

## Calibration Data

Instrument Name : Automated 3 Part Cell Counter  
 Make : Nihon Kohden  
 Model : MEK-6420P  
 Serial no : 52464  
 Calibration date : 31st December 2021  
 Installation place : Institute Of Pharmacy-Nirma University, Ahmedabad

CALIBRATION RUN DATA					
Sample No.	WBC	RBC	HGB	HCT	PLT
1	9.00	4.31	13.30	40.3	240
2	8.90	4.38	13.30	40.8	252
3	9.00	4.32	13.40	40.3	241
4					
5					
6					
7					
8					
9					
10					
<b>Mean</b>	8.97	4.41	13.33	40.47	244.33
SD	0.06	0.04	0.06	0.29	7
CV%	0.64	0.9	0.43	0.7	2.7

<b>Acceptable CV%</b>	Within 2.0%	Within 1.5%	Within 1.5%	Within 1.5%	Within 4%
<b>Result status</b>	<b>PASS</b>	<b>PASS</b>	<b>PASS</b>	<b>PASS</b>	<b>PASS</b>

\*Precision study performed on the analyzer using a blood samples.

For Nihon Kohden India Pvt. Ltd.

Name : shiv Shankar Dey

Designation : Assistant Manager



## Precision Check Data

Instrument Name : Automated 3 Part Cell Counter  
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 Calibration date : 31st December 2021  
 Installation place : Institute Of Pharmacy-Nirma University, Ahmedabad

PRECISION RUN DATA					
Sample No.	WBC	RBC	HGB	HCT	PLT
1	11.00	4.72	10.40	31.6	344
2	10.50	4.67	10.30	31.2	369
3	10.70	4.78	10.30	31.9	358
4	10.50	4.69	10.30	31.4	356
5	10.50	4.72	10.30	31.4	381
6	10.70	4.69	10.40	31.4	377
7	10.60	4.70	10.30	31.2	369
8	10.70	4.73	10.40	31.4	372
9	10.80	4.76	10.30	31.8	382
10	10.70	4.66	10.30	31.0	375
Mean	10.67	4.73	13.00	44.5	368
SD	0.16	0.0	0.05	0.3	12
CV%	1.47	0.8	0.37	0.6	3

Acceptable CV%	Within 2.0%	Within 1.5%	Within 1.5%	Within 1%	Within 4%
Result status	PASS	PASS	PASS	PASS	PASS

\*Precision study performed on the analyzer using a blood samples.

For Nihon Kohden India Pvt. Ltd.  
 Name : shiv Shankar Dey  
 Designation : Assistant Manager



## Certification of Calibration

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Instrument Name	: Automated 3 Part Cell Counter
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Model	: MEK-6420P
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This is to certify that the above mentioned instrument has been successfully calibrated on **31st Dec 2021** with MEK-CAL lot no-**PLUS 21Z** bearing expiry till **5th Jan , 2022**. During the calibration of the analyser, all CBC parameters were calibrated.

Ran Quality Controls **MEK-3D (Low, Normal, and High) Lot no-21Y** bearing expiry of **5th Feb 2022**, Result found within specified range.

Based on the manufacture recommended calibration interval the next due date of calibration is on **30th Dec 2022**. Validity  $\pm$  30days. Or depends on QC performance/subject to replacement or change in hardware.

For Nihon Kohden India Pvt. Ltd.

**Name : shiv Shankar Dey**

**Designation : Assistant Manager**



## **Installation Qualification**

## **Operation Qualification**

**&**

## **Performance Qualification**

Instrument Name	:	Automated 3 Part Cell Counter
Make	:	Nihon Kohden
Model	:	MEK -6420P
Serial no	:	52464



## Validation Report

Instrument Name	:	Automated 3 Part Cell Counter
Make	:	Nihon Kohden
Model	:	MEK -6420P
Serial no	:	52464
Supplier Name	:	Nihon Kohden India Private Limited
Contact Name & Address	:	Institute of Pharmacy- Nirma University, Ahmedabad



## Approval of IQ/OQ/PQ Procedure

Both Institute of Pharmacy- Nirma University, Ahmedabad and Nihon Kohden India Private jointly responsible for the installation of Automated 3 Part Cell CounterMEK -6420P (52464) in the pathology laboratory

VALIDATION TEAM FROM VENDOR:

Name : shiv Shankar Dey  
Designation : Assistant Manager  
Signature : \_\_\_\_\_  
Nihon Kohden India Private Limited

VALIDATION TEAM FROM PATHOLOGY LABORATORY:

Name :  
Designation :  
Signature :  
Date :

CUSTOMER AUTHORIZATION:

Name :  
Designation :  
Signature :  
Date :



## II. INSTRUCTIONS

- 1 This document is to be completed at the time the instrument is installed at its current location Institute of Pharmacy- Nirma University, Ahmedabad and set up
- 2 An authorized (Company) representative will check the instrument and enter the specific data related to installation, operational and performance qualification.
- 3 Employee of Pathology laboratory will verify each result and sign the result. Validation team will carry this out.
- 4 All validation from the normal specification to include and problems with installation will be noted under COMMENTS.

## III. SCOPE

This installation qualification protocol is performed on the Automated 3 Part Cell Counter MEK -6420P (52464) located in pathology.

This protocol defines the documentation that is used to evaluate the instrument installation in accordance with the manufacturer's specifications and intended usage.

Successful completion of this protocol verifies that this instrument has been installed, operated in accordance with the intended usage.

Installation checks are performed to verify that the instrument has been installed with proper connection and utilities.

Operational qualification will evaluate the instrument have operational features available for the successful operation of instrument in accordance with the manufacturer's specifications.

Performance qualification will verify the actual functioning or performance of instrument manufacturer's specifications.



**IV. CERTIFICATE OF PURCHASE ORDER COMPLIANCE:**

I certify to the best of my knowledge, the instrument Automated 3 Part Cell Counter MEK -6420P (52464) has been installed in pathology is in compliance with the specification of the agreement order

**V. INSTRUMENT DESCRIPTION:**

S.no.	Instrument identification	Verified	Date
1	Automated 3 Part Cell Counter	Yes	31st Dec 21
2	Nihon Kohden	Yes	31st Dec 21
3	Model:MEK -6420P	Yes	31st Dec 21
4	Instrument ID	Yes	31st Dec 21
5	Serial no.52464	Yes	31st Dec 21
6	Size : As per speciifcation given	Yes	31st Dec 21
7	Power : As per speciifcation given	Yes	31st Dec 21

**VI. UTILITIES :**

S.no.	Instrument identification	Yes/No	Date
1	Environmental condition as required. (Free from dust, electrical and magnetic interference) Temperature: 15 – 30 OC Humidity: 30 to 85 % non condensing	Yes	31st Dec 21
2	Adequate space for installation: (As per the specification given)	Yes	31st Dec 21
3	Electrical Outlets: Actual voltage on site (228 VAC)	Yes	31st Dec 21
4	Grounded	Yes	31st Dec 21
5	Connected through UPS	Yes	31st Dec 21
6	Waste Liquid	Yes	31st Dec 21





**VII. THE INSTRUMENT HAS BEEN CHECKED FOR THE FOLLOWING :**

S.no.	Instrument identification	Yes/No	Date
1	Instrument is identified	Yes	31st Dec 21
2	Manufacturer's specification are included	Yes	31st Dec 21
3	Accessories / Consumables are listed	Yes	31st Dec 21
4	Equipment manual from the manufacturer	Yes	31st Dec 21

**ACCESSORIES / CONSUMABLES:**

The following accessories were supplied with the instrument

S.no.	Description	Qty	Verified by	Date
1	Accessories box	1	Yes	31st Dec 21

**VIII. LIST OF MANUALS AND CERTIFICATES**

Supplier provided the following with the instrument

S.no.	Particulars	Available or not	Date
1	Operating Manual	Yes	31st Dec 21
2	Invoice	Yes	31st Dec 21
3	Safety instruction (equipment manual)	Yes	31st Dec 21
4	Training records	Yes	31st Dec 21
5	if any other	NO	31st Dec 21

**IX. MAINTENANCE:**

The instrument listed within this document will be placed under the control of Institute of Pharmacy- Nirma University, Ahmedabad Pathology laboratory institution with respect to proper maintenance procedure as detailed in the operator's manual.

A trained analyst using the manual provided with the instrumentation can perform basic and operation maintenance. Upon expiration of the warranty period vendor will offer.

Several levels of maintenance agreement and performance testing service to assist you in maintaining compliance. Contacting your local representative and requesting the additional service agreement can supply additional information.



**X. INSTALLATION PROCEDURE:**

- 1 Installation of Hardware and Software  
Follow the instruction mentioned in the installation guide.
  
- 2 Installation of Printer  
Follow the instruction mentioned in the installation guide.

## Operation Qualification:

Instrument Name	:	Automated 3 Part Cell Counter
Make	:	Nihon Kohden
Model	:	MEK -6420P
Serial no	:	52464

**XI. OPERATIONAL QUALIFICATION:**

Following features/ functions are available in the instrument as per manufacturer's specification and verified e.g. Start-up, Calibration, quality control, maintenance checks.

S.no.	Test Name	Y/N	Test Procedure	Date
1	Start up	Yes	Retest Testing	31st Dec 21
2	Calibration Feature	Yes	Calibration Performance	31st Dec 21
3	Quality Control	Yes	Control Running	31st Dec 21
4	Maintenance	Yes	Operation Maintenance	31st Dec 21

Printouts of the above features / tests attached (Yes/No)

Yes



## **CERTIFICATE OF TRAINING:**

### **1. Operator and Maintenance Training**

This certifies that the technicians listed below have received basic user training for the system described.

<b>S.no.</b>	<b>Training Program</b>	<b>Signature</b>	<b>Date</b>
1	Instrument Set-up	Yes	31st Dec 21
2	System Operation	Yes	31st Dec 21
3	Basic troubleshooting	Yes	31st Dec 21

**Traning given by : Name : shiv Shankar Dey**  
**Designation : Assistant Manager**

Training attended by :  
1. Mrs.Shital Panchal



## Performance Qualification :

Instrument Name	:	Automated 3 Part Cell Counter
Make	:	Nihon Kohden
Model	:	MEK -6420P
Serial no	:	52464

Following are the steps required to validate your instrument and method.

- 1 Run QC samples (Low, Normal and Abnormal) and verifies the values with acceptable range given in the insert of quality control samples

**Printouts attached from instrument (Yes/No) Yes**

- 2 Run 10 time patient sample into the system and calculate the %CV. Acceptance limits of %CV ( $\leq 5\%$ ) shall be considered.

**Printouts attached from instrument (Yes/No) Yes**

QC RESULTS : PASS/FAIL= PASS  
PRECISION CHECK : PASS/FAIL= PASS

VALIDATION TEAM FROM VENDOR:

Name : shiv Shankar Dey  
Designation : Assistant Manager

Signature : \_\_\_\_\_  
Nihon Kohden India Private Limited

VALIDATION TEAM FROM PATHOLOGY LABORATORY:

Name :  
Designation :  
Signature :  
Date :

CUSTOMER AUTHORIZATION:

Name :  
Designation :  
Signature :  
Date :

