
|  | **1 .** |  | QC-01-011.00, Effective date: 29 Nov 2006 (New Edition) |
|  | 2. |  | QC-01-011.01, Effective date: 20 Nov 2008, LCR No.CR1108373D, Date of Issue: 19 Nov 2008 |
|  | 3. |  | QC-01-011.02, Effective Date: 30 Au,s1 2013 TR No.133973, Date of Issue: 22 May 2013 |
|  | **4.** |  | QC-01-011.03, Effective Date: **l j** J ' · |  |
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PT. **Merck** Sharp Dohme Pharma Tbk

HPLC DATASHEET

Document No: QC-01-008 05

Approved by:

Effective Date:

1 J ., ltl 2016

Datasheet No:

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Supers eded No: QC-01-008 .04

Prepared by:

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Data Testing

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Reviewed by:

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Page I of 2



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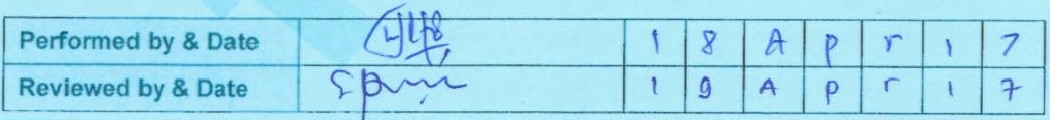
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**System Suitability**

**Parameters Met Yes No**

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1. QC-01-008.00, Effective Date. 17 Jan 2005, initial release
2. QC-01-008.01, Effective Date: 09 Aug 2006, LCR No.CRQC0806085, Date of Issue: 08 Aug 2006

3 QC-01-008.02 , E:ffect,ve Date · 11 Feb 2008, LCR No.CR0208045D, Date of Issue: 05 Feb 2008

4. QC-01-008.03 , Effective Date: 20 Nov 2008, LCR No.CR1108372D, Date of Issue: 18 Nov 2008

5 QC-01-008.04 , Effective Date: 11 Jun 2013 TR No.133968, Date of Issue: 22 May 2013

6. QC-01-008.05, Effective Date: **1** .)

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Page **2** of2





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1. QC-01 -001 .00, Effect ive Date: 25 Juli 2003
2. QC-01-001.01, Effective Date: 18 Jan 2005, LCR No.01QC0105014, Date of Issue: 17 Jan 2005

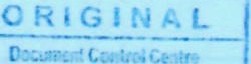
3. QC-01-001.02, Effective Date: 11 Jun 2013, TR No.133963, Date of Issue: 22 May 2013

**4.** QC-01-001.03, Effective Date: 1 3 *JL;;:* "c...,"l'":

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| **Prepared by:**  ?J "- | | **Reviewed by:**  C ""' ..- 101"4-··-'b | **Apprqved by:**  **/4** {.-:' (C ]Ul | |

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| Supen eded No:  **QC-01-001.02** | | |  | WEIGHING RECORD | | | | | Document No:  **QC-01-001.03** | |
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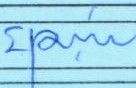
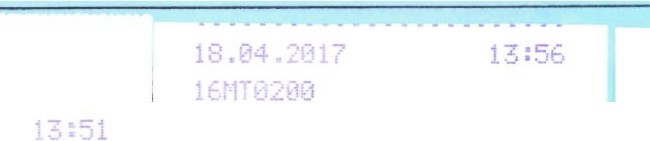
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**History :**

1. QC-01-001.00, Effective Date: 25 Juli 2003
2. QC-01-001.01, Effective Date: 18 Jan 2005, LCR No.01QC0105014, Date of Issue: 17 Jan 2005
3. QC-01-001.02, Effective Date: 11 Jun 2013, TR No.133963, Date of Issue: 22 May 2013

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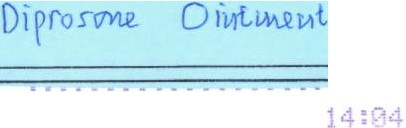
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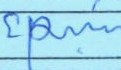
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| **Prepared by:**  T; '"' | | **Reviewed by:**,  c | - | I O jV '"' \b | **Apprcwed by:**  ( *1: \ ... IG* Jun | | (- |

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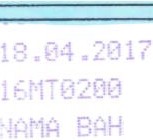
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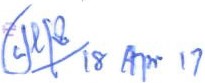
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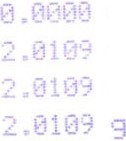
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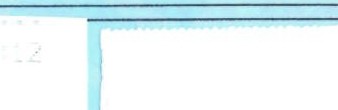
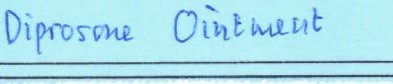
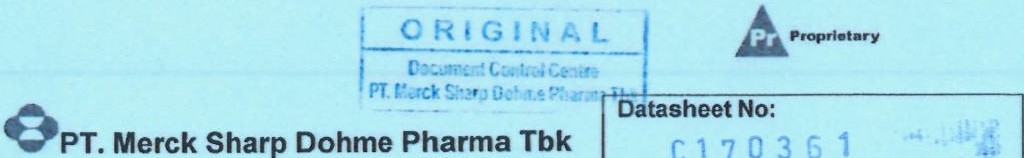
1. QC-01-001.00. Effective Date: 25 Juli 2003
2. QC-01- 001.01, Effective Date: 18 Jan 2005, LCR No.01QC0 105014,Date of Issue: 17 Jan 2005
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1. QC-01-001.00, Effective Date: 25 Juli 2003
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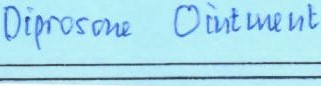
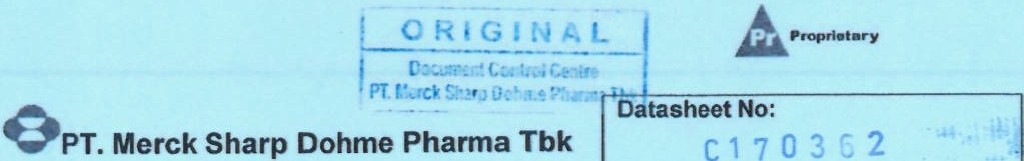
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| **Superseded No:**  **QC-0 1-001.02** | | **WEIGHING RECORD** | | | | **Document No:**  **QC-01-001.03** | | |
| **Prepared by:**  J.,f}.':..\_:{. "; | r ""' '" |  | **Reviewed by:** .,  c | -..- I OJV '" 'b | **Apprcwed by:**  , </c.t. *"1-tf :.*• - | | 1  \0 | ,  W"I ...., |

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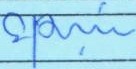




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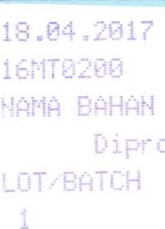
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1. QC-01-001.00, Effective Date: 25 Juli 2003
2. QC-01-001 .01, Effective Date: 18 Jan 2005, LCR No.01QC0105014, Date of Issue: 17 Jan 2005
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1. QC-01-001.00, Effective Date: 25 Juli 2003
2. QC-01-001.01, Effective Date: 18 Jan 2005, LCR No.01QC0105014, Date of Issue: 17 Jan 2005

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3. QC-01-001.0 2, Effective D ate: 11 Jun 2013, TR No.133963, Date of Issue: 22 May 2013

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**software** Systemsuitability

***PT. Schering Plough Indonesia Tbk.***

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***Quality Control* T**

***Analytical Report*** 15

Sample Name: Bet-dip std-1 Sample Type: Standard

Vial: 25

Injection #: 1

Injection Volume: 10.00 ul Run lime: 22.0 Minutes

Acquired By: aalfiani

Sample Set Name: 6BDPA002\_St9 inv Acq. Method Set: BDPA\_BetDip Met Set Processing Method BDPA\_ProcMetLC02 Channel Name: 2487Channe l 1

Proc. Chnl. Descr.: 2487Channe l 1

Date Acquired: Tuesday, April 18, 2017 1:26:42 Prv1 wrr

Date Processed: Wednesday, April 19, 2017 7:33:27 AM wrr

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**Auto-Scaled Chromatogram**

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2.00 4.00 6.00 8.00 10.00 12.00 14.00 16.00 18.00 20.00 22.00

Minutes

**Peak Results**

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | Name | RT | Area | Height | Annnt | USP Resoh.tion | USP Tailing | USP Plate COUll | KPrirre | |
| 1 | Beta--diJYO | 9.080 | 875982 | 52844 | 50.300 |  | 1.0 | 6834.0 |  | 8.1 |
| : 2 | Beclo-diJYO | 11 .18€ | 962159 | 47428 | 1.000 | 4.2 | 1.0 | 6908.4 | 10.2 | |

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Reported by User: Alfiani, Alfiani (aalfiani) Report Method: Sy stemSu itability

Report Method ID: 1 07 4

Page: 1 of 1

Project Name: Pandaan\2017\_Q1\BDPA Bet.Dip\_TemplatE

Date Printed : Wednesd ay , April 19, 201i 9:21:58 AM Asia/Jakartc

***r/jJ*** Sc ring )llg

Report Method: Std Samp

**Quality Control**

### Analytical Report

Report ed by: Alfiani, Alfian i (aalfia Project: Pandaan \2017 Q1\BISys: 13 LC0300

Sample Name: 6BDPA002 st 9 middle 2, Sample Type : Unknow n, Standard

Vial: 26, 28, 29, 31, 25, 32, 27, 30

Injection #: 1, 2, 3 Injection V olume: 10.00 ul

Run Time: 22.0, 16.0 Minutes Sample Set Name: 6BDPA002 \_St9 inv

Acquired By: aalfiani

Date Ac quired: Tuesday, April 18, 2017 1:26:42 Ac q. Method Set: BDPA\_BetDip Met Set

Date Proces sed: Wednesday, April 19, 2017

Processing Method: BDPA ProcMetLC02 Processed by aalf iani/GBL\_Chemist

Sample Set Start DatE Tuesday, April 18, 2017 1:25:4 2

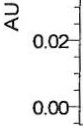
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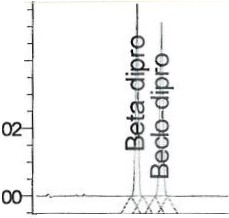
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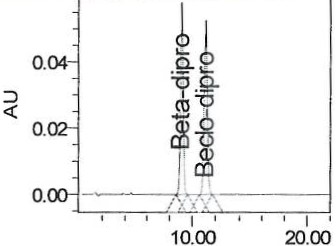
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Bet-dip std-1;

**Mirues**

Bet-dip std-1 ;

10.00

**Minutes**

Bet -dip s td- 1;

20.00

Tuesday, April 18,

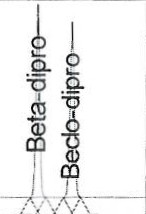
2017 1:26:4 2 PI\/I

W IT; lnj Id 1890

Tuesday, April 18,

2017 1:49:36 **PI\/I**

WIT; lnj Id 1893



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Tuesday, April 18,

2017 2:12:31 PI\/I

W IT; lnj Id 1895

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Bet-dip std- 2; Tuesday, A pril 18, 2017 3:20:15 **PI\/I**

W IT; lnj Id 19 21

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Bet-dip s td-2; Tuesday, April 18,

2017 3:37:27 PI\/I

W IT; lnj Id 192 3

Bet-dip s td-2; Tuesday, April 18, 2017 3:54:22 PM

WIT; lnj Id 1926

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**Mirues**

Bet-dip s td- 2; Tuesday , April 18, 2017 3:20:15 **PI\/I**

WIT; lnj Id 1921

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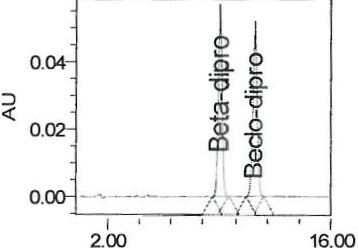
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Bet-dip std-2; Tuesday, April 18, 2017 3:37:27 **PI\/I**

W IT; lnj Id 1923

Bet-dip std -2; Tuesday , April 18, 2017 3:54:22 PI\/I



Mirues

W IT; lnj Id 1926

Sample Set: 6BDPA00 2\_St9 inv Printed 9:22:33 AM ,Wednesday, A Page: 1 of 6

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Report Method: Std Samp

**Quality Control**

### Analytical Report

Reported by: Alfiani, Alfiani (aalfia Project: Pandaan\2017 Q1\BISys: 13 LC0300

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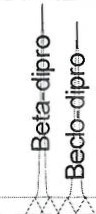
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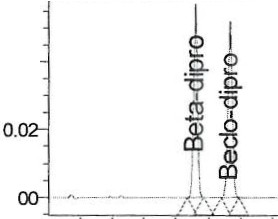
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Bet-dip std-2; Tuesday, April 18,

2017 4:46:19 **PM**

WIT; lnj Id 1949

Bet-dip std-2; Tuesday, April 18,

2017 5:38:00 **PM**

WIT; lnj Id 1981

**Name : Beclo-dipro**

Bet-dip std-2; Tuesday, April 18,

2017 6:29:35 PM

WIT; lnj Id 1990

**Cal Curve Id: 2065**

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**c110120**

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | SM"ple Narre | Nine | Vial | hi | RT  {rrin) | Area | Amlunt | Area  {µV'sec) | ResponseFactor | Manual |
| 1 | Bet-dp std-1 | Beclo-dipro | 25 | 1 | 11.18€ | 962159 | 1.000 | 962159 | 962158.56289 | No |
| 2 | Bet-dip std-1 | Beclo-dipro | 25 | 2 | 11.16S | 982150 | 1.000 | 982150 | 982150.37084 | No |
| 3 | Bet-d p std-1 | Beclo-dipro | 25 | 3 | 11.167 | 981822 | 1.000 | 981822 | 981821.57993 | No |
| 4 | Bet-dip std-2 | Beclo-dipro | 26 | 1 | 11.11e | 98211E | 1.000 | 98211E | 982115.3979: | No |
| 5 | Bet-cip std-2 | Beelo-dipro | 26 | 1 | 11.11e | 98211E | 1.000 | 98211E | 982115.3979: | No |
| 6 | Bet-dip std-2 | Beclo-cipro | 26 | 2 | 11.17S | 973171 | 1.000 | 973171 | 973171.14986 | No |
| 7 | Bet-dip std-2 | Becio-dipro | 26 | 2 | 11.175 | 973171 | 1.000 | 973171 | 973171.14986 | No |
| 8 | Bet-dip stcl-2 | Beelo-dipro | 26 | 3 | 11.181 | 972500 | 1.000 | 972500 | 972500.20089 | No |
| 9 | Bet-dpstcl-2 | Beelo-dipro | 26 | 3 | 11.181 | 972500 | 1.000 | 972500 | 972500.20089 | No |
| 10 | Bet-dp stcl-2 | Beelo-dipro | 26 | 1 | 11.21e | 975301 | 1.000 | 975301 | 975301.28351 | No |
| 11 | Bet-dp stcl-2 | Beclo-dipro | 26 | 1 | 11.257 | 982848 | 1.000 | 982848 | 982847.54637 | No |
| 12 | Bet-dip stcl-2 | Beclo-dipro | 26 | 1 | 11.283 | 984721 | 1.000 | 984721 | 984721.03671 | No |
| Mean |  |  |  |  | 11.2 | 977048 |  |  |  |  |
| % RSD |  |  |  |  | 0.3 | 0.7 |  |  |  |  |

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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | SM"ple Narre | Nine | Vial | lrj | RT  (rrin) | Area (µV' sec) | ResponseFactor | Stdl/lA (rrg) | Labet\_Strength | Std  Potency | Std  Dilution | lrj Id |
| 1 | Bet-dip std-1 | Beelo-dipro | 25 | 1 | 11.186 | 962159 | 962158.56289 | 1.000 |  |  |  | 1890 |
| 2 | Bet-d p std-1 | Beclo-dpro | 25 | 2 | 11.169 | 982150 | 982150.37084 | 1.000 |  |  |  | 1893 |
| 3 | Bet-dip std-1 | Beclo-dpro | 25 | 3 | 11.167 | 981822 | 981821.57993 | 1.000 |  |  |  | 1895 |
| 4 | Bet-dip std-2 | Beclo-dipro | 26 | 1 | 11.178 | 98211! | 982115.3979: | 1.000 |  |  |  | 1921 |
| 5 | Bet-dip std-2 | Beclo-cipro | 26 | 2 | 11.179 | 973171 | 973171.14986 | 1.000 |  |  |  | 1923 |
| 6 | Bet-dip std-2 | Beclo-dipro | 26 | 3 | 11.181 | 972500 | 972500.20089 | 1.000 |  |  |  | 1926 |
| Mean |  |  |  |  | 11.2 | 975653 | 975652.87805 |  |  |  |  |  |
| %RSD |  |  |  |  | 0.1 | 0.82026 | 0.82026 |  |  |  |  |  |

**Cal Curve Id: 2074**

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | SM"ple Narre | Natre | Vial | lrj | RT  (rrin) | Area (µV'sec) | ResponseFactor | *Std I/IA*  (rrg) | Label\_Strength | *Std*  Potency | Std  Dilution | lrj Id |
| 1 | Bet-dip std-2 | Beclo-dpro | 26 | 1 | 11.178 | 98211! | 982115.3979: | 1.000 |  |  |  | 1921 |
| 2 | Bet-dp std-2 | Beclo-dipro | 26 | 2 | 11.179 | 973171 | 973171.14986 | 1.000 |  |  |  | 1923 |

Sample Set: 6BDPA002\_St9 inv Printed 9:22:33 AM 1Wednesday, A Page: 2 of6



Report Method: Std Samp

## Quality Control

#### Analytical Report

Reported by: Alfiani, Alfiani (aalfia Project: Pandaan\2017\_Q1\8ISys: 13\_LC0300

**Cal Cur ve Id: 2074**

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | **Sen-pie**  **Narre** | **Ncrre** | **Vial** | Iii | RT  (nin) | ***kea***  (µV'sec) | **ResponseFactor** | **StdW.**  (rrg) | Label\_Strength | Std Potency | Std Dilution | Iii Id |
| 3 | Bet-cip std-2 | **Beclo-dipro** | 26 | 3 | 11.181 | 972500 | 972500.20089 | **1.000** |  |  |  | 1926 |
| **4** | Bet-cip std-2 | Beclo-dipro | 26 | 1 | 11.218 | 975301 | 975301.28351 | 1.000 |  |  |  | 1949 |
| 5 | Bet-dp std-2 | **Beclo-dipro** | 26 | 1 | 11.257 | **982848** | 962847.54637 | **1.000** |  |  |  | 1981 |
| 6 | Bet-dip std-2 | Beclo-dipro | 26 | **1** | 11.283 | 984721 | 984721.03671 | 1.000 |  |  |  | 1990 |
| Mean |  |  |  |  | 11.2 | 978443 | 978442.77021 |  |  |  |  |  |
| %RSD |  |  |  |  | 0.4 | 0.55091 | 0.55091 |  |  |  |  |  |

**Ca l Cu r ve Id: 2064**

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | Sen-pie  Narre | Narre | Vial | Iii | RT  (nin) | *kea*  (µV'sec) | ResponseFactcr | StdW.  (rrg) | Label\_Streng th | Std Potency | Std Dilution | Iii Id |
| 1 | Bet-cip st d-1 | Beta-dipro | 25 | 1 | 9.080 | 875982 | 0.01810 | 50.300 | 0.64000 | 0.99300 | 400.00000 | 1800 |
| 2 | Bet-cip std-1 | Beta-dipro | 25 | *2* | 9.070 | 894512 | 0.01811 | 50.300 | 0.64000 | 0.99300 | 400.00000 | 1893 |
| 3 | Bet-dip std-1 | Beta-dipro | 25 | 3 | 9.065 | 893521 | 0.01809 | 50.300 | 0.64000 | 0.99300 | 400.00000 | 1895 |
| 4 | Bet-cip std-2 | Beta-dipro | 26 | 1 | 9.075 | 889691 | 0.01808 | 50.100 | 0.64000 | 0.99300 | 400 .00000 | 1921 |
| 5 | Bet-cip std-2 | Beta-dipro | 26 | 2 | 9.076 | 882612 | 0.01810 | 50.100 | 0.64000 | 0.99300 | 400 .00000 | 1923 |
| 6 | Bet-dip std-2 | Beta-dipro | 26 | 3 | *9.on* | 882197 | 0.01811 | 50.100 | 0.64000 | 0.99300 | 400 .00000 | 1926 |
| Mean |  |  |  |  | 9.1 | 886419 | 0.01810 |  |  |  |  |  |
| %RSD |  |  |  |  | 0.1 | 0.82576 | 0.05357 |  |  |  |  |  |

**Ca l Cur ve Id: 2073**

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | Sen-pie  Narre | Narre | Vial | lrf | RT  (nin) | *kea*  (µV'sec) | ResponseFactor | StdW.  (rrg) | Label\_Strength | Std Potency | Std Dilution | Iii Id |
| 1 | Bet-dip std-2 | Beta-dipro | 26 | 1 | 9.075 | 889691 | 0.01808 | 50.100 | 0.64000 | 0.99300 | 400 .00000 | 1921 |
| 2 | Bet-dip std-2 | Beta-dipro | 26 | 2 | 9.076 | 882612 | 0.01810 | 50.100 | 0.64000 | 0.99300 | 400.00000 | 1923 |
| 3 | Bet-dip std-2 | Beta-dipro | 26 | 3 | *9.on* | 882197 | 0.01811 | 50.100 | 0.64000 | 0.99300 | 400.00000 | 1926 |
| 4 | Bet-dip std-2 | Beta-dipro | 26 | **1** | 9.104 | 884226 | 0.01810 | 50.100 | 0.64000 | 0.99300 | 400.00000 | 1949 |
| 5 | Bet-dip std-2 | Beta-dipro | 26 | **1** | 9.133 | 890540 | 0.01809 | 50.100 | 0.64000 | 0.99300 | 400.00000 | 1981 |
| 6 | Bet-op std-2 | Beta-dipro | 26 | 1 | 9.153 | 892927 | 0.01810 | 50.100 | 0.64000 | 0.99300 | 400.00000 | 1990 |
| Mean |  |  |  |  | 9.1 | 887032 | 0.01810 |  |  |  |  |  |
| %RSD |  |  |  |  | 0.4 | 0.51642 | 0.05433, |  |  |  |  |  |

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**llC-01-008.05**



Sample Set: 6BDPA002\_St9 inv Printed 9:22:33 AM ,Wednesday, A Page: 3 of 6

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Report Method: Std Samp

Quality Control

#### Analytical Report

Reported by: Alfiani, Alfiani (aalfia Project: Pandaan\2017 O1\BISys: 13 LC0300

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Tuesday, Ap ril 18, 2017 4:11:50 **PM** W IT;

6BDPA002 st 9 top 1; lnj 1;

lnj Id 1943

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Tuesday, April 18, 2017

4:29:02 PM WIT;

6BDPA002 st 9 top 2; lnj 1;

lnj Id 1946

Tuesday, April 18, 2017

5:03:31 PM wrr;

6BDPA002 st 9 middle 1; lnj 1; lnj Id 1952

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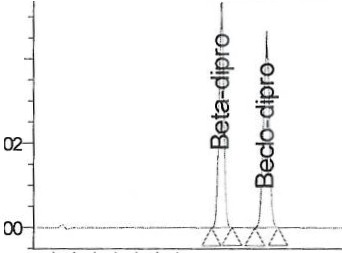
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Tuesday, A pr il 18, 2017 5:20:44 PM W IT;

6BDPA002 s t 9 middle 2; lnj 1; lnj Id 1961

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Tuesday, April 18, 2017

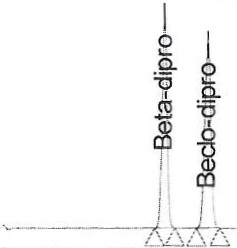
5:55:11 PM WIT;

6BDPA002 st 9 bottom 1;

lnj 1; lnj Id 1984

5.00 10.00 15.00

**Mirues**



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Tuesday, April 18, 2017

6:12:21 **PM WIT;**

6BDPA002 st 9 bottom 2;

lnj 1; lnj Id 1987

**Sam pie Name: 6BDPA002 st 9 bottom 1**

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | **Na-re** | Vial | l rj | RT | Nea | Iii Id | PeakTwe | **Min.Jal** |
| 1 | Beclo-dipro | 31 | 1 | 11.27( | 891457.1 | 1984 | ! Std | No |
| Mean |  |  |  | 11.27( | 89145 7 |  |  |  |
| % RSD |  |  |  |  |  |  |  |  |

**Sam pie Name: 6BDPA002 st 9 bottom 2**

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | Na-re | Vial | lrj | RT | Area | lri Id | P eakTwe | **Ma'll.181** |
| 1 | Becl o-dipro | 32 | 1 | 11.27( | 921547.7 | 1987 | Int Std | No |
| Mean |  |  |  | 11.27( | 921548 |  |  |  |
| %RSD |  |  |  |  |  |  |  |  |

Sam p ie Name: 6BDPA002 st 9 middle 1

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| --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | Na-re | Vial | lrj | RT | Nea | lnj Id | PeakT)Pe | Minial |
| 1 | Becl o-dipro | 29 | 1 | 11.241 | 891158.C | 1952 | Int Std | No |
| Mean |  |  |  | 11.241 | 8911 58 |  |  |  |
| % RSO |  |  |  |  |  |  |  |  |

Sample Set: 6BDPA002\_St9 inv Printed 9:22:33 AM 1Wednes day, A Page: 4 of 6



Report Method: Std Samp

## Quality Control

#### Analytical Report

Repo r ted by: A lfiani, Alfiani (aalfia Projec t: Pand aan\2017 Q1\8ISys: 1 3 LC0300

**Sample Name: 6BDPA002 st 9 middle 2**

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | **Ncrre** | Vial | lri | RT | P.i-ea | lri Id | PeakTwe | **Ma'lUai** |
| 1 | Beelo-dipro | 30 | 1 | 11.231: | 910969.5 | 1961 | Int Std | No |
| **Mean** |  |  |  | **11.231:** | 910970 |  |  |  |
| %RSD |  |  |  |  |  |  |  |  |

**Sample Name: 6BDPA002 st 9 top 1**



**Sam pie Name: 6BDPA002 s t 9 top 2**

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | Ncrre | Vial | lri | RT | *Area* | lri Id | PeakTwe | Maroal |
| 1 | Beclo-dipro | 27 | 1 | 11.174 | 904964.6 | 1943 | Int Std | No |
| M ean |  |  |  | 11.17< | 904965 |  |  |  |
| %RSO |  |  |  |  |  |  |  |  |

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | **Ncrre** | Vial | lnj | RT | *Area* | lri Id | PeakTwe | Manual |
| 1 | Beelo-dipro | 28 | 1 | 11.181 | 915654.8 | 1946 | Int Std | No |
| Mean |  |  |  | 11.181 | 915655 |  |  |  |
| %RSD |  |  |  |  |  |  |  |  |

**Sam pie Name: 6BDPA002 st 9 top 1**

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## cno120

**o.c-01-ooa.os**



|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | **Sa-rpleNare** | Narre | **Vial** | lrj | RT | *Nea*  (µV"sec) | ResponseFactor | **Amx.rt** | **Sa-rpl**eV\eight  {g) | Dilution |
| 1 | 68DPA002 st 9 top1 | Beclo-dipro | 27 | 1 | 11.17< | 904965 | 904964.56879 | 1.00000 | 2.0134 | 10.0000 |
| Mean |  |  |  |  | 11.17< |  |  | 1.00000 |  |  |
| % R SD |  |  |  |  |  |  |  |  |  |  |

**Sam pie Nam e : 6BDPA00 2 st 9 top 2**

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | SarrpleNarre | Narre | Vial | lrj | RT | *Nea*  {µV"sec) | ResponseFactor | Arroult | SarrpeV\eight  {g) | Dilution |
| 1 | 68DPA002 st 9 top 2 | Bec l o-dipro | 28 | 1 | 11.181 | 915655 | 915654.82835 | 1.00000 | 2.011:; | 10.0000 |
| Mean |  |  |  |  | 11.181 |  |  | 1.00000 |  |  |
| %RSD |  |  |  |  |  |  |  |  |  |  |

**Sample Name: 6BDPA002 st 9 middle 1**

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | SarrpleNare | Nare | Vial | lrj | RT | *Area*  {µV"sec) | ResponseFactcr | ArrOlrt | Sa-rpleV\eig ht  {g) | Dilliion |
| 1 | 680PA002 st 9 niddle 1 | Beclo-dipro | 29 | 1 | 11.241 | 89115€ | 8911 57.9927i | 1.00000 | 2.0134 | 10.0000 |
| Mean |  |  |  |  | 11.241 |  |  | 1.00000 |  |  |
| % RSD |  |  |  |  |  |  |  |  |  |  |

**Sam ple Nam e: 6BDPA00 2 st 9 middle 2**

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | SarrpleNare | Nare | Vial | lrj | RT | *Nea*  (µV"sec) | ResponseFactor | Arrou1t | &vrpleV\eig ht  {g) | Diltiion |
| 1 | 68DPA002 st 9 niddle 2 | Beclo-dpro | 30 | 1 | 11.231: | 910970 | 910969.54703 | 1.00000 | 2.0050 | 10 .0000 |
| Mean |  |  |  |  | 11.231: |  |  | 1 .00000 |  |  |
| % R SD |  |  |  |  |  |  |  |  |  |  |

**Sam pie Name: 6BDPA002 st 9 bottom 1**

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | SarrpeNaTe | **Nare** | **Vial** | lrj | RT | *Nea*  (µV"se)c | ResponseFactcr | **ArrOlrt** | **&vrpl**eV\eig ht  (g) | Dilliion |
| 1 | 6BOPA002 st 9 bottom1 | Bec lo-dipro | 31 | 1 | 11.27( | 891457 | 891457.07665 | 1.00000 | 2.0071 | 10.0000 |
| Mean |  |  |  |  | 11.27( |  |  | 1.00000 |  |  |
| %RSD |  |  |  |  |  |  |  |  |  |  |

Sample Set: 6BDPA002\_S t9 inv Print ed 9:22 :33 AM ,Wednesday, A Page: 5 of 6

 **Quality Contra I**

**Analytical Report**

Report Method: Std Samp Reported by: A lfiani, A lfiani (aalf ia Project: Pandaan\2017 O1\BISys : 13 LC0300

**Sam pie Name: 6BDPA002 st 9 bottom 2**

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | **SarrpeNa,re** | **Na,re** | **Vial** | lrj | RT | ***Nea***  (µV\*sec) | ResponseFactor | **Arro.rt** | **Sarp!**eV\eight (g) | Dil u ion |
| 1 | 68DPA002 st 9 bottom 2 | Beclo-cipro | 32 | 1 | 11.27( | 921548 | 921547.69426 | 1.0000'.l | 2.0109 | 10.0000 |
| Mean |  |  |  |  | 11.27( |  |  | 1.0000'.l |  |  |
| %RSD |  |  |  |  |  |  |  |  |  |  |

**Sam pie Name: 6BDPA002 st 9 top 1**

7

***G170120***

**ac-01-ooa .05**



|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | SarpleNcrre | Narre | Vial | lrj | RT | Area (µV\*sec) | ResponseFactor | /J.ssay | fl.ssey  %LS | Cal Ctr1e Id | Arro.rt | SITTpleV\eight (g) | Dilution |
| 1 | 68DPA002 st 9 tq:>1 | Beta-dipro | 27 | 1 | 9.070 | 867976 | 0.00364 | 0.65353 | 102.11474 | 2073 | 263.25654 | 2.0134 | 10.0000 |
| Mean |  |  |  |  | 9.070 |  |  | 0.65353 | 102.11474 |  | 263.25654 |  |  |
| %RSD |  |  |  |  |  |  |  |  |  |  |  |  |  |
| **Sam p** | | | | | | **ie Name: 6BDPA002 st 9 top 2** | | | | | | | |
|  | SarpleNa,re | Narre | Vial | lrj | RT | Nea (µV\*sec) | ResponseFactor | /J.ssay | /J.ssey  %LS | Cal Ctr-..e Id | Amlu1t | Sa,-ple\/\eght (g) | Dilution |
| 1 | 68DPA002 st 9 tq:> 2 | Beta-cipro | 28 | 1 | 9.076 | 859059 | 0 .00364 | 0.63997 | 99.99501 | 2073 | 25'1.79177 | 2.011, | 10.0000 |
| Mean |  |  |  |  | 9.076 |  |  | 0.63997 | 99.99501 |  | 25'1.79177 |  |  |
| %RSD |  |  |  |  |  |  |  |  |  |  |  |  |  |

**Sam pie Name: 6BDPA002 st 9 mid die 1**

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | SarrpeNa,re | Na,re | Vial | lrj | RT | Area (µV\*sec) | ResponseFactor | /J.ssa,; | kisay  %LS | Cal C tr 1e  Id | Am:lult | SarrprN.Jeig tt (g) | Dilution |
| 1 | 68DPA002 st 9 rriddle1 | Beta-dipro | 29 | 1 | 9.120 | 844128 | 0.00364 | 0.64543 | 100.84769 | 2073 | 259.99002 | 2.0134 | 10.0000 |
| Mean |  |  |  |  | 9.120 |  |  | 0.64543 | 100.84769 |  | 259.99002 |  |  |
| % RSD |  |  |  |  |  |  |  |  |  |  |  |  |  |

**Sample Name: 6BDPA0 02 st 9 middle 2**

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | SarrpeNare | Nam | Vial | lnj | RT | Nea (µV\*sec) | ResponseFactor | fl.ssay | kisay  %LS | Cal Ctrle Id | Amlult | Sarrpe\f\Jejgt( (g) | Dilution |
| 1 | 68DPA002 st 9 rriddle 2 | Beta-dipro | 30 | 1 | 9.120 | 856166 | 0.00363 | 0.64308 | 100.48055 | 2073 | 259.04352 | 2.0050 | 10.0000 |
| Mean |  |  |  |  | 9.120 |  |  | 0.64308 | 100.48055 |  | 259.04352 |  |  |
| %RSD |  |  |  |  |  |  |  |  |  |  |  |  |  |

**Sample Name: 6BDPA002 st 9 bottom 1**

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | SarrpeNa,re | N.n-e | Vial | lrj | RT | Area (µV\*sec) | ResponseFactor | /lssay | kisay  %LS | Cal Ctr-..e Id | .ArrOl..nt | Sarrpe\/lJejgtt (g) | Dilution |
| 1 | 68DPA002 st 9 bottom 1 | Beta-dipro | 31 | 1 | 9.141 | 844402 | 0.00363 | 0.64744 | 101.16308 | 2073 | 260.80312 | 2.0071 | 10.0000 |
| Mean |  |  |  |  | 9.141 |  |  | 0.64744 | 101.16308 |  | 260.80312 |  |  |
| % RSD |  |  |  |  |  |  |  |  |  |  |  |  |  |

**Sample Name: 6BDPA002 st 9 bottom 2**

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | SarrpeNa,re | **N.n-e** | Vial | lrj | RT | *Nea*  (µV\*sec) | ResponseFactor | /lssay | k.sey  %LS | Cal  **CU'1e**  Id | **Amlu1t** | Sarrc:fo\f\Jejg **tt**  (g) | Dilution |
| 1 | 68DPA002 st 9 bottom 2 | Beta-dipro | 32 | 1 | 9.143 | 869430 | 0.00364 | 0.64365 | 100.5'1001 | 2073 | 259.27415 | 2.0109 | 10.0000 |
| Mean |  |  |  |  | 9.143 |  |  | 0.64365 | 100.57001 |  | 259.27415 |  |  |
| %RSD |  |  |  |  |  |  |  |  |  |  |  |  |  |

Sample Set: 6BDPA002 \_St9 inv Printed 9:22:33 AM 1Wednesday, A Page: 6 of 6

Vial

---.&-BDPA002 St9 inv in Pandaan\201L Q1\BDPA Bet.Dip\_JemJ:ililte on EMPWPRD3 as aalfiani/ GBL\_Chemist- Alter Sample Set

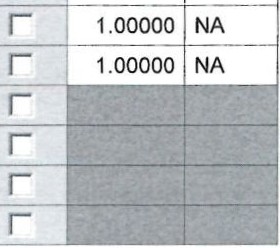
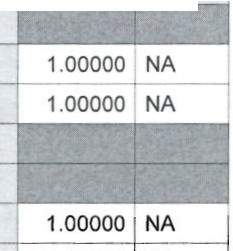
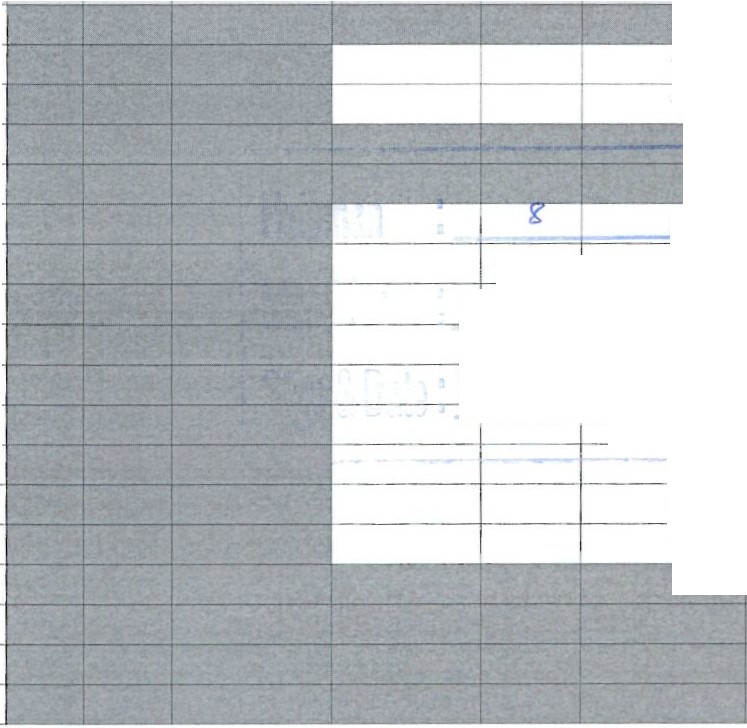
ln jl # of Label S I N S I T L ev e l Funct,·on Meth0d Set *I*

Reference

La be l

V

(ut) lnjs ampe ame ampe ype Report Method



T

Processing

Bath Vessel Transfer Time RI Senstiivity Solvent SampleWeight Dilution Altered AUW\_SG Ave\_lD

2

3

Normal

Don't Process or Report Don't Process or Report Normal

Normal

Don't Process or Report Don't Process or Report Don't Proce ss or Report

1.0000

1.0000

r

1.0000 r

1.0000

r

r

6

7

8

r

2.0134 10.0000 r

r

**Q**

**C 170** 20

2.0112

10.0000

**01-0 8.05** 1 . 00 00

1.0000 r

1.00000 NA

1.00000 NA

-"-r

- -.

12 I

Don't Process or Report

Don't Process or Repo\_rt Don't Process or Report

--r.oooo 1 .0 000 r 1.00000 NA

2.0071 10 .0000

2.0109 10.0000

1.0000 1.0000

r

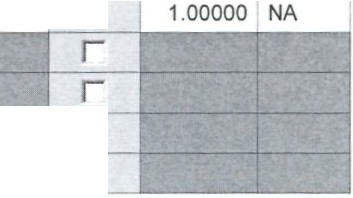
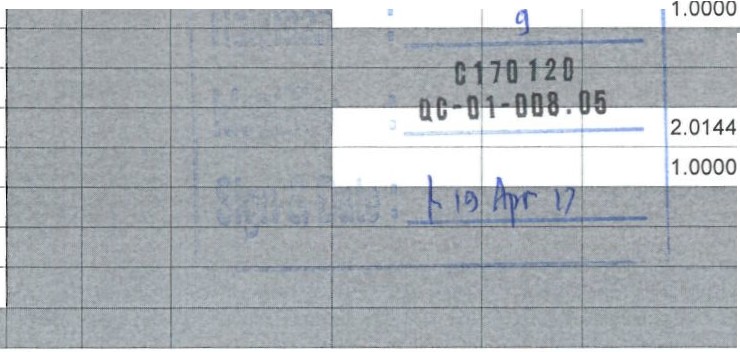
1.00000 NA

1. Don't Process or Report
2. Don't Process or Report
3. Normal
4. Normal
5. Normal
6. Normal

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | | | | | | | | Clear Calibration | BDPA\_Betoip Met Set |  |
| 2 | 25 | 10.0 | 3 | a | Bet-dip std-1  ---- | Standard  -<-- | | Inject Standards | BDPA\_BetDip Met Set |
| 3 | 26 10.0 3 b Bet-dip std-2 Standard | | | | | | Inject Standards | | BDPA\_BetDip Met Set |
| 4 |  |  |  |  |  |  | Calibrate | | BDPA\_Betoip Met Set | a\* b\* |
| 5 |  |  |  |  |  |  | Clear Calibration | | BDPA\_BetDip Met Set |  |
| 6 | 27 | 10.0 | 1 | C | 6BDPA002 st 9 top 1 | Unknown | Inject Samples | | BDPA\_BetDipMet Set |  |
| 7 | 28 | 10.0 |  | d | 6BDPA002 st 9 top 2 | Unknown | Inject Samples | | BDPA\_BetDip Met Set |  |
| 8 | 26 | 10.0 | 1 | e | Bet-dip std-2 | Standard | Inject Standards | | BDPA\_BetDip Met Set |  |
| 9 | 29 | 10.0 |  |  | 6BDPA002 st 9 middle 1 | Unknown | Inject Samples | | BDPA\_BetDip Met Set |  |
| 10 | 30 | 10.0 |  | g | 6BDPA002 st 9 middle 2 | Unknown | Inject Samples | | BDPA\_BetDip Met Set |  |
| 11 | 26 | 10.0 |  | h | Bet-dip std-2 | Standard | Inject Standards | | BDPA\_BetDip Met Set |  |
| 12 | 31 | 10.0 |  |  | 6BDPA002 st 9 bottom 1 | Unknown | Inject Samples | | BDPA\_BetDip Met Set |  |
| 13 | 32 | 10.0 |  | i | 6BDPA002 st 9 bottom 2 | Unknown | Inject Samples | | BDPA\_BetDip Met Set |  |
| 14 | 26 | 10.0 |  | k | Bet-dip std-2 | Standard | Inject Standards | | BDPA\_BetDip Met Set |  |
| 15 |  |  |  |  |  |  | Calibrate | | BDPA\_BetDip Met Set | b\* e\* h\* k\* |
| 16 |  |  |  |  |  |  | Quanlitate | | BDPA\_BetDip Met Set | c\* d \* f' g\* i\* j\* I |
| 17 |  |  |  |  |  |  | Summarize Custom Fields | |  |  |
| 18 |  |  |  |  |  |  | Clear Calibration | | BDPA\_BetDip Met Set |  |
|  | | | | | | | Inject Standards | | BDPA\_BetDip Met Set |  |
| Inject Standards | | BDPA\_BetDip Met Set |  |
| Calibrate | | BDPA\_BetDip Met Set | I\* m\* |
| Clear Calibration | | BDPA\_BetDip Met Set |  |
| Inject Samples | | BDPA\_BetDip Met Set |  |
| Inject Standards | | BDPA\_BetDip Met Set |  |
| Calibrate | | BDPA\_BetDip Met Set | **m\* o\*** |
| Quantitate | | BDPA\_BetDip Met Set | I n\* |
| Summarize Custom Fields | |  |  |
| Condition Column | | FlusshingOff\_60LC03 |  |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| 9 | Don't Process or Report I | -- 2.0134 | 10.0000 | **r** 1.00000 NA |
| 10 |  | *'L* 2.0050 | 10.0000 | r 1.00000 NA |

- - - ---=6=B-D=PA002=-=St9:·...:•.n:.:-v=--i"n-'--P':...a::::n.d aan\2017\_9 1\BDPA Bet.Dip\_Tern late on EMPWPRD3 as aalfiani/GBL Chemist -Alter Sam Set



I I

Processing

Bath Vessel j Transfer Time RI Sensitivity Solvent SampleWeight Dilution Altered AUW\_SG Ave\_lD

19 Don't Process or Report 20

21

22

23

1. Don't Process or Report
2. Normal 26

27

28

1.0000

1.0000 r

1.0000 r

r

1.00000 NA

1.00000 NA

r

10.0000 I

1.0000 r

1.00000 NA

r

r

Don't Process or Report

Normal

Normal

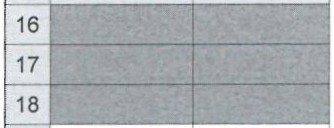
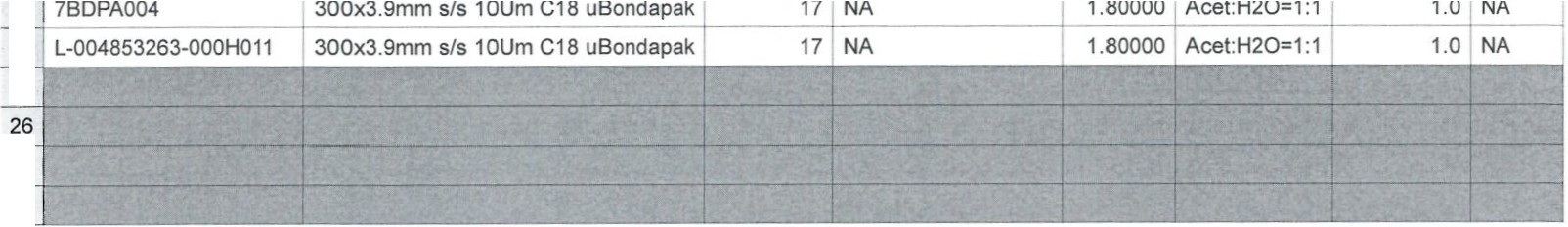
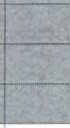
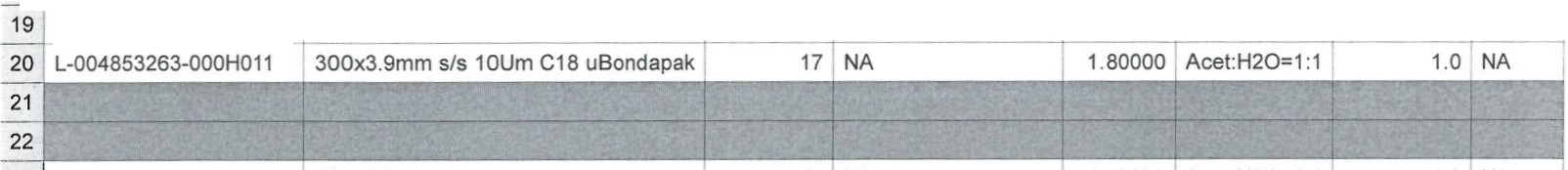
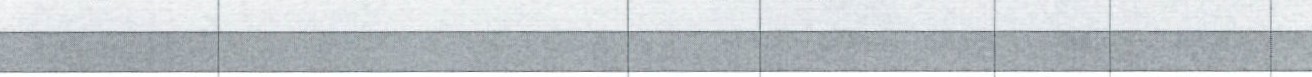
Don't Process or Report

Normal

Normal



l Batch\_lD ColumnNameC0 I Column\_lD I Column\_Temperature FlowRate Mobile\_Phase No\_of\_Tabs Pre\_No



2 L-004853263-000H011

3 L-004853263-000H011

300x3.9mm si s 10Um C18 uBondapak 300x3.9mm si s 10Um C18 uBondapak

17 NA---

17 NA

1 .80000 Acet:H2O=1:1

1.80000 Acet:H2O=1:1

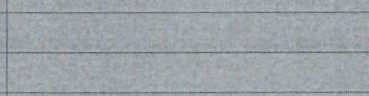
1.0 NA

1.0 **NA**

4 t--- - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - 1--- - -+- - - - - 1--- - - -1 1

5

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 6 | 6BDPA002 st 9 top 1 | 300x3.9mm s/s 10Um C18 uBondapak | 17 | **NA** | 1 .80000 | Acet:H2O=1:1 | 1.0 I | NA |
| 7 | 6BDPA002 st 9 top 2 | 300x3.9mm si s 10Um C18 uBondapak | 17 | **NA** | 1 .80000 | Acet:H2O=1:1 | 1.0 | **NA** |
| 8 | L-004853263-000H011 | 300x3.9mm s/s 10Um C18 uBondapak | 17 | **NA** | 1. 80000 | Acet:H20=1:1 | 1.0 | **NA** |
| 9 | 6BDPA002 st 9 middle 1 | 300x3.9mm s/s 10Um C18 uBondapak | 17 | NA | 1.80000 | Acet:H2O=1:1 | 1.0 | NA |
| 10 | 6BDPA002 st 9 middle 2 | 300x3.9mm s/s 10Um C18 uBondapak | 17 | **NA** | 1.80000 | Acet:H2O=1:1 | 1.0 | **NA** |
| 11 | L-004853263 -000H011 | 300x3 .9mm sis 10Um C18 uBondapak | 17 | **NA** | 1 .80000 | Acet:H2O=1:1 | 1.0 | **NA** |
| 12 | 6BDPA002 st 9 bottom 1 | 300x3.9mm si s 10Um C18 uBondapak | 17 | NA | 1.80000 | Acet:H2O=1:1 | 1.0 | **NA** |
| 13 | 6BDPA002 st 9 bottom 2 | 300x3.9mm s/s 10Um C18 uBondapak | 17 | **NA** | 1 .80000 | Acet:H2O=1:1 | 1.0 | NA |
| 14 | L-004853263-000H011 | 300x3.9mm s/s 10Um C18 uBondapak | 17 | **NA** | 1.80000 | Acet:H2O=1:1 | 1.0 | **NA** |
| 15 |  |  |  |  |  |  |  |  |
| 16 |  |  |  |  |  |  |  |  |
| 17 |  |  |  |  |  |  |  |  |
| 18 |  |  |  |  |  |  |  |  |
|  | L-004853263-000H011 | 300x3.9mm sis 10Um C18 uBondapak | 17 | NA | 1.80000 | Acet:H2O=1:1 | 1.0 | NA |



--

23 7BDPA004 300x3.9mm s/s 10Um C18 uBondapak 17 NA

t- - -

-1 - - -- -- - - - - -

24 j L-004853263-00H0011 300x3.9mm s/s 10Um C18 uBondapak 17 NA

25

27

28

Samp\_Type Wavelength

# --

Samp\_Type Wavelength

|  |  |  |
| --- | --- | --- |
|  | Samp\_Type Wavelength | |
| 6 |  | 254.00000 |
| 7 | unknown | 254.00000 |
| 8  9 | standard | 254.00000 |
| unknown | 254.00000 |
|  | unknown | 254.00000 |

Samp\_Type Waveel ngth

1. standard
2. standard

----,

254.00000

254.00000

unknown -

11Istandadr

1. unknown
2. unknown

254.00000

254.00000

254.00000

--t

14 standard 254.00000 19 standard

5 f-15----1,..--------- 20 standard

4

254.00000

254.00000 1

- - - - - 6"=-Bi' DPA002\_St9inv in Pandaan\2017\_O1\BDPABet.Dip\_Template on EMPWPRD3 as aalfiani/GBL\_Chemist - Alter Sample Set

21

22

Samp\_TypeIWavelength

23 unknown 254.00000

24 standard 254.00000



25

26

27

28

*\0*

**C 17 0120**

**QC-01- 008.05**

