



# National Quality Control Laboratory

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## SAMPLE INFORMATION FORM

Date Sample Submitted: \_\_\_\_\_ Laboratory Reference No: \_\_\_\_\_

Product Generic/Brand Name: \_\_\_\_\_

Product Chemical Name: \_\_\_\_\_

Product Description: \_\_\_\_\_

Product Presentation: \_\_\_\_\_

Label claim: \_\_\_\_\_

Batch/Lot No: \_\_\_\_\_ Product License No: \_\_\_\_\_

Date of manufacture: \_\_\_\_\_ Date of Expiry: \_\_\_\_\_

Name of Client and Address: \_\_\_\_\_

Client Reference No: \_\_\_\_\_

Manufacturer: \_\_\_\_\_

Country of Origin: \_\_\_\_\_ Samples Issued: \_\_\_\_\_ Samples Returned: \_\_\_\_\_

Test(s) requested: \_\_\_\_\_ Limits: \_\_\_\_\_ Monograph (specify year and exact page): \_\_\_\_\_

a) _____	_____	U.S.P _____
b) _____	_____	B.P. _____
c) _____	_____	Ph. Eur. _____
d) _____	_____	Ph. Intl. _____
e) _____	_____	Other's _____
f) _____	_____	_____

Analyst: \_\_\_\_\_ 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: \_\_\_\_\_

## ASSAY DATA FORM

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### ASSAY

Standard Preparation for Assay:

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Sample Preparation for Assay:

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## DISSOLUTION

Standard Preparation for Dissolution:

### Dissolution Conditions

	1 <sup>st</sup> Run	2 <sup>nd</sup> Run	3 <sup>rd</sup> 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  $\lambda$  (nm): \_\_\_\_\_ Injection Vol ( $\mu$ L): \_\_\_\_\_

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

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_ Flow Rate (mL/min): \_\_\_\_\_  
Pump Pressure (bars): \_\_\_\_\_

### DISSOLUTION

Column No: \_\_\_\_\_ Type of Column: \_\_\_\_\_  
Column Temp (°C): \_\_\_\_\_  
Detection  $\lambda$  (nm): \_\_\_\_\_ Injection Vol ( $\mu$ L): \_\_\_\_\_

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						