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 Address: Chemonics Kenya Pharma LLC
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) Identification		U.S.P
b) Dissolution		B.P.
c) Assay		Ph. Eur.
d) Uniformity of Weight		Ph. Intl.
e) pH		Other's
f)		

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				
2				
3				
4				
5				
6				
7				
8				
9				
10				
11				
12				
13				
14				
15				
16				
17				
18				
19				
20				
Total:	_____		_____	
Avg:	_____		_____	
Calculation of Deviation Limits:				

Comments: _____

CHROMATOGRAPHIC CONDITIONS:

ASSAY

Column No:	196	Type of Column:	Xterra RP 18, 25cm
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:	Hypersil BDS Cyano, 15 cm
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						