

PERFORMANCE VERIFICATION TEST CERTIFICATE
HANSON - DISSOLUTION TESTER

Model : CD14
Serial Number : 1222-1529

Customer ID : PT MERSIFARMA TIRMAKU MERCUSANA
Address : Jl. Raya Bogor KM. 31 No. 52, Cisalak, Depok.

Apparatus	Specification		Result		Status
	GM	%CV	GM	%CV	
Basket	81 - 94	4.3	88	3.6	Passed
Paddle	45 - 57	5.4	53	3.4	Passed

Note:

USP Prednisone Calibrator Tablet
Test Interpretation

: Lot R182R0
:Single-stage test

Performed by:
PT AbadiNusa Usahasemesta

End User


AbadiNusa

Rizky Rafi Rahmawan
Date : 26 Agustus 2025


(..... Juwita Restani)



Performance Verification Test Calculation Tool

Laboratory Information (optional)

Date performed:	08/26/2025
Operator:	Rizky Rafi Rahmawan
Assembly ID:	PT. Mersifarma Tirmaku Mercusana
Note book:	CD14
Notes:	SN. 1222 - 1529

Apparatus 1 -- 1-stage test for equipment with 12 positions

Acceptance criteria for USP Prednisone Tablets RS
Dissolution Performance Verification Standard - Prednisone 1222818, R182R0

GeoMean, lower	81
GeoMean, upper	94
%CV, upper	4.3

Data	
Vessel 1	83.940
Vessel 2	91.339
Vessel 3	91.686
Vessel 4	89.027
Vessel 5	89.143
Vessel 6	89.721
Vessel 7	87.062
Vessel 8	86.368
Vessel 9	85.212
Vessel 10	91.571
Vessel 11	85.558
Vessel 12	82.321

Test Results		
Combined GeoMean	88	Meets
Combined %CV	3.6	Meets

Signature: _____



PASSES

PVT Calculation Tool V2.0

Performance Verification Test Calculation Tool

Laboratory Information (optional)

Date performed:	08/26/2025
Operator:	Rizky Rafi Rahmawan
Assembly ID:	PT. Mersifarma Tirmaku Mercusana
Note book:	CD14
Notes:	SN. 1222 - 1529

Apparatus 2 -- 1-stage test for equipment with 12 positions

Acceptance criteria for USP Prednisone Tablets RS
Dissolution Performance Verification Standard - Prednisone 1222818, R182R0

GeoMean, lower	45
GeoMean, upper	57
%CV, upper	5.4

Data	
Vessel 1	55.542
Vessel 2	51.402
Vessel 3	54.229
Vessel 4	54.835
Vessel 5	51.301
Vessel 6	51.806
Vessel 7	52.513
Vessel 8	54.128
Vessel 9	50.998
Vessel 10	53.219
Vessel 11	50.695
Vessel 12	50.089

Test Results		
Combined GeoMean	53	Meets
Combined %CV	3.4	Meets

Signature:  **PASSES**

PVT Calculation Tool V2.0

PERHITUNGAN PVT DISSOLUTION TESTER	
Nama customer : PT. Mersifarma Tirmaku Mercusana	Serial Number: 1222-1529

$$C = \frac{\text{Bobot standard} \times \% \text{ STD}}{\text{Faktor pengenceran standard} \times 100}$$

% STD : Kadar standar Prednisone pada CoA (%)

$$\% \text{ Kadar} = \frac{\text{Abs Sampel} \times C \times 500}{\text{Abs Standard} \times 10 \text{ mg}}$$

C : Konsentrasi standar (mg/mL)
10 mg : Label claim tablet Prednisone (L)
500 : Volume media (V)

BASKET, step 1

No.	Abs Std	Abs Sampel	Kadar	In	Average Kadar	Average Ln	GM 1	VAR	exp var -1	% CV 1
%	99,6									
1	0,429	0,726	83,940	4,430	87,746	4,4739	88	0,0013	0,001288	3,6
2		0,790	91,339	4,515						
3		0,793	91,686	4,518						
4		0,770	89,027	4,489						
5		0,771	89,143	4,490						
6		0,776	89,721	4,497						
7		0,753	87,062	4,467						
8		0,747	86,368	4,459						
9		0,737	85,212	4,445						
10		0,792	91,571	4,517						
11		0,740	85,558	4,449						
12		0,712	82,321	4,411						
V	500									
L	10									
M	12,50									
C	0,00996									
RESULTS							Pass			Pass

Syarat Performance Verification Test Prednisone R182R0

Apparatus	No. of vessel	Single-stage		Two-Stage			
				1st stage		2nd stage	
		GM	%CV	GM	%CV	GM	%CV
Basket	6	81 - 94	4,4	83 - 91	3,3	81 - 94	4,4
	7		4,3				4,3
	8		4,2				4,2
	12		4,3	Not Applicable			
	14						

Abs Prednisone RS USP	
1	0,429
2	0,429
3	0,429
4	0,429
5	0,429
6	0,429
Average	0,429

Nama dan Tanda tangan
Application Support



Rizky Rafi Rahmawan

Nama dan tanda tangan
Customer



(.....Juwita Rihani.....)

