DECODING PHARMA

QUALITY ASSURANCE DEPARTMENT

STANDARD OPERATING PROCEDURE	
Department: Quality Assurance	**SOP No.:**
Title: Standard Operating Procedure for Lab QA	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

1.0 OBJECTIVE:

To lay down a procedure for Lab QA in "Quality Control Department".

2.0 SCOPE:

This SOP is applicable for Lab QA in Quality Control Department of …….

3.0 RESPONSIBILITY:

Executive /Officer Lab QA/Designee.

4.0 ACCOUNTABILITY:

Head- Quality Control

Head- Quality Assurance

5.0 DEFINITION:

Quality assurance (QA) is aimed at ensuring quality test results. Quality assurance involves activities both inside and outside laboratory, good laboratory practice and proper management skill. The Lab QA is a total process whereby the quality of lab reports can be guaranteed.

6.0 Procedure :

6.1 General

6.1.1 The manufacture shall be conducted under the direct supervision of competent technical staff with prescribed qualifications and practical experience in the relevant dosage and / or active pharmaceutical products .

6.1.2 The head of the Quality Control Laboratory shall be independent of the manufacturing unit. The testing shall be conducted under the direct supervision of competent technical staff who shall be whole time employees of the licensee.

6.1.3 Personnel for Quality Assurance and Quality Control operations shall be suitably qualified and experienced.

6.1.4 Written duties of technical and Quality Control personnel shall be laid and followed strictly.

6.1.5 Number of personnel employed shall be adequate and in direct proportion to the workload.

6.2 Lab QA persons :

6.2.1 Lab QA shall be qualified, Trained and practical experience in Lab related document and procedures.

6.2.2 One or two Lab QA person in QC Dept. having the full Knowledge about the document and system of the QC should be selected as the lab QA person.

6.2.3 These lab QA person shall explain the things to the auditors.

6.2.4 Lab QA person check all the points of QC.

6.3 Lab QA person plan the Audit in following way.

6.3.1 Laboratory Entry

6.3.1.1 Check the Entry & Exit SOP followed in QC change room.

6.3.1.2 Check the cleaning of change room

6.3.1.3 Visitor disposable garments kept in place

6.3.1.4 Disinfectant availability

6.3.1.5 Used garments bin in change room

6.3.2 Verify the cleaning of laboratory

6.3.2.1 Change room

6.3.2.2 Document Room

6.3.2.3 Instrument lab (I^{st} & II^{nd})

6.3.2.4 Weighing area

6.3.2.5 Wet chemistry lab

6.3.2.6 Washing area

6.3.2.7 Chemical store

6.3.3 To Verify the Temperature monitoring record filled as per SOP timely.

6.3.4 Quality Control Analyst

6.3.4.1 To confirmed that employees are qualified for their positions by having a current Job description and Section as per training programme .

6.3.4.2 Check the training file of employee & performed the activity as per JD.

6.3.4.3 Trained person are available in QC of their particular work.

6.3.4.4 Check the analyst qualification documents.

6.3.4.5 Verify the Daily work distribution.

6.3.5 Instruments

6.3.5.1 Cleaning

6.3.5.2 Qualification (URS,DQ,IQ,OQ & PQ) are carried out

6.3.5.3 Calibration status.

6.3.5.4 Status label

6.3.5.5 Online Log book entry

6.3.5.6 Audit trail log

6.3.5.7 Method updation

6.3.5.8 Mobile phase, solvents use on instrument & valid up to label

6.3.5.9 Column storage condition and relevant log book entry.

6.3.6 Reagents, Chemicals & Solvents

6.3.6.1 All solid and liquid reagent used in QC checked the labeled i.e. date of receipt, opening date, and used before date.

6.3.6.2 General reagent, Volumetric solution, Indicator solution labeling and preparation record.

6.3.6.3 Storage of chemical

6.3.7 Log books

6.3.7.1 Check the log book entry, timing, cutting, overwriting, Sr. No., activity performed timing.

6.3.7.2 Online entry or relevant entry

6.3.8 Glassware

6.3.8.1 Check the grade of glassware

6.3.8.2 Certificate of glass ware

6.3.8.3 Issuance record of glassware

6.3.8.4 Washing and drying status

6.3.9 Standards

6.3.9.1 Reference standard and Impurity Storage.

6.3.9.2 Usage & Consumption record of Reference standard and Impurity

6.3.9.3 Working standard issuance and vial usage record

6.3.9.4 Working standard preparation record

6.3.10 Procedures

6.3.10.1 Testing method are validate with proper reference.

6.3.10.2 SOP management

6.3.10.3 Pharmacopeia status

6.3.10.4 SOP & procedure (SPC/STP) shall be issued by QA.

6.3.10.5 Every steps shall be documented as per procedure.

6.3.10.6 Every MOA is reviewed and evaluated toughly.

6.3.10.7 Are there any OOS result found and what are the actions taken.

6.3.10.8 Laboratory Incidents, deviation and change controls

6.3.11 Sampling

6.3.11.1 Method of sampling and Sampling plan

6.3.11.2 Sampling checklist

6.3.11.3 Sampling tools to be used

6.3.11.4 Precautions (to avoid contamination) as per SOP

6.3.11.5 Sampling device cleaning and utilization log

6.3.11.6 AQL verification of Packing material

6.3.11.7 Sampling procedure of Raw material and Packing material.

6.3.11.8 Control samples entries are made properly according to SOP.

6.3.11.9 RLAF record and cleaning record of Sampling area

6.3.12 Weighing

6.3.12.1 Calibration and Daily verification of balance

6.3.12.2 Online Log book entry

6.3.13 Chromatography

6.3.13.1 Check the solvent used in HPLC grade

6.3.13.2 Solvent and mobile phase bottle Labelling.

6.3.13.3 Method version

6.3.13.4 Audit trail

6.3.13.5 Instrument and processing method

6.3.13.6 Check the system suitability

6.3.14 Lab QA shall be verify the reports of Finished Product, Raw Material, Packing Material, Stability and calibration & validation record etc. every alternative intervals.

6.3.15 Lab QA assure the every activity of laboratory and complies the non-compliance point.

6.3.16 Lab QA shall be verify the Stability Chamber room relevant Record.

6.4 Lab QA person shall audit the QC dept on weekly basis.

6.5 Lab QA shall prepare the audit report followed by Head QA approval.

6.6 After audit, Lab QA Officer/Executive shall give one copy of check list to Quality control department to filled the non-compliance.

7.0 ABBREVIATION:

Pvt.	:	Private
Ltd	:	Limited
QC	:	Quality Control
SOP	:	Standard Operating Procedure

AQL	:	Acceptance Quality level
HPLC	:	High pressure liquid chromatography
FTIR	:	Fourier transformed infrared spectrophotometer
UV	:	Ultra violet
LPC	:	Liquid particle counter
TOC	:	Total organic carbon
KF	:	Karl fisher Apparatus
MOA	:	Method of analysis
STP	:	Standard testing procedure

8.0. ANNEXURES:

ANNEXURES	NAME OF ANNEXURE	FORMAT No.
Annexure – I	Lab QA checklist for Quality Control	

9.0 DISTRIBUTION:

- Master Copy — Quality Assurance Department
- Controlled Copy — Quality Control Department

10.0 REFERENCES:

- In-house

11.0 REVISION HISTORY:

Revision No.	Change Control No.	Details of Changes	Reason of Changes	Effective Date	Done By
00	Not Applicable	Not Applicable	New SOP		

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Annexure –I
LAB QA CHECKLIST FOR QUALITY CONTROL

Date :

S.No.	Check Point (Not Limited To)	Observation			Checked By	Remarks
		YES	NO	NA		
1.	**QC Change room:**					
	Check the Cleaning of change room , it should be cleaned					
	Visitor disposable garments kept in place					
	Disinfectant availability					
	Disposal garment bin in place, it should be cleaned					
	Any other observation noticed :					
2.	**Documentation Room:**					
	Floor, walls, table, windows glasses, Computer, it should be cleaned					
	Temperature monitoring with record (It should be within specified range)					
	Check the Waste bins, it should be cleaned					
	Document (RM,PM,FG, stability, GLP) should be found in systematic manner.					
	Dynamic pass box should be cleaned					
	Dynamic pass box record should be found ok					
	Any other observation noticed					
3.	**Instrument Room Ist:**					
	Floor, walls, table, windows glasses, it should be cleaned					
	Temperature monitoring with record (It should be within specified range)					
	Check the Waste bins, it should be cleaned					
	HPLC, FTIR, UV, Karl fisher titrator, LPC, Polarimeter instrument found should be cleaned					

Date :

S.No.	Check Point (Not Limited To)	Observation			Checked By	Remarks
		YES	NO	NA		
	Check the "Status Label" of Instrument for following details: Inst. ID, Sample/Product Name, Batch No, Test name, Analyzed & checked by with date ensure that the details are match with Sample request.					
	Mobile phase, Solvents, HPLC water bottle label should be found within specified period.					
	HPLC below check point shall be checked. i) Log Book (Instrument & Column) ii) Instrument method/Processing method parameter iii) Mobile phase preparation record iv) Integrated chromatograph with integration parameters v) Product/Sample worksheet online entry					
	FTIR log book, etc record shall be verified and found ok					
	UV-Spectrophotometer log book, etc record shall be verified and found ok					
	Polarimeter log book, etc record shall be verified and found ok					
	Karl fisher log book, used KF reagent and dry methanol etc record shall be verified and found ok					
	LPC log book, Log browser, used 70 % IPA, WFI , EM test etc record shall be verified and found ok					
	Any other observation noticed					
4.	**Instrument Room IInd:**					
	Floor, walls, table, windows glasses, it should be cleaned					
	Temperature monitoring with record (It should be within specified range)					
	Check the Waste bins, it should be cleaned					

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S.No.	Check Point (Not Limited To)	Observation			Checked By	Remarks
		YES	NO	NA		
	Instrument i.e. Tap density, melting point, Potentiometer, TOC analyzer, Cold chamber it should be cleaned					
	Check the Tap density log book shall be verified and found ok					
	Check the melting point log book shall be verified and found ok					
	Check the Potentiometer log book & instrument data shall be verified and found ok					
	Check the TOC analyzer log book etc shall be verified and found ok					
	Check the Cold chamber data logger print, temperature and kept material condition shall be verified and found ok					
	Any other observation noticed					
5.	**Weighing Room**					
	Floor, walls, balance table, it should be cleaned					
	Check the Waste bins, it should be cleaned					
	Check the Cleaning of the balances, it should be cleaned					
	Check the daily verification of the balances, it should be found ok					
	Balance log book, WS consumption record should be found ok					
	Working standard used vials in desiccators should be found valid period & desiccators silica gel should be in dry condition (Blue color)					
6.	**Wet lab :**					
	Floor, walls, table, windows glasses, reagent table, Wash bin it should be cleaned					

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Date :

S.No.	Check Point (Not Limited To)	Observation			Checked By	Remarks
		YES	NO	NA		
	Temperature monitoring with record (It should be within specified range)					
	Fuming hood, heating plate, water bath, pH meter, Conductivity meter, Muffle furnace, hot air over, Vacuum over, UV cabinet, TLC chamber, Visual inspection, Autoclave, Sonicator, its should be cleaned					
	Check the Waste bins, it should be cleaned					
	Check the daily verification of the pH meter, conductivity meter, it should be found ok					
	All liquid and solid material used in wet lab proper label, Date of receipt, opening date, used before date shall be mention every chemical.					
	Volumetric solution, Reagent, Indicator, proper labeled and preparation records is available.					
	pH meter, conductivity meter, Muffle furnace, hot air over, Vacuum over, UV cabinet, Visual inspection, Autoclave, Sonicator log book, it should be found ok					
	Analyst performed the analysis activity checked the sample reconciliation, method, solvents, diluents, mobile phase preparation, STD& sample preparation tray, used glassware, weighing procedure, it should be found ok					
	Hot air oven used for glassware drying check the cleaning & drying procedure, it should be found ok.					
	Check dry HPLC bottle for sample collection for water etc, it should be found clear and dry.					
	Any other observation noticed					
7.	**Washing Area**					
	Floor, walls, Wash bin, glassware stand, it should be cleaned					
	Check safety saver cleaning, water flow and usage					

Date :

S.No.	Check Point (Not Limited To)	Observation			Checked By	Remarks
		YES	NO	NA		
	record, it should be found ok					
	For glassware cleaning reagent 0.5 % Teepol & Nitric acid should be available in washing area.					
	Any other observation noticed					
8.	**Chemical Store**					
	To check the inward register (Receipt & Issuance) Record it should be found ok					
	Every Reagent stored in chemical store it should be labeled.					
	Reagent & Chemical Stock shall be up to date.					
	Storage condition of reagent shall be mentioned					
	Any other observation noticed					
9.	**Report Review Observation (Finished) :** **Checked By/Date :**					
10	**Report Review Observation (Raw material) :** **Checked By/Date :**					

Date :

S.No.	Check Point (Not Limited To)	Observation			Checked By	Remarks
		YES	NO	NA		
11.	**Report Review Observation (Packing Material) :** **Checked By/Date :**					
12.	**Report Review Observation (Stability) :** **Checked By/Date :**					
13.	**Other observation (If any)** **Checked By/Date :**					

Report prepared By/Date : **Report Approved By/Date :**

Note: After checking as per check list Lab QA Officer/Executive shall give one copy to Quality control department to filled the non-compliance**.**