National Quality Control Laboratory
Hospital Road , KNH Complex, P.O. Box 29726, 00202 Nairobi, Kenya
Telephone: 2726963, +254 - 020 - 3544525/30 • Fax: 2718073
Email: info@nqcl.go.ke Website: www.nqcl.go.ke

SAMPLE INFORMATION FORM

Date Sample Submitted: 2016-10-23 Laboratory Reference No: NDQC201610BAT

Product Generic/Brand Name: PACLITAXEL USP CONCETRATE

Product Chemical Name: Paclitaxel USP 6mg

Product Description:

Product Presentation: yyry

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

Batch/Lot No: 56 Product License No: PLN9089

Date of manufacture: Aug 2016 Date of Expiry: Dec 2016

Name of Client and Address:

Client Reference No:

Manufacturer: MYLAN LABS LTD

Country of Origin: INDIA Samples Issued: 35 Vials Samples Returned

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

Analyst: Mary Magda Signature: Date:

Checked by: Signature: Date:

Approved by: Signature: Date:

ASSAY DATA FORM

ASSAY

Standard Preparation for Assay:

Sample Preparation for Assay:

CHROMATOGRAPHIC CONDITIONS:

ASSAY

Column No: _____ Type of Column: ,

Column Temp (°C): _____

Detection λ (nm): _____ Injection Vol (µL): _____

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

_____ Flow Rate (mL/min): _____

_____ Pump Pressure (bars): _____

_____

DISSOLUTION

Column No: _____ Type of Column: ,

Column Temp (°C): 4

Detection λ (nm): 6 Injection Vol (µL): 6

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

4545 Flow Rate (mL/min): 5

_____ Pump Pressure (bars): 5

_____

REFERENCE SUBSTANCES:

NO	Reference Substances/Related Substances	NQCL Code/Batch	Purity (%)
1.			
2.			
3.			
4.			
5.			

REAGENTS USED						
	Reagent Name	Manufacturer	Lot/Batch No.	Date Opened	Expiry Date	Remarks
1.						
2.						
3.						
4.						
5.						
6.						
7.						
8.						

EQUIPMENT USED					
	Equipment Name	NQCL No./Code	Date of Last Calibration	Date of Next Calibration	Remarks
1.					
2.					
3.					
4.					
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				**Mary Magda**		
2						
3						
4						
5						
6						
7						