STANDARD OPERATING PROCEDURE	
Department: Quality Assurance	**SOP No.:**
Title: Preparation of Master Lists	**Effective Date:**
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1.0 PURPOSE

To provide the procedure for preparation of master list.

2.0 SCOPE

2.1 This SOP is applicable for preparation of master list for Standard operating Procedure, Equipment's, Accessories, Instruments, Departmental Staff, FDA Approved Competent Technical staff, Product, Drain Points, Sampling Points of Potable Water, Purified Water, Compressed Air, Boiler Steam, Authorised Persons for Entry into Restricted Area, Standard test Specifications, Standard test Procedures, General test Procedures, Process validation cum report, BMR, BPR, MFR and Approved vendor, list of area coding at ……...

3.0 REFERENCE(S) & ATTACHMENTS

3.1 References

3.1.1 In-house

3.2 Attachments

3.2.1 Attachment- I: Index of Standard operating Procedure

3.2.2 Attachment- II : Amendment to Index of Standard operating Procedure

3.2.3 Attachment- III : List of Equipment's /Accessories/Instruments

3.2.4 Attachment- IV : Amendment to List of Equipment's /Accessories/Instruments

3.2.5 Attachment-V : List of Departmental Staff

3.2.6 Attachment- VI : Amendment to List of Departmental Staff

3.2.7 Attachment- VII : List of FDA Approved Competent Technical staff

3.2.8 Attachment- VIII : Amendment to List of FDA Approved Competent Technical staff

3.2.9 Attachment- IX : List of Products

3.2.10 Attachment- X : Amendment List of Products

3.2.11 Attachment- XI : List of Drain Points/Sampling Points of Potable Water/Purified Water/Compressed Air /Boiler Steam.

3.2.12 Attachment- XII : Amendment to List of Drain Points/Sampling Points of Potable Water/Purified Water/ Compressed Air/Boiler Steam.

3.2.13 Attachment- XIII : List of Authorised Persons for Entry into Restricted Area.

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3.2.14 Attachment- XIV : Amendment to List of Authorised Persons for Entry into Restricted Area.
3.2.15 Attachment- XV : List of Standard test Specifications (STS)
3.2.16 Attachment- XVI : Amendment to List of Standard test Specifications (STS)
3.2.17 Attachment- XVII : List of Standard test Procedures (STP)
3.2.18 Attachment- XVIII : Amendment to List of Standard test Procedures (STP)
3.2.19 Attachment- XIX : List of General test Procedures (GTP)
3.2.20 Attachment- XX : Amendment to List of General test Procedures (GTP)
3.2.21 Attachment- XXI : List of Process Validation Protocol cum Report
3.2.22 Attachment- XXII : Amendment to List of Process Validation Protocol cum Report
3.2.23 Attachment- XXIII : List of BMR/ BPR/ MFR
3.2.24 Attachment- XXIV : Amendment to List of BMR/ BPR/ MFR
3.2.25 Attachment- XXV : List of Approved Vendor
3.2.26 Attachment- XXVI : Amendment to List of Approved Vendor
3.2.27 Attachment- XXVII : List of Area Coding

4.0 DEFINITION & ABBREVIATION(S)

4.1 Definitions

4.1.1 Nil

4.2 Abbreviations

4.2.1 QA: Quality Assurance
4.2.2 FG: Finished Goods
4.2.3 QC: Quality Control
4.2.4 STS: Standard Test Specification
4.2.5 STP: Standard Test Procedure
4.2.6 GTP: General Test Procedure
4.2.7 SOP: Standard Operating Procedure

5.0 RESPONSIBILITY:

5.1 User Department/QA Department:

5.1.1 To prepare required master list.

5.2 Concerned Department Head:

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5.2.1 To review the respective master list prepared by concerned department person.

5.3 Quality Assurance:

5.3.1 To review the applicable master list.

5.4 QA Head:

5.4.1 To approve the master lists.

5.4.2 To ensure implementation of the defined procedure.

5.5 Plant Head:

5.5.1 To authorize the applicable master list.

5.5.2 To ensure implementation of the defined procedure.

6.0 Distribution

I. Quality Assurance
II. Quality Control
III. Production
IV. Ware house
V. Engineering
VI. Human resource and Administration.
VII. Environment, Health and Safety

7.0 PROCEDURE:

7.1 Prepare index of Standard operating Procedure as per Attachment-I.

7.2 Prepare Amendment to index of Standard operating Procedure as per Attachment- II.

7.3 Prepare list of Equipment's/Accessories/Instruments as per Attachment-III.

7.4 Prepare Amendment to list of Equipment's/Accessories/Instruments as per Attachment-IV.

7.5 Prepare List of Departmental Staff as per Attachment-V.

7.6 Prepare Amendment to list of Departmental Staff as per Attachment-VI.

7.7 Prepare list of FDA Approved Competent Technical Staff as per Attachment-VII.

7.8 Prepare Amendment to list of FDA Approved Competent Technical Staff as per Attachment-VIII.

7.9 Prepare list of Products as per Attachment-IX.

7.10 Prepare Amendment to list of Products as per Attachment-X.

7.11 Prepare list of Drain Points/Sampling Points of Potable Water/Purified Water/Compressed Air/Boiler Steamas per Attachment- XI.

7.12 Prepare Amendment to list of Drain Points/Sampling Points of Potable Water/Purified Water/Compressed Air / Boiler Steamas per Attachment- XII.

7.13 Prepare list of Authorised Persons for Entry into Restricted Areaas per Attachment-XIII.

7.14 Prepare Amendment to list of Authorised Persons for Entry into Restricted Areaas per Attachment-XIV.

7.15 Prepare list of Standard Test Specification (STS) as per Attachment- XV.

7.16 Prepare Amendment to list of Standard Test Specification (STS) as per Attachment- XVI.

7.17 Prepare list of Standard Test Procedures (STP) as per Attachment- XVII.

7.18 Prepare Amendment to list of Standard Test Procedures (STP) as per Attachment- XVIII.

7.19 Prepare list of General Test Procedures (GTP) as per Attachment- XIX.

7.20 Prepare Amendment to list of General Test Procedures (GTP) as per Attachment- XX.

7.21 Prepare list of Process validation protocol cum report as per Attachment- XXI.

7.22 Prepare Amendment to list of Process validation protocol cum report as per Attachment- XXII.

7.23 Prepare list of BMR/BPR/MFR as per Attachment- XXIII.

7.24 Prepare Amendment to list of BMR/BPR/MFR as per Attachment- XXIV.

7.25 Prepare list of Approved Vendor as per Attachment- XXV.

7.26 Prepare Amendment to list of Approved Vendor as per Attachment- XXVI.

7.27 Prepare list of area coding as per Attachment- XXVII.

7.28 All Master lists shall be revised as and when required or every six months interval if any changes are to be made based on amendment list. Revision is not required in case if there are no any changes/updates to be made in the Master list.

7.29 If there are any updates to be made in the master list within the six month interval period from date of approval of Master list then the updates such as addition/deletion/changes are to be updated in the respective amendment list. The updates made in the amendment list are to be updated in the Master list during the six monthly revision of Master list.

8.0 REVISION HISTORY

Version No.	00	Effective Date	
Details of revision: New SOP Prepared			

DECODING PHARMA

QUALITY ASSURANCE DEPARTMENT

STANDARD OPERATING PROCEDURE	
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Attachment-I

INDEX OF STANDARD OPERATING PROCEDURES

Block: _____ **Department: _____**

S.No.	Title	SOP No.	Approval date	Effective Date	Next Review date

Prepared By	Reviewed By	Approved By
Quality Assurance	Quality Assurance	QA Head
Date :	Date :	Date :

DECODING PHARMA

QUALITY ASSURANCE DEPARTMENT

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Attachment-II

AMENDMENT TO

INDEX OF STANDARD OPERATING PROCEDURES

Block: _____ **Department: _____**

S.No.	Title	SOP No.	Reference Change Control No.	Added/ Deleted	Approval date	Effective Date	Prepared By QA (Sign & Date)

DECODING PHARMA

QUALITY ASSURANCE DEPARTMENT

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Attachment-III

LIST OF EQUIPMENTS/ACCESSORIES/INSTRUMENTS

Block: _____ **Department: _____**

S.No.	Name	Make	Model	Code No.	Capacity/ Speed/Size	Name of Area/ Line No. where installed

Prepared By	Reviewed By	Approved By
Quality Assurance	**Quality Assurance**	**QA Head**
Date :	**Date :**	**Date :**

STANDARD OPERATING PROCEDURE	
Department: Quality Assurance	**SOP No.:**
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Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

Attachment-IV

AMENDMENT TO

LIST OF EQUIPMENTS/ACCESSORIES/INSTRUMENTS

Block: _____ **Department: _____**

S.No.	Name	Make	Model	Code No.	Capacity/ Speed/Size	Reference Change Control No.	Added/ Deleted	Name of Area/ Line No. where installed	Prepared/ Allocated By QA (Sign and Date)

DECODING PHARMA

QUALITY ASSURANCE DEPARTMENT

STANDARD OPERATING PROCEDURE	
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Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

Attachment- V

LIST OF DEPARTMENTAL STAFFS

Block: _____ **Department: _____**

S.No.	Name	Employee code	Qualification	Date of Joining	Previous Experience (in Years)

Prepared By	Reviewed By	Approved By
HR Department	HR Head	QA Head
Date :	Date :	Date :

STANDARD OPERATING PROCEDURE	
Department: Quality Assurance	**SOP No.:**
Title: Preparation of Master Lists	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

Attachment- VI

AMENDMENT TO

LIST OF DEPARTMENTAL STAFFS

Block: _____ **Department: _____**

S.No.	Name	Employee code	Qualification	Date of Joining	Previous Experience (in Years)	Added/ Removed	Prepared By HR (Sign and Date)

STANDARD OPERATING PROCEDURE	
Department: Quality Assurance	**SOP No.:**
Title: Preparation of Master Lists	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

Attachment-VII

LIST OF FDA APPROVED COMPETENT TECHNICAL STAFF

S.No.	Name	Employee Code	Department	Approved by FDA in Section	Govt. of	Approval date
1.						
2.						
3.						
4.						
5.						
6.						
7.						

Prepared By	Approved By	Authorised By
Quality Assurance	**QA Head**	**Plant Head**
Date:	**Date:**	**Date:**

STANDARD OPERATING PROCEDURE	
Department: Quality Assurance	**SOP No.:**
Title: Preparation of Master Lists	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

Attachment-VIII
AMENDMENT TO

LIST OF FDA APPROVED COMPETENT TECHNICAL STAFF

S.No.	Name	Employee Code	Department	FDA Approved in Section	Approval date	Prepared By QA (Sign and Date)

DECODING PHARMA

QUALITY ASSURANCE DEPARTMENT

STANDARD OPERATING PROCEDURE	
Department: Quality Assurance	**SOP No.:**
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Supersedes: Nil	**Review Date:**
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Attachment-IX

LIST OF PRODUCT

S.No.	Product Name	Label Claim	Pack Size	Shelf Life	Product Code	FDA License No.

Prepared By	Approved By	Authorised By
Quality Assurance	QA Head	Plant Head
Date:	Date:	Date:

STANDARD OPERATING PROCEDURE	
Department: Quality Assurance	**SOP No.:**
Title: Preparation of Master Lists	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

Attachment- X
AMENDMENT TO

LIST OF PRODUCT

S.No.	Product Name	Label Claim	Pack Size	Shelf Life	Product Code	License No.	Approved on Dated	Prepared By QA (Sign and Date)

DECODING PHARMA

QUALITY ASSURANCE DEPARTMENT

STANDARD OPERATING PROCEDURE	
Department: Quality Assurance	**SOP No.:**
Title: Preparation of Master Lists	**Effective Date:**
Supersedes: Nil	**Review Date:**
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Attachment- XI

LIST OF DRAIN POINTS/SAMPLING POINTS OF POTABLE WATER/PURIFIED WATER/ COMPRESSED AIR/BOILER STEAM

S.No.	Drain Point/ Sampling Point Code No.	Name of Area	Area Code No.	Department Name	Block	Type of Sampling Points (System point or User point)

Prepared By	Approved By	Authorised By
Quality Assurance	QA Head	Plant Head
Date :	Date :	Date :

STANDARD OPERATING PROCEDURE	
Department: Quality Assurance	**SOP No.:**
Title: Preparation of Master Lists	**Effective Date:**
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Attachment- XII

AMENDMENT TO LIST OF DRAIN POINTS / SAMPLING POINTS OF POTABLE WATER/PURIFIED WATER/COMPRESSED AIR/ BOILER STEAM

S.No.	Drain Point/ Sampling Point Code No.	Name of Area	Area Code No.	Department Name	Block	Type of Sampling Points (System point or User point)	Reference Change Control No.	Allocated/ Prepared By QA (Sign & Date)

DECODING PHARMA

QUALITY ASSURANCE DEPARTMENT

STANDARD OPERATING PROCEDURE	
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Attachment- XIII

LIST OF AUTHORISED PERSONS FOR ENTRY INTO RESTRICTED AREA

Block: _____ Department: _____ Area: _____

S.No.	Name of Persons	Employee Code

NOTE:

1. Listed persons are authorized to enter into the restricted area.
2. Visitor and other person entering inside the area needs to be accompanied by any of the above listed authorized person only.

Prepared By	Approved By	Authorised By
Quality Assurance	**QA Head**	**Plant Head**
Date :	**Date :**	**Date :**

STANDARD OPERATING PROCEDURE	
Department: Quality Assurance	**SOP No.:**
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Attachment- XIV

AMENDMENT TO

LIST OF AUTHORISED PERSONS FOR ENTRY INTO RESTRICTED AREA

Block: _____ Department: _____ Area: _____

S.No.	Name of Persons	Employee Code	Authorised on Dated	Prepared By QA (Sign & Date)	Approved By QA Head (Sign & Date)

NOTE:

1. Listed persons are authorized to enter into the restricted area.
2. Visitor and other person entering inside the area needs to be accompanied by any of the above listed authorized person only.

STANDARD OPERATING PROCEDURE	
Department: Quality Assurance	**SOP No.:**
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Attachment- XV

LIST OF STANDARD TEST SPECIFICATION (STS)

S.No.	Title	STS No.	Approval date	Effective Date

Prepared By	Reviewed By	Approved By
QC Department	QC Head	QA Head
Date:	Date:	Date:

DECODING PHARMA

QUALITY ASSURANCE DEPARTMENT

STANDARD OPERATING PROCEDURE	
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Attachment- XVI

AMENDMENT TO
LIST OF STANDARD TEST SPECIFICATION (STS)

S.No.	Title	STS No.	Reference CC No.	Added/ Deleted	Approval Date	Effective Date	Allocated/ Prepared By QC (Sign & Date)

DECODING PHARMA

QUALITY ASSURANCE DEPARTMENT

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Attachment- XVII

LIST OF STANDARD TEST PROCEDURES (STP)

S.No.	Title	STP No.	Approval date	Effective Date

Prepared By	Reviewed By	Approved By
QC Department	QC Head	QA Head
Date:	Date:	Date:

STANDARD OPERATING PROCEDURE	
Department: Quality Assurance	**SOP No.:**
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Supersedes: Nil	**Review Date:**
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Attachment- XVIII

AMENDMENT TO
LIST OF STANDARD TEST PROCEDURES (STP)

S.No.	Title	STP No.	Reference CC No.	Added/ Deleted	Approval date	Effective Date	Allocated/ Prepared By QC (Sign & Date)

DECODING PHARMA

QUALITY ASSURANCE DEPARTMENT

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Attachment- XIX

LIST OF GENERAL TEST PROCEDURES (GTP)

S.No.	Title	GTP No.	Approval date	Effective Date

Prepared By	Reviewed By	Approved By
QC Department	QC Head	QA Head
Date :	Date :	Date :

DECODING PHARMA

QUALITY ASSURANCE DEPARTMENT

STANDARD OPERATING PROCEDURE	
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Attachment XX

AMENDMENT TO

LIST OF GENERAL TEST PROCEDURES (GTP)

S.No.	Title	GTP No.	Reference CC No.	Added/ Deleted	Approval date	Effective Date	Allocated/ Prepared By QC (Sign & Date)

STANDARD OPERATING PROCEDURE	
Department: Quality Assurance	**SOP No.:**
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Supersedes: Nil	**Review Date:**
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Attachment- XXI

LIST OF PROCESS VALIDATION PROTOCOL CUM REPORT

S.No.	Product Name	Protocol cum Report No.	Prepared By QA Sign/Date	Approval date	Effective Date

Prepared By	Reviewed By	Approved By
Quality Assurance	Quality Assurance	QA Head
Date:	Date:	Date:

STANDARD OPERATING PROCEDURE	
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Attachment- XXII

AMENDMENT TO LIST OF PROCESS VALIDATION PROTOCOL CUM REPORT

S.No.	Product Name	Protocol cum Report No.	Prepared By QA Sign/Date	Reviewed By QA Sign/Date	Approval Date	Effective Date	Allocated/ Prepared By QA (Sign & Date)

DECODING PHARMA

QUALITY ASSURANCE DEPARTMENT

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Attachment- XXIII

LIST OF MFR/BMR/BPR

S.No.	Product Name	Label Claim	Product Code	MFR No.	Approval Date	BMR No.	Approval Date	BPR No.	Approval Date

Prepared By	Reviewed By	Approved By
Quality Assurance	Quality Assurance	QA Head
Date:	Date:	Date:

DECODING PHARMA

QUALITY ASSURANCE DEPARTMENT

STANDARD OPERATING PROCEDURE	
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Attachment- XXIV

AMENDMENT TO

MFR/BMR/BPR

S.No.	Product Name	Label Claim	Product Code	MFR No.	Approved onDated	BMR No.	Approved onDated	BPR No.	Approved on Dated	Allocated/ Prepared By QA (Sign & Date)

DECODING PHARMA

QUALITY ASSURANCE DEPARTMENT

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Attachment- XXV

LIST OF APPROVED VENDOR

S.No.	Vendor Name	Address	Approval Date

Prepared By	Reviewed By	Approved By
Quality Assurance	Quality Assurance	QA Head
Date:	Date:	Date:

STANDARD OPERATING PROCEDURE	
Department: Quality Assurance	**SOP No.:**
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Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

Attachment- XXVI
AMMENDMENT TO LIST OF APPROVED VENDOR

S.No.	Vendor Name	Address	Approval Date	Allocated/Prepared By QA (Sign & Date)