



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Superseded No: QC-01-011.03	Data Sheet Check List Variable Database Empower for Analysis with HPLC and GC Method	Document No: QC-01-011.04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

Product Name/Purpose	<i>Diprosone Ointment</i>
Batch No	<i>6BDPA002 & 9 (inves); 7BDPA004</i>
Test	<i>Betamethasone dipropionate assay</i>

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

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

Keterangan: *MA*

Performed by & Date	<i>[Signature]</i>	1	8	A	P	R	1	7
Verified by & Date	<i>[Signature]</i>	1	8	A	P	R	1	7

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

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

Reviewed by & Date	<i>[Signature]</i>	1	9	A	P	R	1	7
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History:

- QC-01-011.00, Effective date: 29 Nov 2006 (New Edition)
- QC-01-011.01, Effective date: 20 Nov 2008, LCR No. CR1108373D, Date of Issue: 19 Nov 2008
- QC-01-011.02, Effective Date: 30 Aug 2013, TR No. 133973, Date of Issue: 22 May 2013
- QC-01-011.03, Effective Date: **13 JUN 2016**



Effective Date: 13 JUN 2016	PT. Merck Sharp Dohme Pharma Tbk	Datasheet No: C170120
Superseded No: QC-01-008.04		Document No: QC-01-008.05
Prepared by: <i>[Signature]</i> 07 Jun 16	Reviewed by: <i>[Signature]</i> 10 Jun 16	Approved by: <i>[Signature]</i> 10 Jun 16

Data Testing

Test	Betamethasone Dipropionate assay		Procedure Doc	TICH0013.07	
HPLC ID	13-LC03.00	Calibration Due Date	Jan 18	Instrument Use Log	Yes <input checked="" type="checkbox"/>
Column Name	300 x 3.9 mm 10 μ m C18 uBondapak			Column Use Log	Yes <input checked="" type="checkbox"/>
Guard Column	NA				
Injection Volume	10 μ L				

Mobil Phase

No	Reagent Name	Lot No	Expiry Date
1	Acetonitrile	I 830330	30 Apr 19
2	H ₂ O	NA	NA
		NA	
		18 Apr 17	

(Keterangan) Acetonitrile : H₂O = 1000 ml : 1000 ml

Diluents

No	Reagent Name	Lot No	Expiry Date	Vol (ml)
1	H ₂ O	NA	NA	60
2	Methanol	I 844007	31 Jul 19	540
NA	NA	NA	NA	NA

(Keterangan) NA

