

Installation Qualification and Checklist

Mindrax BS-430

Customer Name : Dr. Pankaj Diagnostics & Research Centre Pvt. Ltd.
Customer Address : B-27, Sachiwalay Colony, 200 m south of Kendriya Vidyalay Main Gate,
Kankarbagh, Patna, Bihar - 800020
Contact Person : Mr. Deepak Kumar
Instrument Model : BS-430 Chemistry
Analyzer Serial No. : YX-14005478

Site survey done and pre-installation checklist was made and found that the site is complying to all the Requirements The instrument packaging was checked and opened for installation.

Initial Inspection of the unit carried out and the details are as follows:

System Condition Report:

System delivered in satisfactory condition and no external physical damage observed on the same, Package was kept in good Condition as per the directional indicators like not tilt, indicating the system has not been subjected to mechanical shocks or stored in any manner, so as to cause any damage to the same.

Found all the required accessories are present.

- 1.
- a. Any Physical Damage to the shipment : Yes No
 - b. Accessories as per packing List : Yes No
2. Environmental Conditions.
- a. Air Conditioned Environment Available : Yes No
 - b. Room free of Rodents/ Insects/ Pests : Yes No
 - c. Humidity is less than 80 % : Yes No

3. General Cleanliness Around Site : Acceptable Not Acceptable

4. Power Requirements.

a. Uninterrupted Power Supply Available.

- UPS Rating -No star rating. 15KVA Online UPS
- Type of batteries - 12V-100AH x 30
- Back up Time - 2 hours
- Incoming AC Power: 229V
- Earth Voltage - 3V

5. Verified all Instruments Components and Accessories : Yes

6. Installed all Accessories as per the Instrument Set - Up Procedure Below : Yes

- a. Inspect all shipping cartons for possible damage. Check to make sure all kits necessary for the installation of the instrument are present.
- b. Assembled Sampler & Photometric Module, User PC, Keyboard.
- c. Installed the System Hardware, Computer & Printer.
- d. Checked the Electrical Power supply and Voltage.
- e. Load Supplies on the system (Water , Wash Solution, Cleaning Solution)
- f. Checked all cable connections & tubing's of Sample, Reagent Syringes.
- g. Checked all Electronic Boards are properly plugged in.
- h. Aligned the Wash Nozzle Dispense, Aspirate Probes, and Reagent, Sample Probe.
- i. Installed the current Software Version.

Installation Certificate

This is to certify that the BS-240 Chemistry Analyzer Instrument Serial number **YX-14005478** have been successfully Installed and commissioned at as per the Installation Procedure & Checklist.



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SAGAR GALAXY, IInd Floor, LSC, Mayur Vihar - II, New Delhi -110091

Tel.: 22784431, 22784432,

e-mail : priman@primanindia.com / email : admin@primanindia.com

Website : www.primanindia.com

Name: MD ALI MEHDI
Designation: Service Engineer
Date: 01rd-March-2022

Name:
Designation:
Date:

Thanking You
Yours Faithfully,
For Priman Instruments Pvt. Ltd.

Authorized Signatory

Operational Qualification

With reference to the Installation Procedure and Checklist and the studies carried out in the BS-430 Chemistry Analyzer Serial number YX-14005478, meets all criteria outlined for Operational Qualification.


Operational Qualification Checklist & System Calibration

- | | |
|--|--|
| 1. Check Instrument and console power System. | Ok <input checked="" type="checkbox"/> |
| 2. Instrument startup and going to Standby mode without errors | Ok <input checked="" type="checkbox"/> |
| 3. Configuring chemistry, racks and other settings. | Ok <input checked="" type="checkbox"/> |
| 4. Check and verify all hardware components. | Ok <input checked="" type="checkbox"/> |
| 5. Verify reagent carrousels and temperatures within range. | Ok <input checked="" type="checkbox"/> |
| 6. Prime instrument and check for any leakages. | Ok <input checked="" type="checkbox"/> |
| 7. Perform cuvette wash and check cuvette status | Ok <input checked="" type="checkbox"/> |
| 8. Inspect the Sample and Reagent Water Dispense test from jet & Probes. | Ok <input checked="" type="checkbox"/> |
| 9. Checked aspirate & dispense probes from Wash Nozzle Unit. | Ok <input checked="" type="checkbox"/> |
| 10. Checked all mechanical performance of the system. | Ok <input checked="" type="checkbox"/> |

Study data has determined that the system described in this document either meets all criteria outlined in this Operational Qualification protocol. All exceptional conditions if any have been addressed.

The Analyzer is ready for Performance Qualification

Protocol Performed By:

Signature : 
Name : Md Ali Mehdi

Designation : Service Engineer
Date : 01rd -**March**-2022

Customer Authorization:



Signature :

Customer Name : Dr. Pankaj Diagnostics & Research Centre Pvt. Ltd.
Customer Address : B-27, Sachiwalay Colony, 200 m south of Kendriya Vidyalay Main Gate,
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Contact Person : Mr. Deepak Kumar
Instrument Model : BS-430 Chemistry
Analyzer Serial No. : YX-14005478

Thanking You

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Performance Qualification

TABLE OF CONTENTS

S. No.	Title	Description
1.	Calibration Verification	Run calibration for available parameters (Refer Regent Guide)
2.	Quality Control Verification	Run minimum 1 level of Quality control for all calibrated parameters and results should be within 2sd of manufacture range.
3.	Precision	Minimum 20 replications should be run for each assay to verify the CV% limits. Check the results with manufacturer CV% guideline. (Guideline enclosed)

4.	Carryover	Carryover study should be completed as per CAP guidelines/ EP Evaluator 8.0.0. for available parameters (Guideline enclosed)
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SYSTEM CERTIFICATION

Study data has determined that the BS-430 system (S/N: YW-14005478) described in this document either meets all criteria outlines in the IQ OQ PQ Qualifications Protocol, or exceptional conditions have been identified and documentation included. Exceptional conditions, if any have been addressed.

Report Performed By: Priman India Pvt. Ltd. Representative

Name : Md Ali Mehdi Hassan Haidry

Title : IQ OQ PQ QUALIFICATIO

Signature :



Company : **Priman India Pvt. Ltd.** Representative



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Website : www.primanindia.com

Customer Authorizations: Dr. Pankaj Diagnostics & Research Centre Pvt. Ltd.

Name :
Title : IQ OQ PQ QUALIFICATION
Signature :
Date :

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