



Catatan Hasil Kalibrasi Internal
Internal Calibration Record
Dissolution Tester

No. : F-PM-01-31

Rev. : 00

Berlaku/Date : 03 September 2014

No. Fasilitas / <i>Facility No.</i>	:	Kapasitas / <i>Capacity</i>	:
No. Kode Kalibrasi/ <i>Calibration code</i>	:	Lokasi/ <i>Location</i>	:
Merek / <i>Brand</i>	:	Bidang / <i>Department</i>	:
Tipe / <i>Type</i>	:	No. Protap Cara Kalibrasi / <i>SOP</i>	:
No. seri / <i>Serial Number</i>	:	Nama Petugas / <i>Name</i>	:

Kalibrator yang digunakan <i>Calibrator</i>	Tanggal Kalibrasi Kalibrator <i>Cal. date of Calibrator</i>	Tanggal Rekalibrasi Kalibrator <i>Recal. date of Calibrator</i>
1. Tachometer 2. Stopwatch 3. Thermometer 4. Dial test Indicator 5. USP Prednisone tablet RS		

[illegible]

1. Tes Kecepatan 50 rpm

Calibration of Speed 50 rpm

[illegible]

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[illegible][illegible]

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Calibration of Timer

Tanggal / Date :

IRH (%) :

Room temp. (°C)	:
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Waktu/ Time (min)	Penunjukan Alat/ Reading		Selisih/ Diff. (detik/sec.)	Syarat / Requirement (detik/sec.)	Kesimpulan/ Conclusion	Paraf Petugas/ Signature	Paraf Asman/ Sign. of Asst. Manager
	Display Display	Stopwatch standard (Reff.)					
15							
30							
45							
60							
90							

Calibration of Centering

Tanggal / Date :

RH (%) :

Room temp. (°C) :

Pengujian/ Measurement	Chamber 1		Chamber 2		Chamber 3		Chamber 4		Chamber 5		Chamber 6	
	Paddle	Basket	Paddle	Basket	Paddle	Basket	Paddle	Basket	Paddle	Basket	Paddle	Basket
1												
2												
3												
4												
5												
Maximum Centering												
Syarat/ Requirement												
Kesimpulan/ Conclusion												
Paraf petugas/ Signature												
Paraf Asman/ Sign.of Asst. Manager												



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6. Kalibrasi Wobble

Calibration of Wobble

Tanggal / Date :

RH (%) :

Room temp. (°C) :

Pengujian/ Measurement	Chamber 1		Chamber 2		Chamber 3		Chamber 4		Chamber 5		Chamber 6	
	Paddle	Basket	Paddle	Basket	Paddle	Basket	Paddle	Basket	Paddle	Basket	Paddle	Basket
1												
2												
3												
4												
5												
Maximum Wobble												
Syarat/ Requirement												
Kesimpulan/ Conclusion												
Paraf petugas/ Signature												
Paraf Asman/ Sign. of Asst. Manager												

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7. **A. Kalibrasi menggunakan Tablet Kalibrator USP**
Performance Test using USP Calibrator tablet RS

Data I

USP Calibrator Tablet	USP Prednisone 10 mg Tablet Calibrator RS			USP Prednisone 10 mg Tablet Calibrator RS		
No. Lot						
Method						
RPM						
Tanggal / Date						
Room temp. (°C)						
RH (%)						
Data	W Std :	Factor :	Abs. Std :	W Std :	Factor :	Abs. Std :
						
						
	W Tablet (mg)	Absorbance (AU)	Kadar/Assay (%)	W Tablet (mg)	Absorbance (AU)	Kadar/Assay (%)
	1.			1.		
	2.					
	3.			2.		
	4.					
	5.			3.		
	6.					
	7.			4.		
	8.					
	9.			5.		
	10.					
	11.			6.		
	12.					
	Rata-rata/Average (GM) =			Rata-rata/Average (GM) =		
	CV (%) =			CV (%) =		
Syarat / Requirement						
Kesimpulan / Conclusion						
Paraf petugas / Signature						
Paraf Asman / Sign. of Asst. Manager						

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B. Kalibrasi menggunakan Tablet Kalibrator USP

Performance Test using USP Calibrator tablet RS

Data II

USP Calibrator Tablet	USP Prednisone 10 mg Tablet Calibrator RS			USP Prednisone 10 mg Tablet Calibrator RS		
No. Lot						
Method						
RPM						
Tanggal / Date						
Room temp. (°C)						
RH (%)						
Data	W Std :	Factor :	Abs. Std :	W Std :	Factor :	Abs. Std :
						
						
	W Tablet (mg)	Absorbance (AU)	Kadar/Assay (%)	W Tablet (mg)	Absorbance (AU)	Kadar/Assay (%)
	1.			1.		
	2.			2.		
	3.			3.		
	4.			4.		
	5.			5.		
	6.			6.		
	7.					
	8.					
	9.					
	10.					
	11.					
	12.					
	Rata-rata/Average (GM) =			Rata-rata / Average (GM) =		
	CV (%) =			CV (%) =		
Syarat / Requirement						
Kesimpulan / Conclusion						
Paraf petugas / Signature						
Paraf Asman / Sign. of Asst. Manager						