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SAMPLE INFORMATION FORM

Date Sample Submitted: 2015-01-22 Laboratory Reference No: 3COMPONENTS

Product Generic/Brand Name: PANTAZOL 40mg IV INJECTION

Product Chemical Name: PANTOPRAZOLE

Product Description:

Product Presentation:

Label claim: Each vial contains PANTOPRAZOLE 40mg

Batch/Lot No: 3525 Product License No: 123

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: C03/123/456

Manufacturer: MYLAN LABS LTD

Country of Origin: INDIA Samples Issued: 30 Capsules 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: 19-02-2015

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: _____

ASSAY DATA FORM

ASSAY

Standard Preparation for Assay:

Sample Preparation for Assay:

DISSOLUTION

Standard Preparation for Dissolution:

Dissolution Conditions

	1st Run	2nd Run	3rd Run
Dissolution Medium:			
Volume used:			
Apparatus:			
Rotations per minute:			
Time (min)			

Describe below any subsequent dilutions after the dissolution:

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): _____ _____

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

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

_____ Flow Rate (mL/min): _____

_____ Pump Pressure (bars): _____

_____

REFERENCE SUBSTANCES:

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

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): _____

_____

REFERENCE SUBSTANCES:

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

pH MEASUREMENTS

Outline the Sample Preparation Procedure

Determination of pH :

No.	Sample pH Readings
1.	
2.	
3.	
4.	
	Mean:

pH of the Sample : _____

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						
2						
3						
4						
5						
6						
7						