

CALIBRATION CERTIFICATE

INSTRUMENT NAME : TURBOCHEM PRIME
SERIAL NO : 20665
SOFTWARE VERSION : V1.0.9
INSTALLED AT : WELL CARE PATH LAB

INSTALLED ON : 27/09/2022
DATE OF CALIBRATION : 21/09/2024
NEXT CALIBRATION DUE : 20/09/2025

MECHANISM MOVEMENT CHECK	REMARK
SAMPLE/REAGENT TRAY	
<input type="checkbox"/> SAMPLE/REAGENT TRAY ROTATIONS	OK
<input type="checkbox"/> REAGENT COOLING	OK
REACTION CUVETTE UNIT	
<input type="checkbox"/> CUVETTE CONDITION	GOOD
<input type="checkbox"/> CUVETTE ROTATION	GOOD
<input type="checkbox"/> LAMP	GOOD
<input type="checkbox"/> DRY BATH TEMPERATURE	OK
<input type="checkbox"/> CUVETTE WASHING	GOOD
<input type="checkbox"/> CUVETTE OVERFLOW	NOT HAPPENING
PROBE MECHANISM	
<input type="checkbox"/> WASH POT ALIGNMENT	OK
<input type="checkbox"/> REAGENT ASPIRATION POSITION (INNER)	OK
<input type="checkbox"/> REAGENT ASPIRATION POSITION (OUTER)	OK
<input type="checkbox"/> SAMPLE ASPIRATION POSITION(INNER)	OK
<input type="checkbox"/> SAMPLE ASPIRATION POSITION(MIDDLE)	OK
<input type="checkbox"/> SAMPLE ASPIRATION POSITION(OUTER)	OK
<input type="checkbox"/> CUVETTE DISPENSE POSITION	OK
<input type="checkbox"/> PROBE WASHING	OK
<input type="checkbox"/> PROBE LIQUID LEVEL DETECTION	OK
MIXER MECHANISM	
<input type="checkbox"/> WASH POT ALIGNMENT	OK
<input type="checkbox"/> MIXER WASHING	OK
<input type="checkbox"/> MIXER ROTATION	OK
<input type="checkbox"/> CUVETTE VS MIXER	OK

WATER AND DETERGENT TANK

- | | |
|--|---------------|
| <input type="checkbox"/> WATER LEVEL SENSORS | OK |
| <input type="checkbox"/> DETERGENT LEVEL SENSORS | OK |
| <input type="checkbox"/> WATER HEATER | OK |
| <input type="checkbox"/> LEAK IN WATER LINE | NOT HAPPENING |

PHOTOELECTRIC STABILITY

Photoelectric stability gain should be in between 20000 to 60000

FILTER(NM)	GAIN
340	47243
405	47663
450	47013
510	46442
546	48491
578	47628
630	48790
670	48908

WE HERE BY CONFIRM **TURBOCHEM PRIME** HAS PASSED ALL THE ABOVE QUALITY CHECKS AND WORKING IN GOOD CONDITIONS.

KINDLY FIND ATTACHMENT OF PRECISION DATA FROM **TURBOCHEM PRIME**

For CPC DIAGNOSTICS PVT LTD.,


Authorised Signatory.



CORPORATE OFFICE

No.70/6,Old No.108/6,4th floor,Westminister,Dr.Radhakrishnan Salai,Mylapore,Chennai-600004.
Phone No:044-23460168/169

CUSTOMER AND INSTRUMENT DETAILS

MODEL NO : TURBOCHEM PRIME
SERIAL NO : 20665
DISTRIBUTOR : CPC DIAGNOSTICS PVT. LTD,CHENNAI
CUSTOMER NAME : WELL CARE PATH LAB.
ENGINEER (FOR CPC DIAGNOSTICS PVT. LTD.)

SIGNATURE : For CPC DIAGNOSTICS PVT LTD.,


Authorised Signatory.



NAME : MR. MAGESHWARAN
DESIGNATION : SENIOR TECHNICAL MANAGER
COMPANY : CPC DIAGNOSTICS PVT. LTD.
CUSTOMER (FOR WELL CARE PATH LAB)

SIGNATURE : 

NAME : 

DESIGNATION :

For Wellcare Path Lab

Authorized Signatory

INSTALLATION QUALIFICATION

ENVIRONMENTAL REQUIREMENT

Installation Environment Conditions

- * Place should not be subjected to direct sunlight
- * Place should be flat and minimum of dust.

Power And Noise Conditions

- * The power supply for the instrument should be nearer to the instrument (less than 10m)
- * The switchboard connector should be 15A type connector.
- * The power supply should be from a 2KVA on line UPS

Temperature And Humidity Conditions

- * The temperature of the analyzer room should be between 18 - 27°C
- * The temperature fluctuation during the analysis should be $\pm 2^\circ\text{C}$

❖ Water Supply And Drainage Conditions

- * Inner diameter of the drainage hose should be greater than 48mm
- * The purity of the DI water must under a conductivity of $\leq 1\mu\text{s/cm}$.
- * The height of the drainage system should be below the lower level of the analyzer.

❖ Dimensions Of System Main Units (Unit: mm)

- * Analyzer Length 1200mm x Width 800mm x Height 800mm

Power Supply

- * Voltage 230/50 Hz (India)

THIS IS TO CERTIFY THAT THE INSTALLATION SPACE IS MEETING ALL THE ABOVE MENTIONED REQUIREMENT FOR OPERATING THE TURBOCHEMPRIME FULLY AUTOMATED BIOCHEMISTRY ANALYZER IN THE CUSTOMER PLACE.

VERIFIED BY : MR.MAGESHWARAN

REVIEWED BY:


(FOR WELL CARE PATH LAB)

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ANALYSER PC QUALIFICATION

COM PORTS AVAILABLE	:YES
ONLINE POSSIBLE	:YES
PROCESSOR SPEED	:3.30GHz
STORAGE CAPACITY	:500Gb
COMMUNICATION PORT	: SERIAL
MONITOR	:17"
MAKER	:LENOVO
OPERATING SYSTEM	:WINDOWS 10 PRO
SOFTWARE CD	:AVAILABLE
PRINTER PORT	:AVAILABLE
PRINTER	:PARALLEL
MAKER	: SAMSUNG
MODEL	: LASER

This is to verify that the specifications are mentioned above is suitable for TURBOCHEMPRIME host computer.

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SYSTEM ENVIRONMENT CONDITIONS

	<u>REMARKS</u>
POWER SUPPLY	: 230/50 Hz AS PER REQUIREMENTS
UPS	: AVAILABLE
CURRENT	: AS PER REQUIREMENTS
DRAINAGE WITHIN 5 M	: AS PER REQUIREMENTS OR DIRECT
WATER (REQUIREMENTS)	
CONDUCTIVITY	: AS PER REQUIREMENTS
RESISTIVITY	: AS PER REQUIREMENTS
BACTERIA FILTER	: AVAILABLE
DEIONIZER	: AVAILABLE
ANALYSER SPACE AVAILABILITY	: AS PER REQUIREMENTS
DETERGENT	: AVAILABLE

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PERFORMANCE QUALIFICATION

INTRODUCTION

This module is giving the idea about the performance of the instrument as per the performance test.

PHOTOELECTRIC STABILITY

This is the test for checking the cuvette condition and the photometer sensitivity, and lamp condition.

THE RESULTS OF THE TEST AS PER THE MANUFACTURES SPECIFICATION AS GIVEN BELOW

	<u>REMARKS</u>
The result of photoelectric stability values should be with in 20000-60000	OK

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TURBOCHEMPRIME QUALITY CONTROL (PRECISION) CHECK LIST

INTRODUCTION

This module is highlighting the reproducibility and pipetting accuracy of the system.

Measuring criteria

- One end point chemistry
- One kinetic chemistry
- Large sample chemistry
- Small sample chemistry
- Only reagent 1 chemistry
- Both R1 and R2 chemistry
- Small volume of R2 chemistry

DETAILS OF REAGENTS,CALIBRATORS AND CONTROLS

REAGENTS : Turbochem prime

CALIBRATOR : 1268UE

CONTROL : 1561UN

HERE BY I VERIFYING THAT THE CONTROL RESULT OF THE EXECUTED PARAMETERS ARE WITHIN THE SD RANGE AND CV RANGE.

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OPERATIONAL QUALIFICATION

SYSTEM INFORMATION

SERIAL NO 20665
 SOFTWARE VERSION : V. 1.0.7
 OS VERSION : V. 1.0.8

MECHANISM MOVEMENT CHECK

SAMPLE/REAGENT TRAY

	REMARK
<input type="checkbox"/> SAMPLE/REAGET TRAY ROTATIONS	OK
<input type="checkbox"/> REAGENT COOLING	OK

REACTION CUVETTE UNIT

■ CUVETTE CONDITION	GOOD
■ CUVETTE ROTATION	GOOD
■ LAMP	GOOD
■ DRY BATH TEMPERATURE	OK
■ CUVETTE WASHING	GOOD
■ CUVETTE OVERFLOW	NOT HAPPENING

PROBE MECHANISM

<input type="checkbox"/> WASH POT ALIGNMENT	OK
<input type="checkbox"/> REAGENT ASPIRATION POSITION (INNER)	OK
<input type="checkbox"/> REAGENT ASPIRATION POSITION (OUTER)	OK
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<input type="checkbox"/> PROBE WASHING	OK
<input type="checkbox"/> PROBE LIQUID LEVEL DETECTION	OK

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MIXER MECHANISM

- | | | |
|--------------------------|--------------------|----|
| <input type="checkbox"/> | WASH POT ALIGNMENT | OK |
| <input type="checkbox"/> | MIXER WASHING | OK |
| <input type="checkbox"/> | MIXER ROTATION | OK |
| <input type="checkbox"/> | CUVETTE VS MIXER | OK |

WATER AND DETERGENT TANK

- | | | |
|--------------------------|-------------------------|---------------|
| <input type="checkbox"/> | WATER LEVEL SENSORS | OK |
| <input type="checkbox"/> | DETERGENT LEVEL SENSORS | OK |
| <input type="checkbox"/> | WATER HEATER | OK |
| <input type="checkbox"/> | LEAK IN WATER LINE | NOT HAPPENING |

PHOTOELECTRIC STABILITY

Photoelectric stability gain should be in between 20000 to 60000

FILTER(NM)	GAIN
340	1100
405	1826
450	1829
510	1963
546	2334
578	2268
630	2376
670	2301


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Carry over experiment	
Instrument	TURBOCHEM PRIME
Test Name	GLU

Srl No	sample	mg/dL
1	High1	206.4
2	High2	206.3
3	High3	205.5
4	Low1	11.7
5	Low2	11.2
6	Low3	11.2

CARRYOVER % 0.005

Carry over experiment	
Instrument	Bs 240
Test Name	T-Bill

Srl No	sample	mg/dL
1	High1	4.1
2	High2	4.07
3	High3	4.04
4	Low1	0.29
5	Low2	0.25
6	Low3	0.22

CARRYOVER % 0.261

Carry over experiment	
Instrument	Bs 240
Test Name	TP

Srl No	sample	g/dl
1	High1	8.8
2	High2	8.7
3	High3	8.8
4	Low1	0.5
5	Low2	0.4
6	Low3	0.4

CARRYOVER %

0.119

Carry over experiment	
Instrument	TURBOCHEM PRIME
Test Name	TG

Srl No	sample	mg/dL
1	High1	220.2
2	High2	219.9
3	High3	221.5
4	Low1	11.6
5	Low2	11.6
6	Low3	11.2

CARRYOVER %

0.005

Carry over experiment	
Instrument	Bs 240
Test Name	CREA

Srl No	sample	mg/dL
1	High1	4.71
2	High2	4.77
3	High3	4.75
4	Low1	0.24
5	Low2	0.24
6	Low3	0.24

CARRYOVER %

0.219

Carry over experiment	
Instrument	Bs 240
Test Name	UA



Srl No	sample	mg/dL
1	High1	9.65
2	High2	9.49
3	High3	9.73
4	Low1	0.52
5	Low2	0.49
6	Low3	0.49

CARRYOVER % 0.110

Carry over experiment	
Instrument	TURBOCHEM PRIME
Test Name	UREA

Srl No	sample	mg/dL
1	High1	135.81
2	High2	137.35
3	High3	139.22
4	Low1	8.2
5	Low2	8.25
6	Low3	7.88

CARRYOVER % 0.008

Carry over experiment	
Instrument	TURBOCHEM PRIME
Test Name	ALB

Srl No	sample	g/dl
1	High1	5.1
2	High2	5.2
3	High3	5.1
4	Low1	0.2
5	Low2	0.1
6	Low3	0.2

CARRYOVER % 0.196

Carry over experiment

Instrument	TURBOCHEM PRIME
Test Name	Cho H

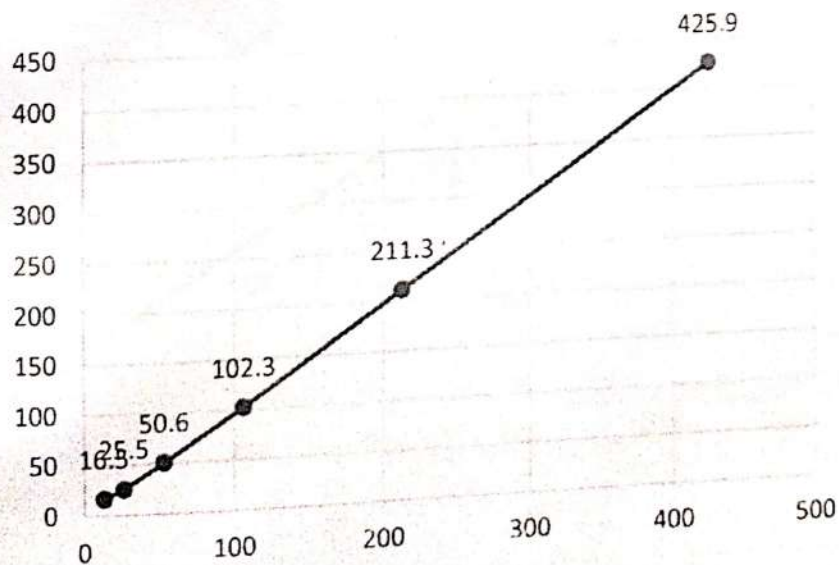
Srl No	sample	mg/dL
1	High1	300.03
2	High2	301.86
3	High3	304.19
4	Low1	20.28
5	Low2	19.28
6	Low3	18.63

CARRYOVER % 0.003

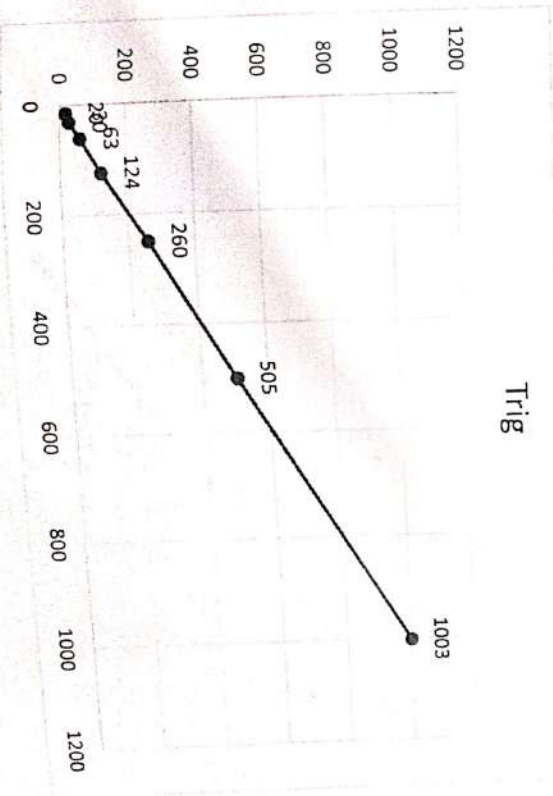


N°	Method	Samp ID	Type	Dil.	Status	Result		
1	UreaUV	sample1:64	N	1.0 0				
2	UreaUV	sample1:32	N	1.0 0	13.309375	16.5		
3	UreaUV	sample1:16	N	1.0 0	26.61875	25.5		
4	UreaUV	sample1:8	N	1.0 0	53.2375	50.6		
5	UreaUV	sample1:4	N	1.0 0	106.475	102.3		
6	UreaUV	sample1:2	N	1.0 0	212.95	211.3		
7	UreaUV	sample1	N	1.0 0	425.9	425.9		
8	UreaUV	sample1	N	1.0 0		429.4		
9	UreaUV	sample1	N	1.0 0		423.8		

Urea



N°	Method	Samp ID	Type	Dil.	Status	Result
1	Trig	sample1:64	N	1.00	15.671875	20
2	Trig	sample1:32	N	1.00	31.34375	30
3	Trig	sample1:16	N	1.00	62.6875	63
4	Trig	sample1:8	N	1.00	125.375	124
5	Trig	sample1:4	N	1.00	250.75	260
6	Trig	sample1:2	N	1.00	501.5	505
7	Trig	sample1	N	1.00	1003	1003
8	Trig	sample1	N	1.00		1007
9	Trig	sample1	N	1.00		997

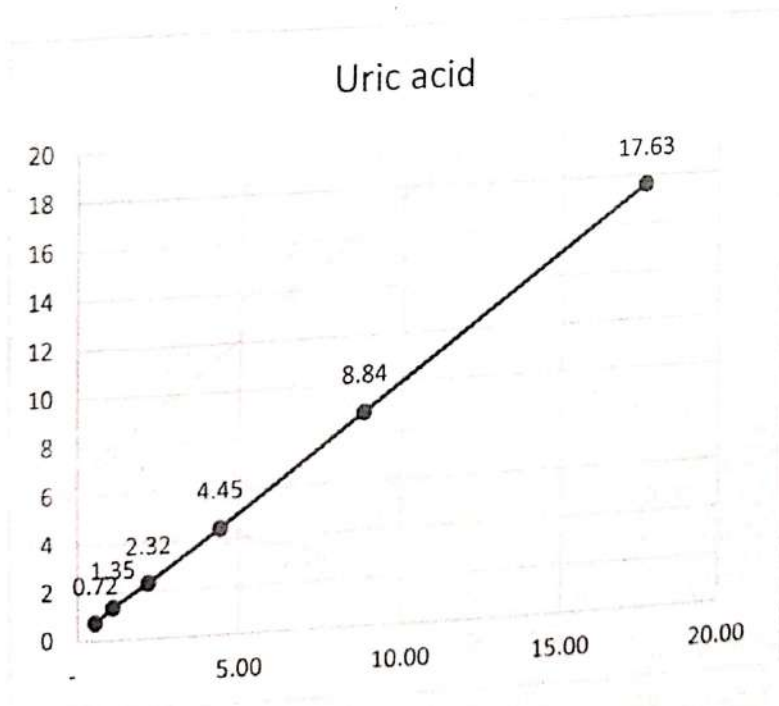


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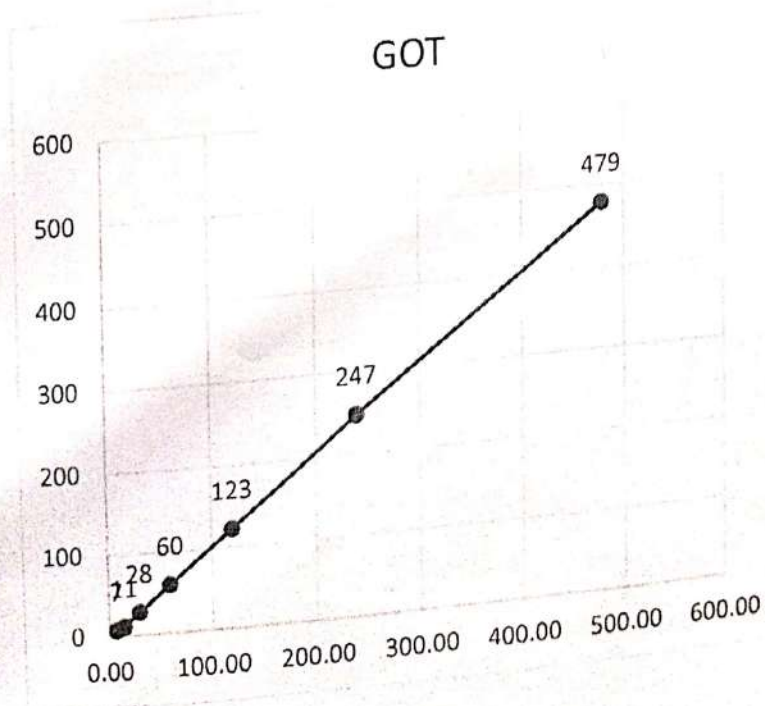
TURBOCHEM PRIME

TURBOCHEM PRIME

Method	Samp ID	Type	Dil.	Status	Result
UA	sample1:32	N	1.00	0.55	0.72
UA	sample1:16	N	1.00	1.10	1.35
UA	sample1:8	N	1.00	2.20	2.32
UA	sample1:4	N	1.00	4.41	4.45
UA	sample1:2	N	1.00	8.82	8.84
UA	sample1	N	1.00	17.63	17.63
UA	sample1	N	1.00		17.39
UA	sample1	N	1.00		17.14



N°	Method	Samp ID	Type	Dil.	Status	Result
1	GOT	sample1:64	N	1.00	7.48	7
2	GOT	sample1:32	N	1.00	14.97	11
3	GOT	sample1:16	N	1.00	29.94	28
4	GOT	sample1:8	N	1.00	59.88	60
5	GOT	sample1:4	N	1.00	119.75	123
6	GOT	sample1:2	N	1.00	239.50	247
7	GOT	sample1	N	1.00	479.00	479
8	GOT	sample1	N	1.00		485
9	GOT	sample1	N	1.00		490



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Precision Study

Replication No.	T.P	T.BIL	T-G	CRE	ALP	I.BILL.	TP	TG	CREA	UA	ALB	CHO
1	5.5	1.18	113.7	1.02	212.7	1.18	5.5	113.7	1.02	5.22	3.3	111.27
2	5.4	1.15	114.4	1.03	214.4	1.15	5.4	114.4	1.03	5.22	3.3	107.17
3	5.4	1.20	116.5	1.03	213.4	1.20	5.4	116.5	1.03	5.28	3.3	108.74
4	5.4	1.18	115.9	1.04	214.3	1.18	5.4	115.9	1.04	5.3	3.3	107.59
5	5.5	1.18	117.6	1.04	212.4	1.16	5.5	117.6	1.04	5.27	3.2	107.03
6	5.4	1.16	115.4	1.02	213.9	1.16	5.4	115.4	1.02	5.28	3.3	106.91
7	5.4	1.16	115.2	1.03	213.9	1.21	5.4	115.2	1.03	5.19	3.3	105.75
8	5.3	1.21	114.4	1.02	215.4	1.17	5.3	114.4	1.02	5.18	3.3	107.83
9	5.4	1.17	116	1.02	213.9	1.17	5.4	116	1.02	5.27	3.4	106.82
10	5.3	1.17	116	1.04	215.2	1.22	5.3	116	1.04	5.28	3.3	105.72
11	5.5	1.22	116.2	1.01	213.5	1.15	5.5	116.2	1.01	5.2	3.3	106.48
12	5.3	1.15	117.1	1.03	215.0	1.14	5.3	117.1	1.03	5.29	3.4	105.35
13	5.4	1.14	113.7	1.01	212.0	1.16	5.4	113.7	1.01	5.24	3.3	105.55
14	5.4	1.16	115.6	1.01	214.0	1.19	5.4	115.6	1.01	5.31	3.4	106.57
15	5.5	1.19	116.7	1.03	212.3	1.21	5.5	116.7	1.03	5.31	3.3	106.92
16	5.4	1.21	115.9	1.02	214.7	1.21	5.4	115.9	1.02	5.29	3.3	105.51
17	5.5	1.21	115.7	1.03	214.4	1.19	5.5	115.7	1.03	5.24	3.3	106.15
18	5.3	1.19	116.2	1.05	214.8	1.17	5.3	116.2	1.05	5.2	3.3	107.27
19	5.3	1.17	115.2	1.17	213.4	1.19	5.3	115.2	1.17	5.29	3.3	104.97
20	5.4	1.19	116.9	1.01	214.5	1.20	5.3	116.9	1.01	5.27	3.3	104.78
Mean	5.40	1.18	115.72	1.03	213.91	1.18	5.40	115.72	1.03	5.26	3.31	106.72
SD	0.07	0.02	1.06	0.03	0.98	0.02	0.08	1.06	0.03	0.04	0.04	1.48
CV%	1.3	1.9	0.9	3.3	0.5	2.0	1.4	0.9	3.3	0.8	1.4	1.4
Limit(%)	≤3.0	≤4.0	≤5.0	≤3.5	≤3.0	≤5.0	≤5.0	≤5.0	≤5.0	≤5.0	≤5.0	≤5.0
Result	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass

Star Bioned Pvt. Ltd.

Asst Application Manager 

Accepted By: 

Date: