

Effective Date:	PT. Merck Sharp Dohme Pharma Tbk		Datasheet No:
13 JUN 2016			C170127
Superseded No: QC-01-011.03	Data Sheet Check List Variable Database Empower for Analysis with HPLC and GC Method		Document No: QC-01-011.04
Prepared by: <i>spain 10 jun 16</i>	Reviewed by: <i>spain 10 jun 16</i>	Approved by: <i>Carlo 10 Jun 16</i>	

Product Name/Purpose	Diprosone Ointment		
Batch No	6BDPA002 & g(inves); 7BDPA004		
Test	Betamethasone dipropionate assay		

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

a. Berat Standard	Yes <input checked="" type="checkbox"/> No <input type="radio"/>
b. Standard Dilution	Yes <input checked="" type="checkbox"/> No <input type="radio"/>
c. Berat Sample/ Volume Sample	Yes <input checked="" type="checkbox"/> No <input type="radio"/>
d. Sample Dilution	Yes <input checked="" type="checkbox"/> No <input type="radio"/>
e. AUW (Tablet Only)	Yes <input type="radio"/> No <input checked="" type="checkbox"/>
f. Label Claim	Yes <input checked="" type="checkbox"/> No <input type="radio"/>
g. Standard Potency	Yes <input checked="" type="checkbox"/> No <input type="radio"/>
h. Sample Set Pre Run	Yes <input checked="" type="checkbox"/> No <input type="radio"/>

Keterangan: *DA*

Performed by & Date	<i>SPB</i>	1 8 A P R 1 7
Verified by & Date	<i>spay</i>	1 8 A P R 1 7

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

a. Berat Standard	Yes <input checked="" type="checkbox"/> No <input type="radio"/>
b. Standard Dilution	Yes <input checked="" type="checkbox"/> No <input type="radio"/>
c. Berat Sample/ Volume Sample	Yes <input checked="" type="checkbox"/> No <input type="radio"/>
d. Sample Dilution	Yes <input checked="" type="checkbox"/> No <input type="radio"/>
e. AUW (Tablet Only)	Yes <input type="radio"/> No <input checked="" type="checkbox"/>
f. Label Claim	Yes <input checked="" type="checkbox"/> No <input type="radio"/>
g. Standard Potency	Yes <input checked="" type="checkbox"/> No <input type="radio"/>

Reviewed by & Date	<i>spain</i>	1 9 A P R 1 7
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**History:**

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 Aug 2013, TR No.133973, Date of Issue: 22 May 2013
4. QC-01-011.03, Effective Date: **13 JUN 2016**



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PT. Merck Sharp Dohme Pharma Tbk

Pr Proprietary

Effective Date:	13 JUN 2016
Superseded No:	QC-01-008.04
Prepared by: <i>Jayamur 07 jun 16</i>	Reviewed by: <i>spm 10 Jun 16</i>



Datasheet No:  
C170120

Document No:  
QC-01-008.05

Approved by:  
*Janitha*  
10 Jun 16Data Testing

Test	Betamethasone Dipropionate assay		Procedure Doc	T1CH0013.07
HPLC ID	13-LC03-00	Calibration Due Date	Jan 18	Instrument Use Log <input checked="" type="checkbox"/>
Column Name	300 x 3.9 mm 10 μm C18 uBondapak		Column Use Log	Yes <input checked="" type="checkbox"/>
Guard Column	NA			
Injection Volume	10 μL			

Mobil Phase

No	Reagent Name	Lot No	Expiry Date
1	Acetonitrile	I830330	30 Apr 19
2	H <sub>2</sub> O	NA	NA
		NA	18 Apr 17

(Keterangan) Acetonitrile : H<sub>2</sub>O = 1000 ml : 1000 mlDiluents

No	Reagent Name	Lot No	Expiry Date	Vol (ml)
1	H <sub>2</sub> O	NA	NA	60
2	Methanol	I844007	31 Jul 19	540
NA	NA	NA	NA	NA

(Keterangan) NA

Effective Date:	13 JUN 2016
Superseded No:	QC-01-008.04



PT. Merck Sharp Dohme Pharma Tbk

### HPLC DATASHEET

Datasheet No:	C170120
Document No:	QC-01-008.05

#### Standard

Standard Name	Lot No	Expiry Date	Potency
Beta-dipro 1 dan 2	L-004853263-000H011	31 Mar 19	99.3 %
Becllo-Dipro	L-004960471-000L002	31 Jul 19	99.7 %
	NA		
	18 Apr 17		

#### Sample

Sample Name	Batch No/ Control No
Diprosone Ointment	6BDPA002 Stg retest .
Diprosone Ointment	7BDPA004
	NA
	18 Apr 17

Refer to Weighing Record No C170355; C170356; C170357; C170361; C170362; C170363 For the printout

(Keterangan) NA

System Suitability Parameters Met	Yes <input checked="" type="checkbox"/>	No <input type="radio"/>
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Performed by & Date	YH	1	8	A	P	r	i	7
Reviewed by & Date	Spry	1	9	A	P	r	i	7

#### History:

- QC-01-008.00, Effective Date: 17 Jan 2005, initial release
- QC-01-008.01, Effective Date: 09 Aug 2006, LCR No.CRQC0806085, Date of Issue: 08 Aug 2006
- QC-01-008.02, Effective Date: 11 Feb 2008, LCR No.CR0208045D, Date of Issue: 05 Feb 2008
- QC-01-008.03, Effective Date: 20 Nov 2008, LCR No.CR1108372D, Date of Issue: 18 Nov 2008
- QC-01-008.04, Effective Date: 11 Jun 2013, TR No.133968, Date of Issue: 22 May 2013
- QC-01-008.05, Effective Date: 13 JUN 2016



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PT. Merck Sharp Dohme Pharma Tbk

Pr Proprietary

Effective Date:	13 JUN 2016
Superseded No:	QC-01-001.02
Prepared by:	<i>Espin</i>


**PT. Merck Sharp Dohme Pharma Tbk**
**WEIGHING RECORD**
**Datasheet No:**  
**C170355**
**Document No:**  
**QC-01-001.03**

Reviewed by:

*Espin 10 Jun 16*

Approved by:

*Janti 10 Jun 16*

Product Name/Purpose	Batch No
Diprosone Ointment	#6BDPA002 #9 retest 18 Apr 17 7BDPA004

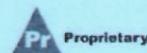
18.04.2017	10:37	18.04.2017	10:43	18.04.2017	10:51
16MT0200		16MT0200		16MT0200	
NAMA BAHAN	Beta dipro 1	NAMA BAHAN	Beta dipro 2	NAMA BAHAN	Beclo dipro
LOT/BATCH	L-004853263-000H011	LOT/BATCH	L-004853263-000H011	LOT/BATCH	L-004960471-000L002
1	0.0000 g	1	0.0000 g	1	0.0000 g
2	0.0503 g	2	0.0501 g	2	0.0303 g
3	0.0000 g	3	0.0000 g	3	0.0000 g
n	3	n	3	n	3
x	0.01677 g	x	0.01670 g	x	0.01010 g
s	0.02904 g	s	0.02893 g	s	0.01749 g
s.rel	173.17 %	s.rel	173.23 %	s.rel	173.17 %
Min	0.0000 g	Min	0.0000 g	Min	0.0000 g
Max	0.0503 g	Max	0.0501 g	Max	0.0303 g
Diff.	0.0503 g	Diff.	0.0501 g	Diff.	0.0303 g
Sum	0.0503 g	Sum	0.0501 g	Sum	0.0303 g
Signature	<i>(JL) 18 Apr 17</i>	Signature	<i>(JL) 18 Apr 17</i>	Signature	<i>(JL) 18 Apr 17</i>

Reviewed by & Date	<i>Espin</i>	1	9	4	P	R	I	T
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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
4. QC-01-001.03, Effective Date: 13 JUN 2016

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PT. Merck Sharp Dohme Pharma Tbk

Effective Date:	13 JUN 2016
Superseded No:	QC-01-001.02
Prepared by:	Spam 07 jun 16

**PT. Merck Sharp Dohme Pharma Tbk**
**WEIGHING RECORD**
**Datasheet No:**  
**C170356**
**Document No:**  
**QC-01-001.03**

Reviewed by:

Spam 10 Jun 16

Approved by:

Janice 10 Jun 16

Product Name/Purpose	Batch No
Diprosone Ointment	6BDPA002 st 9 retest 7BDPA004

18.04.2017 16MT0200 NAMA BAHAN Diprosone ointment LOT/BATCH 6BDPA002 st 9 top 1 1 0.0000 g 2 2.0134 g n 2 x 1.00670 g s ----- s.rel ----- Min 0.0000 g Max 2.0134 g Diff. 2.0134 g Sum 2.0134 g	18.04.2017 16MT0200 NAMA BAHAN Diprosone ointment LOT/BATCH 6BDPA002 st 9 top 2 1 0.0000 g 2 2.0112 g n 2 x 1.00560 g s ----- s.rel ----- Min 0.0000 g Max 2.0112 g Diff. 2.0112 g Sum 2.0112 g	18.04.2017 16MT0200 NAMA BAHAN Diprosone ointment LOT/BATCH 6BDPA002 st 9 Mid 1 1 0.0000 g 2 2.0134 g n 2 x 1.00670 g s ----- s.rel ----- Min 0.0000 g Max 2.0134 g Diff. 2.0134 g Sum 2.0134 g
Signature 	Signature 	Signature 

Reviewed by & Date	Spam	1   9   A   P   r   1   7
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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
4. QC-01-001.03, Effective Date: 13 JUN 2016



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Document Control Centre  
PT. Merck Sharp Dohme Pharma Tbk

Effective Date:	13 JUN 2016
Superseded No:	QC-01-001.02
Prepared by: <i>Espin</i>	Reviewed by: <i>Espin 10 Jun 16</i>



PT. Merck Sharp Dohme Pharma Tbk

Datasheet No:

C170357

Document No:  
QC-01-001.03Approved by:  
*J. S. A. 10 Jun 16*

Product Name/Purpose	Batch No
Diprosone Ointment	6BDPA002 st 9 retest 7BDPA004

18.04.2017 16MT0200 NAMA BAHAN Diprosone ointment LOT/BATCH 6BDPA002 st 9 Mid 2 1 0.0000 g 2 2.0050 g n 2 x 1.00250 g s ----- s.rel ----- Min 0.0000 g Max 2.0050 g Diff. 2.0050 g Sum 2.0050 g  Signature <i>Espin</i> 18 Apr 17	18.04.2017 16MT0200 NAMA BAHAN Diprosone ointment LOT/BATCH 6BDPA002 st 9 Btm 1 1 0.0000 g 2 2.0071 g n 2 x 1.00355 g s ----- s.rel ----- Min 0.0000 g Max 2.0071 g Diff. 2.0071 g Sum 2.0071 g  Signature <i>Espin</i> 18 Apr 17	18.04.2017 16MT0200 NAMA BAHAN Diprosone ointment LOT/BATCH 6BDPA002 st 9 Btm 2 1 0.0000 g 2 2.0109 g n 2 x 1.00545 g s ----- s.rel ----- Min 0.0000 g Max 2.0109 g Diff. 2.0109 g Sum 2.0109 g  Signature <i>Espin</i> 18 Apr 17
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Reviewed by & Date	Espin	19 Apr 17
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## History :

- QC-01-001.00, Effective Date: 25 Juli 2003
- QC-01-001.01, Effective Date: 18 Jan 2005, LCR No.01QC0105014, Date of Issue: 17 Jan 2005
- QC-01-001.02, Effective Date: 11 Jun 2013, TR No.133963, Date of Issue: 22 May 2013
- QC-01-001.03, Effective Date: 13 JUN 2016





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Document Control Centre

## Datasheet No:

C170361

Effective Date: 13 JUN 2016	 PT. Merck Sharp Dohme Pharma Tbk	PT. Merck Sharp Dohme Pharma Tbk Datasheet No: C170361
Superseded No: QC-01-001.02	WEIGHING RECORD	Document No: QC-01-001.03
Prepared by: <i>Ayman. 07 Jun 16</i>	Reviewed by: <i>Espin 10 Jun 16</i>	Approved by: <i>Karina 10 Jun 16</i>

Product Name/Purpose	Batch No
Diprosone Ointment	6BDPA002 B9 7BDPA004

18.04.2017	12122	18.04.2017	13124
1810300		1810300	
Temp. BATH		Temp. BATH	
107.0277		107.0277	
ABDP3002 at 9 top 2		ABDP3002 at 9 mid 1	
1	6.08 g	1	6.08 g
2	6.11 g	2	6.19 g
3	2	3	2
4	6.055 g	4	6.095 g
5	-----	5	-----
6	-----	6	-----
7	-----	7	-----
8	-----	8	-----
9	-----	9	-----
Sum	6.11 g	Sum	6.13 g
Max	6.11 g	Max	6.19 g
Min	6.08 g	Min	6.08 g
Diff.	6.11 g	Diff.	6.19 g
Sum	6.11 g	Sum	6.13 g
Signature	(JLH) 18 Apr 17	Signature	(JLH) 18 Apr 17

Reviewed by & Date Spring 19 April 17

## 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  
4. QC-01-001.03, Effective Date: 13 JUN 2016



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Effective Date: 13 JUN 2016	 PT. Merck Sharp Dohme Pharma Tbk	Datasheet No: C170362
Superseded No: QC-01-001.02	WEIGHING RECORD	Document No: QC-01-001.03
Prepared by: Anggita, 07 Jun 16	Reviewed by: Spirin, 10 Jun 16	Approved by: Yanti, 10 Jun 16

Product Name/Purpose	Batch No
Diprosone Ointment	6BDPA002 A9 7BDPA004

Reviewed by & Date

Spain

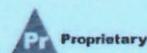
19 April 17

## 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  
4. QC-01-001.03, Effective Date: 13 JUN 2016



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Document Control Centre  
PT. Merck Sharp Dohme Pharma Tbk

Datasheet No:

C170363

Effective Date:	13 JUN 2016
Superseded No:	QC-01-001.02
Prepared by:	Agusw. 07 jun 16

**PT. Merck Sharp Dohme Pharma Tbk**
**WEIGHING RECORD**Document No:  
QC-01-001.03

Reviewed by:

Opini 10 jun 16

Approved by:

Yanitha 10 Jun 16

Product Name/Purpose	Batch No
Diprosone Ointment	6BDPA002 # 9 7BDPA004

18.04.2017	14:40
16MT0200	
NAMA BAHAN	
Diprosone ointment	
LOT/BATCH	7BDPA004
1	0.0000 g
2	2.0144 g
n	2
x	1.00720 g
s	-----
s.rel	-----
Min	0.0000 g
Max	2.0144 g
Diff.	2.0144 g
Sum	2.0144 g
Signature (JDS)	
18 Apr 17	

Reviewed by & Date	Opini	1	9	A	P	R	I	T
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**History :**

- QC-01-001.00, Effective Date: 25 Juli 2003
- QC-01-001.01, Effective Date: 18 Jan 2005, LCR No.01QC0105014, Date of Issue: 17 Jan 2005
- QC-01-001.02, Effective Date: 11 Jun 2013, TR No.133963, Date of Issue: 22 May 2013
- QC-01-001.03, Effective Date: 13 JUN 2016

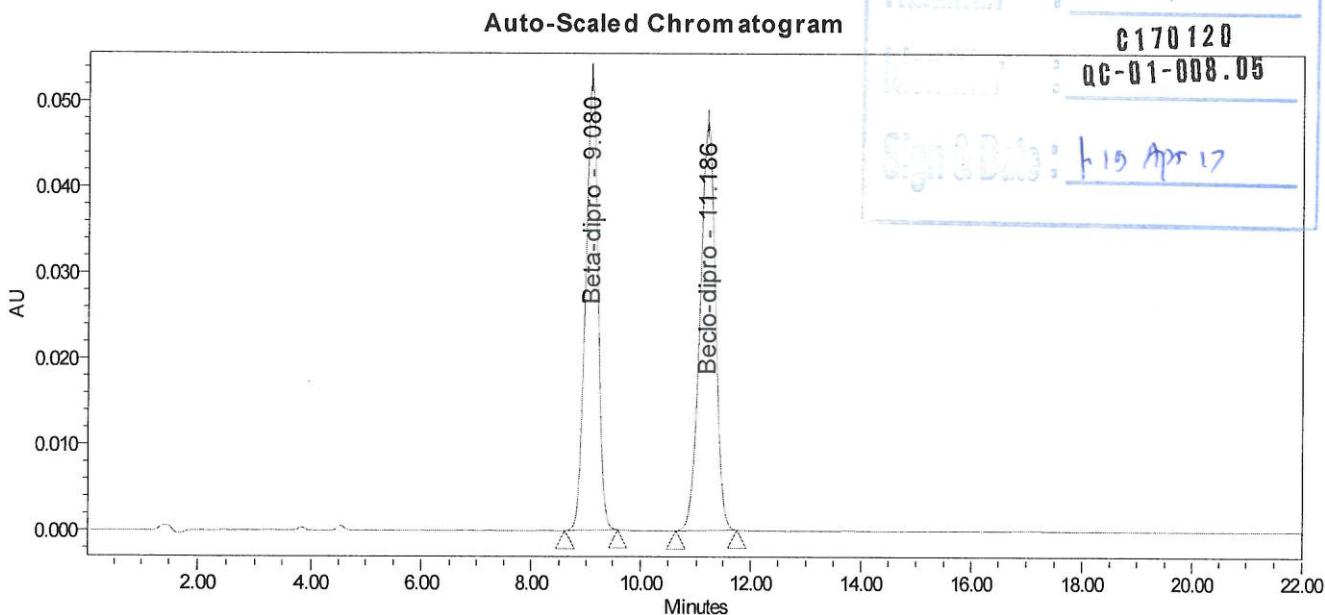


**PT. Schering Plough Indonesia Tbk.**  
**Quality Control**  
**Analytical Report**

Total  
Halaman : 15

Sample Name: Bet-dip std-1  
Sample Type: Standard  
Vial: 25  
Injection #: 1  
Injection Volume: 10.00 ul  
Run Time: 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: 2487Channel 1  
Proc. Chnl. Descr.: 2487Channel 1

Date Acquired: Tuesday, April 18, 2017 1:26:42 PM WIT  
Date Processed: Wednesday, April 19, 2017 7:33:27 AM WIT



**Peak Results**

	Name	RT	Area	Height	Amount	USP Resolution	USP Tailing	USP Plate Count	K Prime
1	Beta-dipro	9.080	875982	52844	50.300		1.0	6834.0	8.1
2	Beclo-dipro	11.186	962159	47428	1.000	4.2	1.0	6908.4	10.2

Reported by User: Alfiani, Alfiani (aalfiani)

Project Name: Pandaan\2017\_Q1\BDPA\_Bet.Dip\_Template

Report Method: SystemSuitability

Date Printed:

Report Method ID: 1074

Wednesday, April 19, 2017

Page: 1 of 1

9:21:58 AM Asia/Jakarta

# Quality Control

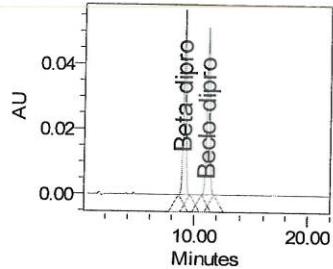
## Analytical Report

Report Method: Std Samp

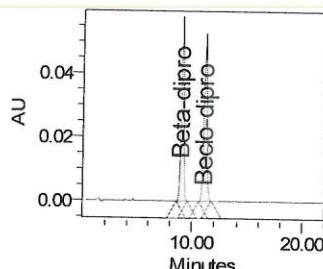
Reported by: Alfiani, Alfiani (aalfia) Project: Pandaan\2017\_Q1\BISys: 13\_LC0300

Sample Name:	6BDPA002 st 9 middle 2,	Acquired By:	aalfiani
Sample Type:	Unknown, Standard	Date Acquired:	Tuesday, April 18, 2017 1:26:42
Vial:	26, 28, 29, 31, 25, 32, 27, 30	Acq. Method Set:	BDPA_BetDip Met Set
Injection #:	1, 2, 3	Date Processed:	Wednesday, April 19, 2017
Injection Volume:	10.00 ul	Processing Method:	BDPA_ProcMetLC02
Run Time:	22.0, 16.0 Minutes	Processed by:	aalfiani/GBL_Chemist
Sample Set Name:	6BDPA002_St9 inv	Sample Set Start Date:	Tuesday, April 18, 2017 1:25:42

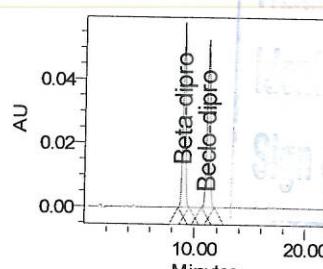
### Standards



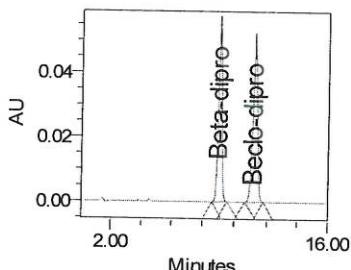
Bet-dip std-1;  
Tuesday, April 18,  
2017 1:26:42 PM  
WIT; Inj Id 1890



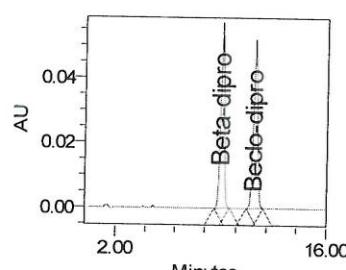
Bet-dip std-1;  
Tuesday, April 18,  
2017 1:49:36 PM  
WIT; Inj Id 1893



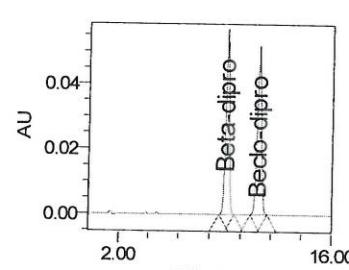
Bet-dip std-1;  
Tuesday, April 18,  
2017 2:12:31 PM  
WIT; Inj Id 1895



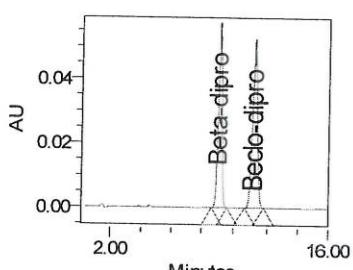
Bet-dip std-2;  
Tuesday, April 18,  
2017 3:20:15 PM  
WIT; Inj Id 1921



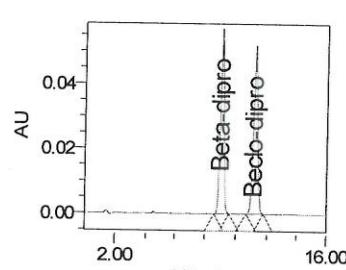
Bet-dip std-2;  
Tuesday, April 18,  
2017 3:37:27 PM  
WIT; Inj Id 1923



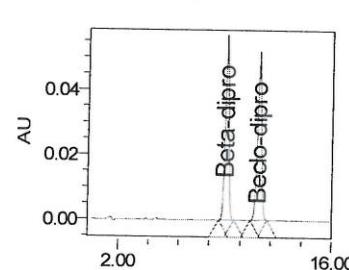
Bet-dip std-2;  
Tuesday, April 18,  
2017 3:54:22 PM  
WIT; Inj Id 1926



Bet-dip std-2;  
Tuesday, April 18,  
2017 3:20:15 PM  
WIT; Inj Id 1921



Bet-dip std-2;  
Tuesday, April 18,  
2017 3:37:27 PM  
WIT; Inj Id 1923

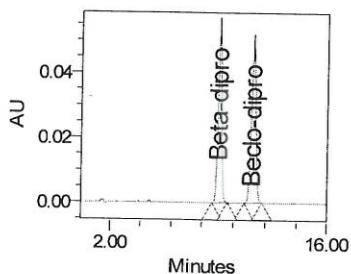


Bet-dip std-2;  
Tuesday, April 18,  
2017 3:54:22 PM  
WIT; Inj Id 1926

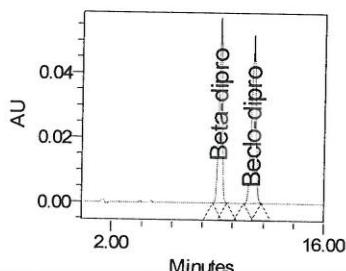
# Quality Control Analytical Report

Report Method: Std Samp

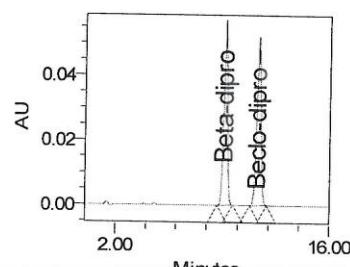
Reported by: Alfiani, Alfiani (aalfia) Project: Pandaan\2017\_Q1\BISys: 13\_LC0300



Bet-dip std-2;  
Tuesday, April 18,  
2017 4:46:19 PM  
WIT; Inj Id 1949



Bet-dip std-2;  
Tuesday, April 18,  
2017 5:38:00 PM  
WIT; Inj Id 1981



Bet-dip std-2;  
Tuesday, April 18,  
2017 6:29:35 PM  
WIT; Inj Id 1990

## Name : Beclo-dipro

	Sample Name	Name	Vial	Inj	RT (min)	Area	Amount	Area ( $\mu V^*sec$ )	ResponseFactor	Manual
1	Bet-dip std-1	Beclo-dipro	25	1	11.186	962159	1.000	962159	962158.56289	No
2	Bet-dip std-1	Beclo-dipro	25	2	11.169	982150	1.000	982150	982150.37084	No
3	Bet-dip std-1	Beclo-dipro	25	3	11.167	981822	1.000	981822	981821.57993	No
4	Bet-dip std-2	Beclo-dipro	26	1	11.178	982115	1.000	982115	982115.3979C	No
5	Bet-dip std-2	Beclo-dipro	26	1	11.178	982115	1.000	982115	982115.3979C	No
6	Bet-dip std-2	Beclo-dipro	26	2	11.179	973171	1.000	973171	973171.14986	No
7	Bet-dip std-2	Beclo-dipro	26	2	11.179	973171	1.000	973171	973171.14986	No
8	Bet-dip std-2	Beclo-dipro	26	3	11.181	972500	1.000	972500	972500.20689	No
9	Bet-dip std-2	Beclo-dipro	26	3	11.181	972500	1.000	972500	972500.20689	No
10	Bet-dip std-2	Beclo-dipro	26	1	11.218	975301	1.000	975301	975301.28351	No
11	Bet-dip std-2	Beclo-dipro	26	1	11.257	982848	1.000	982848	982847.54637	No
12	Bet-dip std-2	Beclo-dipro	26	1	11.283	984721	1.000	984721	984721.03671	No
Mean					11.2	977048				
% RSD					0.3	0.7				

3  
C170120  
QC-01-008.05  
Signature: J.19 Apr 17

## Cal Curve Id: 2065

	Sample Name	Name	Vial	Inj	RT (min)	Area ( $\mu V^*sec$ )	ResponseFactor	Std Wt (mg)	Label_Strength	Std Potency	Std Dilution	Inj Id
1	Bet-dip std-1	Beclo-dipro	25	1	11.186	962159	962158.56289	1.000				1890
2	Bet-dip std-1	Beclo-dipro	25	2	11.169	982150	982150.37084	1.000				1893
3	Bet-dip std-1	Beclo-dipro	25	3	11.167	981822	981821.57993	1.000				1895
4	Bet-dip std-2	Beclo-dipro	26	1	11.178	982115	982115.3979C	1.000				1921
5	Bet-dip std-2	Beclo-dipro	26	2	11.179	973171	973171.14986	1.000				1923
6	Bet-dip std-2	Beclo-dipro	26	3	11.181	972500	972500.20689	1.000				1926
Mean					11.2	975653	975652.87805					
% RSD					0.1	0.82026	0.82026					

## Cal Curve Id: 2074

	Sample Name	Name	Vial	Inj	RT (min)	Area ( $\mu V^*sec$ )	ResponseFactor	Std Wt (mg)	Label_Strength	Std Potency	Std Dilution	Inj Id
1	Bet-dip std-2	Beclo-dipro	26	1	11.178	982115	982115.3979C	1.000				1921
2	Bet-dip std-2	Beclo-dipro	26	2	11.179	973171	973171.14986	1.000				1923

# Quality Control Analytical Report

Report Method: Std Samp

Reported by: Alfiani, Alfiani (aalfia) Project: Pandaan\2017\_Q1\BISys: 13\_LC0300

## Cal Curve Id: 2074

	Sample Name	Name	Vial	Inj	RT (min)	Area ( $\mu$ V*sec)	ResponseFactor	Std Wt (mg)	Label_Strength	Std Potency	Std Dilution	Inj Id
3	Bet-dip std-2	Beclo-dipro	26	3	11.181	972500	972500.20689	1.000				1926
4	Bet-dip std-2	Beclo-dipro	26	1	11.218	975301	975301.28351	1.000				1949
5	Bet-dip std-2	Beclo-dipro	26	1	11.257	982848	982847.54637	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					

## Cal Curve Id: 2064

	Sample Name	Name	Vial	Inj	RT (min)	Area ( $\mu$ V*sec)	ResponseFactor	Std Wt (mg)	Label_Strength	Std Potency	Std Dilution	Inj Id
1	Bet-dip std-1	Beta-dipro	25	1	9.080	875982	0.01810	50.300	0.64000	0.99300	400.00000	1890
2	Bet-dip 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-dip std-2	Beta-dipro	26	1	9.075	889691	0.01808	50.100	0.64000	0.99300	400.00000	1921
5	Bet-dip 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	9.077	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					

## Cal Curve Id: 2073

	Sample Name	Name	Vial	Inj	RT (min)	Area ( $\mu$ V*sec)	ResponseFactor	Std Wt (mg)	Label_Strength	Std Potency	Std Dilution	Inj 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	9.077	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-dip 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					

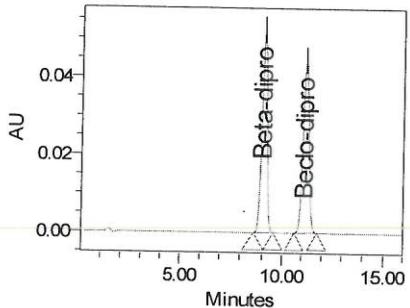
170120	4
QC-01-008.05	
Sign Date: 19 Apr 17	

# Quality Control

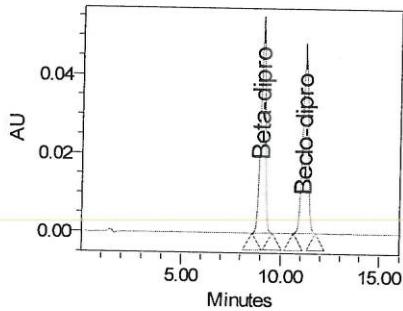
## Analytical Report

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

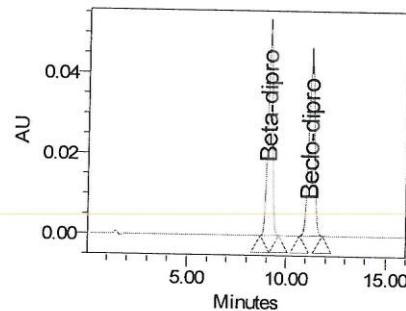
### Samples



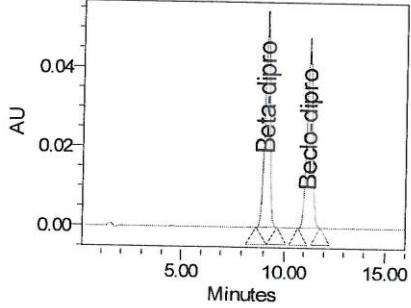
Tuesday, April 18, 2017  
4:11:50 PM WIT;  
6BDPA002 st 9 top 1; Inj 1;  
Inj Id 1943



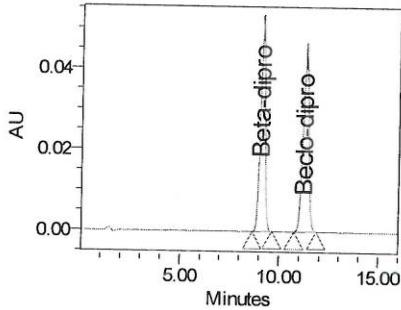
Tuesday, April 18, 2017  
4:29:02 PM WIT;  
6BDPA002 st 9 top 2; Inj 1;  
Inj Id 1946



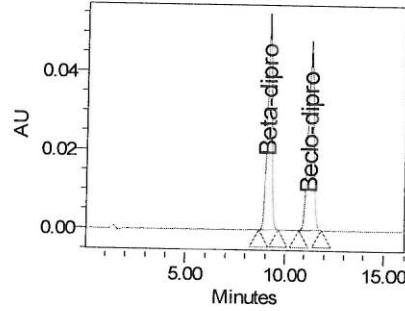
Tuesday, April 18, 2017  
5:03:31 PM WIT;  
6BDPA002 st 9 middle 1;  
Inj 1; Inj Id 1952



Tuesday, April 18, 2017  
5:20:44 PM WIT;  
6BDPA002 st 9 middle 2;  
Inj 1; Inj Id 1961



Tuesday, April 18, 2017  
5:55:11 PM WIT;  
6BDPA002 st 9 bottom 1;  
Inj 1; Inj Id 1984



Tuesday, April 18, 2017  
6:12:21 PM WIT;  
6BDPA002 st 9 bottom 2;  
Inj 1; Inj Id 1987

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

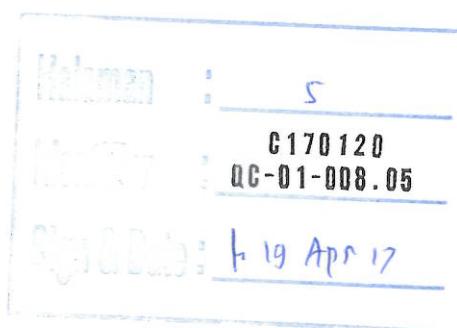
	Name	Vial	Inj	RT	Area	Inj Id	Peak Type	Manual
1	Beclo-dipro	31	1	11.27C	891457.1	1984	Int Std	No
Mean				11.27C	891457			
% RSD								

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

	Name	Vial	Inj	RT	Area	Inj Id	Peak Type	Manual
1	Beclo-dipro	32	1	11.27C	921547.7	1987	Int Std	No
Mean				11.27C	921548			
% RSD								

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

	Name	Vial	Inj	RT	Area	Inj Id	Peak Type	Manual
1	Beclo-dipro	29	1	11.241	891158.C	1952	Int Std	No
Mean				11.241	891158			
% RSD								



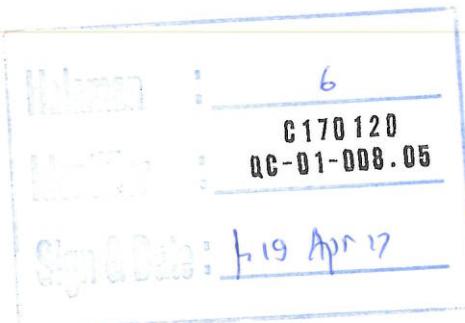
# Quality Control Analytical Report

Report Method: Std Samp

Reported by: Alfiani, Alfiani (aalfia) Project: Pandaan\2017\_Q1\BISys: 13\_LC0300

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

	Name	Vial	Inj	RT	Area	Inj Id	Peak Type	Manual
1	Beclo-dipro	30	1	11.23E	910969.5	1961	Int Std	No
Mean				11.23E	910970			
% RSD								

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

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

	Name	Vial	Inj	RT	Area	Inj Id	Peak Type	Manual
1	Beclo-dipro	27	1	11.174	904964.6	1943	Int Std	No
Mean				11.174	904965			
% RSD								

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

	Name	Vial	Inj	RT	Area	Inj Id	Peak Type	Manual
1	Beclo-dipro	28	1	11.181	915654.8	1946	Int Std	No
Mean				11.181	915655			
% RSD								

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

	SampleName	Name	Vial	Inj	RT	Area ( $\mu V^{\circ}sec$ )	ResponseFactor	Amount	SampleWeight (g)	Dilution
1	6BDPA002 st 9 top 1	Beclo-dipro	27	1	11.174	904965	904964.56879	1.00000	2.0134	10.0000
Mean					11.174			1.00000		
% RSD										

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

	SampleName	Name	Vial	Inj	RT	Area ( $\mu V^{\circ}sec$ )	ResponseFactor	Amount	SampleWeight (g)	Dilution
1	6BDPA002 st 9 top 2	Beclo-dipro	28	1	11.181	915655	915654.82835	1.00000	2.0112	10.0000
Mean					11.181			1.00000		
% RSD										

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

	SampleName	Name	Vial	Inj	RT	Area ( $\mu V^{\circ}sec$ )	ResponseFactor	Amount	SampleWeight (g)	Dilution
1	6BDPA002 st 9 middle 1	Beclo-dipro	29	1	11.241	89115E	891157.99277	1.00000	2.0134	10.0000
Mean					11.241			1.00000		
% RSD										

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

	SampleName	Name	Vial	Inj	RT	Area ( $\mu V^{\circ}sec$ )	ResponseFactor	Amount	SampleWeight (g)	Dilution
1	6BDPA002 st 9 middle 2	Beclo-dipro	30	1	11.23E	910970	910969.54703	1.00000	2.0050	10.0000
Mean					11.23E			1.00000		
% RSD										

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

	SampleName	Name	Vial	Inj	RT	Area ( $\mu V^{\circ}sec$ )	ResponseFactor	Amount	SampleWeight (g)	Dilution
1	6BDPA002 st 9 bottom 1	Beclo-dipro	31	1	11.27C	891457	891457.07665	1.00000	2.0071	10.0000
Mean					11.27C			1.00000		
% RSD										

# Quality Control Analytical Report

Report Method: Std Samp

Reported by: Alfiani, Alfiani (aalfia) Project: Pandaan\2017\_Q1\BISys: 13\_LC0300

## Sample Name: 6BDPA002 st 9 bottom 2

	SampleName	Name	Vial	Inj	RT	Area ( $\mu$ V*sec)	ResponseFactor	Amount	SampleWeight (g)	Dilution
1	6BDPA002 st 9 bottom 2	Beclo-dipro	32	1	11.27C	921548	921547.69426	1.00000	2.0109	10.0000
Mean					11.27C			1.00000		
% RSD										

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QC-01-008.05

19 Apr 17

## Sample Name: 6BDPA002 st 9 top 1

	SampleName	Name	Vial	Inj	RT	Area ( $\mu$ V*sec)	ResponseFactor	Assay	Assay %LS	Cal Curve Id	Amount	SampleWeight (g)	Dilution
1	6BDPA002 st 9 top 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													

## Sample Name: 6BDPA002 st 9 top 2

	SampleName	Name	Vial	Inj	RT	Area ( $\mu$ V*sec)	ResponseFactor	Assay	Assay %LS	Cal Curve Id	Amount	SampleWeight (g)	Dilution
1	6BDPA002 st 9 top 2	Beta-dipro	28	1	9.076	859059	0.00364	0.63997	99.99501	2073	257.79177	2.0112	10.0000
Mean					9.076			0.63997	99.99501		257.79177		
% RSD													

## Sample Name: 6BDPA002 st 9 middle 1

	SampleName	Name	Vial	Inj	RT	Area ( $\mu$ V*sec)	ResponseFactor	Assay	Assay %LS	Cal Curve Id	Amount	SampleWeight (g)	Dilution
1	6BDPA002 st 9 middle 1	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: 6BDPA002 st 9 middle 2

	SampleName	Name	Vial	Inj	RT	Area ( $\mu$ V*sec)	ResponseFactor	Assay	Assay %LS	Cal Curve Id	Amount	SampleWeight (g)	Dilution
1	6BDPA002 st 9 middle 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

	SampleName	Name	Vial	Inj	RT	Area ( $\mu$ V*sec)	ResponseFactor	Assay	Assay %LS	Cal Curve Id	Amount	SampleWeight (g)	Dilution
1	6BDPA002 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

	SampleName	Name	Vial	Inj	RT	Area ( $\mu$ V*sec)	ResponseFactor	Assay	Assay %LS	Cal Curve Id	Amount	SampleWeight (g)	Dilution
1	6BDPA002 st 9 bottom 2	Beta-dipro	32	1	9.143	869430	0.00364	0.64365	100.57001	2073	259.27415	2.0109	10.0000
Mean					9.143			0.64365	100.57001		259.27415		
% RSD													

## 6BDPA002\_St9 inv in Pandaan\2017\_Q1\BDPA Bet.Dip\_Template on EMPWPRD3 as aalfiani/GBL\_Chemist - Alter Sample Set

#	Vial	Inj Vol (uL)	# of Injs	Label	SampleName	Sample Type	Level	Function	Method Set / Report Method	Label Reference
1								Clear Calibration	BDPA_BetDip 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_BetDip 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_BetDip Met Set	
7	28	10.0	1	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	1	f	6BDPA002 st 9 middle 1	Unknown		Inject Samples	BDPA_BetDip Met Set	
10	30	10.0	1	g	6BDPA002 st 9 middle 2	Unknown		Inject Samples	BDPA_BetDip Met Set	
11	26	10.0	1	h	Bet-dip std-2	Standard		Inject Standards	BDPA_BetDip Met Set	
12	31	10.0	1	i	6BDPA002 st 9 bottom 1	Unknown		Inject Samples	BDPA_BetDip Met Set	
13	32	10.0	1	j	6BDPA002 st 9 bottom 2	Unknown		Inject Samples	BDPA_BetDip Met Set	
14	26	10.0	1	k	Bet-dip std-2	Standard		Inject Standards	BDPA_BetDip Met Set	
15								Calibrate	BDPA_BetDip Met Set	b* e* h* k*
16								Quantitate	BDPA_BetDip Met Set	c* d* f* g* i* j*
17								Summarize Custom Fields		
18								Clear Calibration	BDPA_BetDip Met Set	
19	25	10.0	3	l	Bet-dip std-1	Standard		Inject Standards	BDPA_BetDip Met Set	
20	26	10.0	3	m	Bet-dip std-2	Standard		Inject Standards	BDPA_BetDip Met Set	
21								Calibrate	BDPA_BetDip Met Set	l* m*
22								Clear Calibration	BDPA_BetDip Met Set	
23	33	10.0	2	n	7BDPA004	Unknown		Inject Samples	BDPA_BetDip Met Set	
24	26	10.0	2	o	Bet-dip std-2	Standard		Inject Standards	BDPA_BetDip Met Set	
25								Calibrate	BDPA_BetDip Met Set	m* o*
26								Quantitate	BDPA_BetDip Met Set	n*
27								Summarize Custom Fields		
28								Condition Column	FlushingOff_60LC03	

	Processing		Bath	Vessel	Transfer Time	RI Sensitivity	Solvent	SampleWeight	Dilution	Altered	AUW_SG	Ave_ID
1	Normal									<input type="checkbox"/>		
2	Don't Process or Report							1.0000	1.0000	<input type="checkbox"/>	1.00000	NA
3	Don't Process or Report							1.0000	1.0000	<input type="checkbox"/>	1.00000	NA
4	Normal									<input type="checkbox"/>		
5	Normal									<input type="checkbox"/>		
6	Don't Process or Report									<input type="checkbox"/>		
7	Don't Process or Report									<input type="checkbox"/>		
8	Don't Process or Report									<input type="checkbox"/>		
9	Don't Process or Report									<input type="checkbox"/>		
10	Don't Process or Report									<input type="checkbox"/>		
11	Don't Process or Report									<input type="checkbox"/>		
12	Don't Process or Report									<input type="checkbox"/>		
13	Don't Process or Report									<input type="checkbox"/>		
14	Don't Process or Report									<input type="checkbox"/>		
15	Normal									<input type="checkbox"/>		
16	Normal									<input type="checkbox"/>		
17	Normal									<input type="checkbox"/>		
18	Normal									<input type="checkbox"/>		

## 6BDPA002\_St9 inv in Pandaan\2017\_Q1\BDPA Bet.Dip\_Template on EMPWPRD3 as aalfiani/GBL\_Chemist - Alter Sample Set

	Processing	Bath	Vessel	Transfer Time	RI Sensitivity	Solvent	SampleWeight	Dilution	Altered	AUW_SG	Ave_ID
19	Don't Process or Report						1.0000	1.0000	<input type="checkbox"/>	1.00000	NA
20	Don't Process or Report					9	1.0000	1.0000	<input type="checkbox"/>	1.00000	NA
21	Normal								<input type="checkbox"/>		
22	Normal								<input type="checkbox"/>		
23	Don't Process or Report								<input type="checkbox"/>	1.00000	NA
24	Don't Process or Report								<input type="checkbox"/>	1.00000	NA
25	Normal								<input type="checkbox"/>		
26	Normal								<input type="checkbox"/>		
27	Normal								<input type="checkbox"/>		
28									<input type="checkbox"/>		

	Batch_ID	ColumnNameC0	Column_ID	Column_Temperature	FlowRate	Mobile_Phase	No_of_Tabs	Pre_No
1								
2	L-004853263-000H011	300x3.9mm s/s 10Um C18 uBondapak	17	NA	1.80000	Acet:H2O=1:1	1.0	NA
3	L-004853263-000H011	300x3.9mm s/s 10Um C18 uBondapak	17	NA	1.80000	Acet:H2O=1:1	1.0	NA
4								
5								
6	6BDPA002 st 9 top 1	300x3.9mm s/s 10Um C18 uBondapak	17	NA	1.80000	Acet:H2O=1:1	1.0	NA
7	6BDPA002 st 9 top 2	300x3.9mm s/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:H2O=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 s/s 10Um C18 uBondapak	17	NA	1.80000	Acet:H2O=1:1	1.0	NA
12	6BDPA002 st 9 bottom 1	300x3.9mm s/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								
19	L-004853263-000H011	300x3.9mm s/s 10Um C18 uBondapak	17	NA	1.80000	Acet:H2O=1:1	1.0	NA
20	L-004853263-000H011	300x3.9mm s/s 10Um C18 uBondapak	17	NA	1.80000	Acet:H2O=1:1	1.0	NA
21								
22								
23	7BDPA004	300x3.9mm s/s 10Um C18 uBondapak	17	NA	1.80000	Acet:H2O=1:1	1.0	NA
24	L-004853263-000H011	300x3.9mm s/s 10Um C18 uBondapak	17	NA	1.80000	Acet:H2O=1:1	1.0	NA
25								
26								
27								
28								

	Samp_Type	Wavelength
1		
2	standard	254.00000
3	standard	254.00000
4		
5		

	Samp_Type	Wavelength
6	unknown	254.00000
7	unknown	254.00000
8	standard	254.00000
9	unknown	254.00000
10	unknown	254.00000

	Samp_Type	Wavelength
11	standard	254.00000
12	unknown	254.00000
13	unknown	254.00000
14	standard	254.00000
15		

	Samp_Type	Wavelength
16		
17		
18		
19	standard	254.00000
20	standard	254.00000

	Samp_Type	Wavelength
21		
22		
23	unknown	254.00000
24	standard	254.00000
25		
26		
27		
28		

