



# National Quality Control Laboratory

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## SAMPLE INFORMATION FORM

Date Sample Submitted: 2015-03-01 Laboratory Reference No: NDQPRINTEST

Product Generic/Brand Name: PACLITAXEL USP CONCETRATE

Product Chemical Name: Paclitaxel USP 6mg

Product Description: The product is more like in the zone of 5 - 10

Product Presentation: A blister pack of a biconcave shaped drugs in a pack of 3

Label claim: Each mL contains Paclitaxel USP 6mg, Dehydrated Alcohol Ph. Eur. 49.7&v/v

Batch/Lot No: 55 Product License No: 12345

Date of manufacture: 2015-01-01 Date of Expiry: 2015-12-31

Name of Client and Chemonics Kenya Pharma LLC

Address: P.o Box 1325 00606 Nairobi, Kenya

Client Reference No: 123658

Manufacturer: MYLAN LABS LTD

Country of Origin: INDIA Samples Issued: 30 Tablets Samples Returned:

Test(s) requested:	Limits:	Monograph (specify year and exact page):
a) <u>Identification</u>	<u></u>	U.S.P <u></u>
b) <u>Dissolution</u>	<u></u>	B.P. <u></u>
c) <u>Assay</u>	<u></u>	Ph. Eur. <u></u>
d) <u>Uniformity of Weight</u>	<u></u>	Ph. Intl. <u></u>
e) <u>pH</u>	<u></u>	Other's <u></u>
f) <u></u>	<u></u>	<u></u>

Analyst: Mary Magda Signature:  Date:

Checked by:  Signature:  Date:

Approved by:  Signature:  Date:

### UNIFORMITY OF WEIGHT: TABLETS/CAPSULES/SACHETS/VIALS

No.	Tablets/Capsules/ Sachets/Vials (mg)	Empty Capsule/ Sachet/Vial (mg)	Capsule/Sachet/Vial Content (mg)	% Deviation From mean (for deviating tabs/caps)
1	19875.65	85.65	19790.00	0.08
2	19865.23	86.58	19778.65	0.02
3	19862.25	89.58	19772.67	-0.01
4	19851.23	87.65	19763.58	-0.05
5	19853.95	89.56	19764.39	-0.05
6				
7				
8				
9				
10				
11				
12				
13				
14				
15				
16				
17				
18				
19				
20				
Total:	<u>99308.31</u>		<u>98869.29</u>	
Avg:	<u>19861.662</u>		<u>19773.858</u>	
Calculation of Deviation Limits:	-7.5			

Comments: \_\_\_\_\_

## ASSAY DATA FORM

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### ASSAY

Standard Preparation for Assay:

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Sample Preparation for Assay:

## **pH MEASUREMENTS**

### **Outline the Sample Preparation Procedure**

It is a long established fact that a reader will be distracted by the readable content of a page when looking at its layout. The point of using Lorem Ipsum is that it has a more-or-less normal distribution of letters, as opposed to using 'Content here, content here', making it look like readable English. Many desktop publishing packages and web page editors now use Lorem Ipsum as their default model text, and a search for 'lorem ipsum' will uncover many web sites still in their infancy. Various versions have evolved over the years, sometimes by accident, sometimes on purpose (injected humour and the like).

### **Determination of pH :**

<b>No.</b>	<b>Sample pH Readings</b>
<b>1.</b>	8.5
<b>2.</b>	6.9
<b>3.</b>	5.9
<b>4.</b>	0
	<b>Mean: 7.10</b>

**pH of the Sample : 7.10**

## DISINTEGRATION TEST FORM: TABLETS/CAPSULES

### Disintegration Test.

Disintegration Medium: Water

Duration of Test (min): 30

Results observed: The tablet does not integrate in that time.

Comments: This method allows printing text with line breaks.

### FRIABILITY TEST FORM

	<b>Run</b>
Total weight of tablets before test (g)	<b>20.51</b>
Total weight of tablets after test (g)	<b>20.61</b>
Loss (g)	<b>-0.10g</b>

**Run**

$$\% \text{age loss} = \frac{\text{Loss (g)}}{\text{Total weight before test (g)}} \times 100 = \underline{\underline{-0.49\%}}$$

**Comment (s):** COMPLIES

## RELATIVE DENSITY FOR SYRUPS/SUSPENSIONS

### Determination of Suspension/Syrup Relative Density:

Pyknometer Mass (g)	Pyknometer + Water (g)	Pyknometer + Sample (g)
15.65	25.65	26.56
	24.91	25.54
	20.56	22.65
	0	0
	Mean: 23.71	Mean: 24.92

Mass of Water (g): 8.06

Mass of Sample (g): 9.27

$$\text{Relative Density of Sample} = \frac{\text{Mass of Sample (g)}}{\text{Mass of Water (g)}} = \underline{\underline{1.15}}$$

$$\text{Sample Relative Density} = \underline{\underline{1.15}}$$

**CHROMATOGRAPHIC CONDITIONS:****ASSAY**

Column No: 196 Type of Column: \_\_\_\_\_  
Column Temp (°C): 34 \_\_\_\_\_  
Detection λ (nm): 344 Injection Vol (μL): 24

Mobile Phase: Composition (% v/v) & Ratios

v/v% in the multicomponent Flow Rate (mL/min): 55  
Pump Pressure (bars): 22

**DISSOLUTION**

Column No: 197 Type of Column: \_\_\_\_\_  
Column Temp (°C): 56 \_\_\_\_\_  
Detection λ (nm): 89 Injection Vol (μL): 35

Mobile Phase: Composition (% v/v) & Ratios

w/w 10% Flow Rate (mL/min): 95  
Pump Pressure (bars): 45

**REFERENCE SUBSTANCES:**

NO	Reference Substances/Related Substances	NQCL Code/Batch	Purity (%)
1.	Trimethoprim	NQCL-WRS-T7-1	98.74
2.	Sulfamethoxazole	NQCL-PRS-S12-1	0.998
3.			
4.			
5.			



REAGENTS USED						
	Reagent Name	Manufacturer	Lot/Batch No.	Date Opened	Expiry Date	Remarks
1.	METHANOL 2.5L	SCHARLAU	12100707			
2.	SODIUM HYDROXIDE PELLETS	RANKEM	P101L08			
3.	POTASSIUM HYDROXIDE PELLETS	RANKEM	P171J07			
4.						
5.						
6.						
7.						
8.						

EQUIPMENT USED					
	Equipment Name	NQCL No./Code	Date of Last Calibration	Date of Next Calibration	Remarks
1.	Weighing Balance Printer	NQCL/L18/2007/275			
2.	Agilent HPLC M	NQCL/L19/2012/378			
3.	pH Meter	NQCL/L6/1994/101			
4.	UV Detector	NQCL/L19/2010/350			
5.					
6.					
7.					
8.					

### APPENDIX

**Describe in Summary the reagent preparation procedures including mobile phase and buffers.**

**Report any other tests carried out on the sample.**

WORKSHEET TRACKING						
No.	ACTIVITY	FROM: OFFICER/ ANALYST	SIGNATURE	TO: OFFICER/ ANALYST	SIGNATURE	DATE
1	Issuing	Anastacia		Mary Magda		2015-03-01
2	Analysis	Mary Magda		Dr Paul Njaria		
3						
4						
5						
6						
7						