PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

STANDARD OPERATING PROCEDURE	
Department: Quality Assurance	**SOP No.:**
Title: Documentation & Data Control	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

1.0 OBJECTIVE:

To lay down a Procedure for Documentation and Data Control.

2.0 SCOPE:

This SOP is applicable to all Plants and Facilities.

3.0 RESPONSIBILITY:

CQA (Operating Person)	**:**	Preparation, Distribution (To Plant-QA and Corporate Departments), Revision, Retrieval and Destruction of this SOP. Distribution, Retrieval and Destruction of other Corporate Department Formats.
CQA (Operating Manager)	**:**	Review, Training and effective implementation of this SOP (To Plant-QA and other Corporate Departments).
Plant QA (Operating Person)	**:**	Preparation of Plant SOP in accordance with this SOP and Retrieval of this SOP.
Plant QA (Operating Manager):		Training and effective implementation of this SOP to all concerned Departments of Plant.
Respective Departments$ (Operating Person)	**:**	Preparation and revision of Departmental Documents.
Respective Departments$ (Operating Manager)	**:**	Review, Training and effective implementation of Departmental Documents.

Note: $All other Concerned Corporate and Plant Specific Departments excluding CQA & QA.

4.0 ACCOUNTABILITY:

Head CQA	**:**	Approval, Authorization, ensure Training and Implementation of this SOP. Custodian of soft and hard copy of all Master Corporate Documents.
Head QA	**:**	To ensure Training and Effective Implementation of this SOP. Custodian of soft and hard copy of all Master Documents of Plant.
Respective Departments Heads$:		To ensure Training and effective Implementation of Departmental Documents.

Note:

a) In absence of Operating Person, Operating Manager, Department Head, Head QA and Head CQA, their designee shall perform the activities.

b) $ All other Concerned Corporate and Plant Specific Departments excluding CQA & QA.

5.0 ABBREVIATIONS:

BPCR	Batch Production and Control Record
CQA	Corporate Quality Assurance
HOD	Head of the Department
IPQA	Inprocess Quality Assurance
LIMS	Laboratory Information Management System
Ltd.	Limited
MFR	Master Formula Record
No.	Number
QA	Quality Assurance
QC	Quality Control
S. No.	Serial Number
SMF	Site Master File
SOP	Standard Operating Procedure
VMP	Validation Master Plan

6.0 PROCEDURE:

Note: Do not use Gel / Fountain Pen for Signing and Filling the documents.

6.1 Documents Training, Control, Issuance and Retrieval:

6.1.1 All Master documents once finalized, shall be printed on A4 size plain white colored Paper using **"Times New Roman"** Font size 12 with Black Ink.

6.1.2 Printing of Master Documents shall be done on one side of the paper only and shall be signed off with Blue Ink ball point pen by all stakeholders.

6.1.3 SMF, VMP and other Manuals shall be printed on A4 size White Colour Glossy Paper of 100 GSM (Except Cover Page, Cover Page shall be printed on A4 Size White Photo Paper of 180 GSM) with Colour Printing. Printing shall be done on one side of the paper only.

6.1.4 Training shall be imparted by SME/Manager/Head of the User Department to the concerned department and Cross-functional departments with respect to Master document.

6.1.5 Post training, Documents shall be made effective within 10 working days and effective date shall be written in respective column of Header with **Blue Ink Ball Point Pen.**

Note: In case there is a requirement of more than one training sessions, than the document shall be made effective within 10 working days from the date of first Training session imparted.

6.1.6 Master copy shall be stamped as **"MASTER COPY**" on all pages with Blue colour ink as per **Annexure-I "Name and Specimen of Stamps"** and shall sign and date with Blue Ink Ball Point Pen.

6.1.7 All effective master Documents shall be scanned and printed on both the side of A4 size plain white colored pages and shall be stamped as **"CONTROLLED COPY"** with green colour on all pages as per **Annexure-I "Name and Specimen of Stamps"**.

6.1.8 Sign and date in **"CONTROLLED COPY"** shall be done with Black Ink Ball Point Pen**.**

Note: In case there is a need to attach format (s) on the back side of the page than single side printing can be done only for such requirements.

6.1.9 All controlled copy of Documents / Log books / Registers etc. of all the departments shall be issued by CQA/QA after receiving the Request Form for Issuance of Documents as per format shown in **Annexure-II** "**Request Form for Issuance of SOP / Format / Document"**.

Note: Additionally, in case there is a need of any Plant to provide access of Master / Executed Documents through desktop or system, same shall be made applicable with read only rights to all the users.

6.1.10 CQA/QA shall affix issuance slip as per format shown in **Annexure-III** "**Bound Book / Register Issuance Slip"** on the back side of front cover page of Bound Book (Registers, Ledgers, Duplicate / Triplicate Book / Log Books and Pre Printed forms) and Controlled Copy stamp shall be on the right corner of the slip.

Note: No spiral bounding of Log books / Registers / Ledgers etc. shall be allowed.

6.1.11 In case controlled copy of Documents are to be carried out for external / internal purpose, shall be authorized by Head CQA / Head QA as per **Annexure-II "Request Form for Issuance of SOP / Format / Document".**

6.1.12 Additional Page (for recording additional entries) shall be issued by CQA/QA after filling the Request Cum Issuance Form for Additional Pages as per format shown in **Annexure-IV "Request cum Issuance Form for Additional Pages".**

6.1.13 CQA/QA shall maintain the Issuance, Retrieval and Destruction Record of all Documents / Formats as per format shown in **Annexure-V "Documents / Formats Issuance, Retrieval & Destruction Log"**.

6.1.14 In case, if additional space / information are required, an attachment as per Format shown in **Annexure-VI** "**Additional Attachment**" shall be used and enclosed with reference of mother document (i.e. Deviation, Change Control, CAPA, Incident etc.).

6.1.15 All retrieved copies of Documents issued to respective departments of Plant shall be collected by QA Department and destroyed with the help of Paper Shredder.

Note: All the retrieved* copies of *CQA document to be submitted to CQA for destruction.

6.1.16 CQA/QA Department shall maintain the records of destructed documents as per format shown in **Annexure-V "Documents / Formats Issuance, Retrieval & Destruction Log"**.

6.1.17 QC work sheet and data sheet generated through LIMS shall be controlled and issued by QC department itself as per respective Plant QC SOP.

6.1.18 Documents Index shall be prepared by CQA/QA as per format shown in **Annexure-VII "Documents Index"**.

6.1.19 Documents Index shall be updated by CQA/QA on quarterly basis or whenever required.

6.1.20 All personnel shall use Black Ink Ball Point Pen for recording the data.

6.1.21 IPQA personnel shall use Green Ink Ball Point Pen for data entry in the documents (BPCR and Verification Part of Log Books / Formats / Registers etc.)

6.1.22 If any wrong data got generated during recording of data, same shall be invalidated with proper justification and said invalid data shall be attached with valid information / data after stamping with Invalid Copy stamp in Red Ink in Left hand side upper corner.

6.1.23 Report prepared by Computer System for e.g. Audit Compliance Report, Investigation reports etc. shall have no stamp. However, these reports shall be prepared as per the relevant SOP format and shall be signed off where required.

6.1.24 In case, any report prepared by Computer System, required for reference purpose within the organization, the same shall be printed from scanned master document on both the side of the pages and shall be shared with "Reference Copy" stamp as and when required.

6.1.25 In case, any report prepared by Computer System, required for submission to external agencies (i.e. Regulatory, Customers / Partners etc.), the same shall be printed from scanned master document on both the side of the pages and shall be shared with "Uncontrolled Copy" stamp as and when required.

Note:

a) All Plant QA shall create one folder ready wherein all Key documents (in general required for Audit) shall be placed by scanning the master copy of document for smooth & successful conduction of Audit.

b) In case any of Akums Customers during the time of Audit has requested some of the SOPs, Protocols / Executed Documents etc. for review, than the requested document (scanned master document) shall be provided through Vaultize etc. with

Read Only Rights in folder by CQA/QA. These documents shall be available only for maximum of 07 days and shall automatically be removed from the folder.

6.2 Specimens of Stamp:

6.2.1 Specimen of Stamps having Department name as **"Corporate Quality Assurance"** are for the Documents controlled by Corporate Quality Assurance as shown in **Annexure-I "Name and Specimen of Stamps".**

6.2.2 In case of Plant level documents Stamp shall have the department name as **"Quality Assurance"** instead of Corporate Quality Assurance with respective Plant / Subsidiaries name as shown in **Annexure-I "Name and Specimen of Stamps".**

6.2.3 All Stamps shall be kept in lock & key.

6.2.4 For a Specimen of Stamps Location refer as per format shown in **Annexure-IX "Stamps Location for SOP / Format / Document".**

6.2.5 Master Copy Stamp:

6.2.5.1 Master Copy of documents shall be stamped as '**MASTER COPY'** in Blue color ink below square space or right upper corner of the page provided in Header on all the pages and shall be signed by **Blue Ink Ball Point Pen.**

6.2.6 Controlled Copy Stamp:

6.2.6.1 Scanned Master Copy of documents shall be printed on both the side of A4 size plain white colored pages and stamped as **'CONTROLLED COPY'** in Green ink in the right upper corner of the page and shall be signed by **Black Ink Ball Point Pen.**

6.2.7 Display Copy Stamp:

6.2.7.1 After **'CONTROLLED COPY'** stamp document to be issued for display purpose shall be stamped as **'DISPLAY COPY'** in Violet ink on right corner, below Footer.

6.2.8 Additional Page Stamp:

6.2.8.1 Additional pages shall be stamped as **'ADDITIONAL PAGE'** in violet ink at Footer in center and shall be signed by **Black Ink Ball Point Pen** with Controlled Copy stamp at predefined place.

6.2.9 Uncontrolled Copy Stamp:

6.2.9.1 Document that is meant to be submitted / provided to the External Agency (i.e. Regulatory, Customers / Partners etc.) shall be made by printing scanned Master Documents or by photocopying executed documents (Filled BMR/BPR, Log Books, Reports and any other executed formats etc.) on both the side of A4 size plain white colored pages by CQA / QA and shall be stamped as **'UNCONTROLLED COPY'** in Red Ink on left corner of each page below footer.

6.2.9.2 All uncontrolled copy of Documents, provided to external agencies (i.e. Regulatory, Customers / Partners etc.) shall be recorded as per format as shown in **Annexure-X "Issuance Record of Uncontrolled Copy / Reference Copy of SOP / Format / Document"** and retrieval of uncontrolled copy shall not be necessary.

Note: Uncontrolled copy of Documents shall not be issued within the entire organization for internal use.

6.2.10 Obsolete Copy Stamp:

6.2.10.1 Obsolete Copy shall be stamped as '**OBSOLETE COPY'** in Red Ink in the Middle of all the pages and only the first page shall be signed off with date by **Black Ink Ball Point Pen.**

6.2.11 Discontinued Copy Stamp:

6.2.11.1 Master Copy of Documents which is discontinued shall be stamped as '**DISCONTINUED COPY'** in Red Ink at the middle of all the pages and only the first page shall be signed off with date by **Black Ink Ball Point Pen.**

6.2.12 Reviewed Stamp:

6.2.12.1 Any Reference documents from outside Agency received at CQA and QA, shall be reviewed and stamped with **"REVIEWED"** on last page at centre of footer of the document in Violet ink and shall be signed by reviewer with **Black Ink Ball Point Pen.**

6.2.13 Reference Copy Stamp:

6.2.13.1 When multiple copies of any executed document (i.e. filled deviation, Incident, Change Control, training record, batch conversion note etc.) are required for filing with other documents as reference, **"REFERENCE COPY"** stamp in violet ink shall be put above header in centre on both the side of A4 size plain white colored pages**.**

6.2.13.2 Reference copy of any document shall be made by printing of scanned Master Document or by photocopy of executed documents (Filled BMR/BPR, Log Books, Reports and any other executed formats etc.) on both the side of A4 size plain white colored pages by CQA/QA and stamping with Reference Copy stamp.

6.2.13.3 All reference copy of any Documents provided to Plant or Corporate Department shall be recorded as per format as shown in **Annexure-X "Issuance Record of Uncontrolled Copy / Reference Copy of SOP / Format / Document".**

6.2.14 Invalid Copy Stamp:

6.2.14.1 Invalid Copy shall be stamped as '**INVALID COPY'** in Red Ink in the Left hand side upper corner of all wrong documents and shall be signed by **BLACK INK Ball Point Pen.**

6.3 Revision of Documents:

6.3.1 Any change required in the document shall be done at any time during the period after due authorization of Change Control.

6.3.2 If there is discontinuation of document, shall be made through Change Control Procedure.

6.3.3 If periodic review of the document is made with changes in the document, shall be initiated through change control.

6.3.4 Any new document shall be made effective through Change Control Procedure and impact shall be evaluated.

6.3.5 CQA/QA shall provide soft copy of Documents to respective departments at least one week prior from the next due date of revision.

6.4 Archival and Destruction of Documents:

6.4.1 All the Obsolete / Discontinued hard copy of Master Document (i.e. MFR, BPCR etc.) shall be scanned and retained with back up facility for life cycle from the date of Obsolete / Discontinued document.

6.4.2 Hard copy of Obsolete / Discontinued Master Document shall be stored for Five years and destruction shall be done as per format shown in **Annexure-XI "Document Destruction Record".**

6.4.3 After five year from the date of Obsolete / Discontinued, document shall be destroyed through paper shredder.

6.4.4 Routinely used completed/executed Corporate Department's documents shall be submitted to CQA on monthly/yearly basis as per applicability.

6.4.5 Routinely used completed/executed Plant specific documents at site shall be submitted to Quality Assurance Department on monthly/yearly basis as per applicability.

6.4.6 All controlled Retrieved Documents shall be archived in CQA/QA Department with lock and key arrangements.

6.4.7 All Documents and Records shall be stored in a manner to protect them from damage, loss and deterioration.

6.4.8 Documents & Records shall be easily retrievable.

6.4.9 In case if any legal Complain / Issue is noticed then necessary documents / data covering that complaint / issue shall be retained till the resolution of such issues or as required subsequently.

6.4.10 Analytical Method Validation protocols & Reports, Product Quality Review, Process Validation Protocols / Reports, Stability Data & Documents, Qualification & Validation Documents for critical Utilities / System / Equipments, Non-clinical data, Bioavailability & Bioequivalence, Clinical Trials data shall be retained till the lifecycle of the product.

6.4.11 Raw data including electronic data of all validation and stability data shall be retained till the lifecycle of the product.

6.4.12 PV and Stability batches BPCRs shall be retained till the lifecycle of the product (s).

6.4.13 Executed BPCRs (BMR, BPR and Analytical data) and other product related documents and logbooks shall be retained for 5 years from the date of manufacture or 5 years from the date of certification of batch by QP / Authorized person, whichever is later and thereafter QA shall destroy by paper shredding machine.

6.4.14 In case the shelf Life of the product is 5 years than Executed BPCRs (BMR, BPR and Analytical data) and other product related documents and logbooks shall be retained for shelf-life plus 1 year.

6.4.15 Electronic documents and data shall also be maintained as per **Point No. 6.4.10 to 6.4.14.**

6.4.16 QA shall maintain the destruction record of Executed BPCRs (BMR, BPR, and Analytical data).

6.4.17 All Certificates, Equipment / Machines Manuals (Original Copy) shall be retained till the lifecycle of the product by Quality Assurance Department with lock and key arrangements.

6.4.18 Calibration records, Equipment Log & Machine Log shall be preserved up to Five Years from the date of activity.

6.5 Data Control:

6.5.1 Data shall be protected through "User Access Management" by CIT/IT.

6.5.2 Printed hard copy of data, duly signed by the operator of respective department shall be preserved along with the relevant documents, if required.

6.5.3 Backup of data shall be done on schedule basis by application in auto mode by CIT/IT.

6.5.4 The distribution of data to other than user shall be done only after approval of Head CQA/QA.

7.0 ANNEXURES:

ANNEXURE No.	TITLE OF ANNEXURE	FORMAT No.
Annexure-I	Name and Specimen of Stamps	
Annexure-II	Request Form for Issuance of SOP / Format / Document	
Annexure-III	Bound Book / Register Issuance Slip	
Annexure-IV	Request cum Issuance form for Additional Pages	
Annexure-V	Documents / Formats Issuance, Retrieval & Destruction Log	
Annexure-VI	Additional Attachment	
Annexure-VII	Documents Index	
Annexure-VIII	**Addendum for Documents Index**	
Annexure- IX	Stamps Location for SOP / Format / Document	
Annexure-X	Issuance Record of Uncontrolled Copy / Reference Copy of SOP / Format / Document	

Annexure-XI	Document Destruction Record	

***Annexure-VIII discontinued from dated _____.**

8.0 DISTRIBUTION:

- Controlled Copy No. 01 — Corporate Quality Assurance
- Controlled Copy No. 02 — Corporate Information & Technology
- Controlled Copy No. 03 — Corporate Human Resource
- Controlled Copy No. 04 — Corporate Health & Medical Services
- Controlled Copy No. 05 — Corporate Pharmacovigilance
- Controlled Copy No. 06 — Corporate Environment, Health & Safety
- Controlled Copy No. 07 — Corporate DRA
- Master Copy — Corporate Quality Assurance

9.0 REFERENCES:

- US Code of Federal Regulations, Current Good Manufacturing Practice for Finished Pharmaceuticals (21 CFR -Part 211), Food and Drug Administration, 21 CFR, Chapter-I.
- ICH Good manufacturing practice guide for API Q7, Section VI “Documentation and Records”.
- ISO 9001-2008, Clause 4.2: Documentation requirements.
- Guide to GMP for medicinal products Part-1, chapter 4 Documentation PIC/S PE 009-14 (Part I).
- Drugs & Cosmetics Rules 1945.

10.0 REVISION HISTORY:

CHANGE HISTORY LOG

Revision No.	Change Control No.	Details of Changes	Reason for Change	Effective Date	Updated By

PHARMA DEVILS

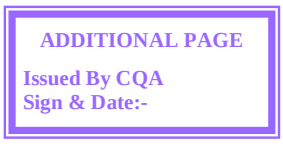
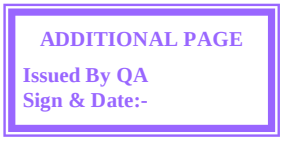
QUALITY ASSURANCE DEPARTMENT

STANDARD OPERATING PROCEDURE	
Department: Quality Assurance	**SOP No.:**
Title: Documentation & Data Control	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

ANNEXURE–I (Specimen Copy)

LOGO	*X----- **LOCATION CORPORATE QUALITY ASSURANCE#

NAME AND SPECIMEN OF STAMPS

NAME OF THE STAMP	SPECIMEN OF STAMP
MASTER COPY	 (For CQA)  (For Plant QA)
CONTROLLED COPY	 (For CQA)  (For Plant QA)
CONTROLLED COPY NO.	 (For CQA)  (For Plant QA)
ADDITIONAL PAGE	 (For CQA)  (For Plant QA)
UNCONTROLLED COPY	 (For CQA)  (For Plant QA)

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Quality Assurance	**SOP No.:**
Title: Documentation & Data Control	**Effective Date:**
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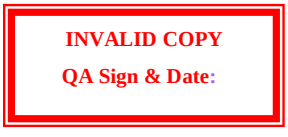
NAME OF THE STAMP	SPECIMEN OF STAMP
OBSOLETE COPY	 **(For CQA)**  **(For Plant QA)**
DISCONTINUED COPY	 **(For CQA)**  **(For Plant QA)**
REVIEWED	 **(For CQA)**  **(For Plant QA)**
DISPLAY COPY	 **(For CQA)**  **(For Plant QA)**
REFERENCE COPY	
INVALID COPY	 **(For CQA)**  **(For Plant QA)**

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

STANDARD OPERATING PROCEDURE	
Department: Quality Assurance	**SOP No.:**
Title: Documentation & Data Control	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

Note: #In case of QA documents Word CQA (Corporate Quality Assurance) shall be replaced with QA (Quality Assurance) in format.
**Location: It is the location of the plant and place.

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

ANNEXURE–II

LOGO	***X-----** **LOCATION **CORPORATE QUALITY ASSURANCE#**
REQUEST FORM FOR ISSUANCE OF SOP / FORMAT / DOCUMENT	

Date:

To,
CQA#

From:

S.No.	SOP / Format / Document Title	SOP / Format / Document No.	Revision No.	No of Copies Required	External / Internal Purpose	Reason for Issuance

Prepared By
Initiating Department
(Sign & Date)

Checked By
Head of the Department
(Sign & Date)

Approved By
Head CQA#
(Sign & Date)

Note: #In case of QA documents Word CQA (Corporate Quality Assurance) shall be replaced with QA (Quality Assurance) in format.
***X=Akums Drugs & Pharmaceuticals Ltd. and its Subsidiaries (For Corporate SOPs) and Plant Name (For Plant SOPs)**
**Location: It is the location of the plant and place.

STANDARD OPERATING PROCEDURE	
Department: Quality Assurance	**SOP No.:**
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Supersedes: Nil	**Review Date:**
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ANNEXURE–III

LOGO	***X-----** **LOCATION **CORPORATE QUALITY ASSURANCE#**		
BOUND BOOK / REGISTER ISSUANCE SLIP			
Title of Document:			
Format No.:		**Effective Date:**	
Department Name:			
No. of Pages:		**From _____ To _____**	
Issued By Operating Person CQA# (Sign & Date)		**Approved By Operating Manager CQA# (Sign & Date)**	

Note: #In case of QA documents Word CQA (Corporate Quality Assurance) shall be replaced with QA (Quality Assurance) in format.
**Location: It is the location of the plant and place.

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

ANNEXURE–IV

LOGO	***X-----** **LOCATION **CORPORATE QUALITY ASSURANCE#**
REQUEST CUM ISSUANCE FORM FOR ADDITIONAL PAGES	

Date:

To,
The Manager CQA#

From:

S.No.	Document / Format Title	Document / Batch / Format No.	Page No.	No. of Copies Required	Reason for Issuance

Prepared By Officer / Executive (Sign & Date)	Checked By Head of Department (Sign & Date)	Approved By Manager CQA# (Sign & Date)	Additional Pages Issued By CQA# Officer / Executive (Sign & Date)

Note: #In case of QA documents Word CQA (Corporate Quality Assurance) shall be replaced with QA (Quality Assurance) in format.
**Location: It is the location of the plant and place.

STANDARD OPERATING PROCEDURE	
Department: Quality Assurance	**SOP No.:**
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Supersedes: Nil	**Review Date:**
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ANNEXURE – V

LOGO	***X-----** **LOCATION **CORPORATE QUALITY ASSURANCE#**

DOCUMENTS / FORMATS ISSUANCE, RETRIEVAL & DESTRUCTION LOG

Year:

Issuance								Retrieval			Destruction		Remarks
S.No.	**Document / Format Title**	**Document / Format No.**	**Revision No.**	**Department**	**No. of Copy Issued**	**Issued By (Sign & Date)**	**Received By (Sign & Date)**	**No. of Copies Retrieved**	**No. of Unfilled / Supersede Copies Retrieved**	**Retrieved By (Sign & Date)**	**Unfilled / Supersede Copy Destroyed By (Sign & Date)**	**Checked By (Sign & Date)**	

Note: #In case of QA documents Word CQA (Corporate Quality Assurance) shall be replaced with QA (Quality Assurance) in format.
**Location: It is the location of the plant and place.

STANDARD OPERATING PROCEDURE	
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ANNEXURE–VI (Specimen Copy)

LOGO	***X-----** **LOCATION **CORPORATE QUALITY ASSURANCE#**
ADDITIONAL ATTACHMENT	

Annexure No.:
Title of Annexure:
Reference of Mother Documents:

Prepared By:	Reviewed By:	Approved By:
Operating Person	Operating Manager	Head CQA#
(Sign & Date)	(Sign & Date)	(Sign & Date)

Note: #In case of QA documents Word CQA (Corporate Quality Assurance) shall be replaced with QA (Quality Assurance) in format.
**Location: It is the location of the plant and place.

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

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ANNEXURE–VII

HEADER:

LOGO	***X-----** **LOCATION **CORPORATE QUALITY ASSURANCE#**
DOCUMENTS INDEX	
Department :	
Effective Date:	
Revision No.:	

BODY:

S.No.	Document Title	Document No.	Revision No.	Effective Date	Revision Date	Remarks

CHANGE HISTORY LOG

Revision No.	Details of Changes	Reason for Change	Effective Date	Updated By

FOOTER:

	Prepared By Operating Person	Checked By Operating Manager	Approved By Head CQA#
Sign			
Date			
Name			

Note: #In case of QA documents Word CQA (Corporate Quality Assurance) shall be replaced with QA (Quality Assurance) in format.
**Location: It is the location of the plant and place.

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QUALITY ASSURANCE DEPARTMENT

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Title: Documentation & Data Control	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

ANNEXURE–IX (Specimen Copy)

STAMPS LOCATION FOR SOP / FORMAT / DOCUMENT

LOGO

***X-----**

**LOCATION

DEPARTMENT#

RESTRICTED CIRCULATION

STANDARD OPERATING PROCEDURE

Title : Documentation and Data Control

SOP No.:		**Department :**	
		Effective Date :	
Revision No.:		**Revision Date :**	
Supersede Revision No.:		**Page No.:**	

CONTROLLED COPY

CORPORATE QUALITY ASSURANCE MASTER COPY Sign..... Date.....

Middle of the Page, Stamp in Red Ink, Only in first Page Sign & Date by **Black Ink** Ball Point

Right Upper Corner of the Page, Stamp in Green Ink, Signed by Black Ink Ball Point Pen

Below Right Upper Corner of the Page, Stamp in Blue Ink, Signed by **Blue Ink** Ball Point Pen

CORPORATE QUALITY ASSURANCE OBSOLETE COPY

Left corner of the Page, Stamp in Red Ink.

Centre of footer of the Page, Stamp in Violet Ink and Signed by Black

Right Corner of the Page Stamp in Violet Ink

	Prepared By	Reviewed By	Approved By	Authorized by
Sig				
Da				
Nam				

CORPORATE QUALITY ASSURANCE UNCONTROLLED COPY

CORPORATE QUALITY ASSURANCE REVIEWED Sign..... Date.....

CORPORATE QUALITY ASSURANCE DISPLAY COPY

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

STANDARD OPERATING PROCEDURE	
Department: Quality Assurance	**SOP No.:**
Title: Documentation & Data Control	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

REFERENCE COPY

OGO

ION

DEPARTMENT#

RESTRICTED

CIRCULATION

STANDARD OPERATING PROCEDURE				
Title : Documentation and Data Control				
SOP No.:		**Department :**		
		Effective Date :		
Revision No.:		**Revision Date :**		
Supersede SOP No.:		**Page No.:**		

Middle of the Page, Stamp in Red Ink, Only in first Page Sign & Date by **Black Ink** Ball Point

Middle of the Page, above header, Stamp in Violet Ink,.

CORPORATE QUALITY ASSURANCE

DISCONTINUED COPY

	Prepared By	Reviewed By	Approved By	Authorized By
Sign				
Date				
Name				

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

STANDARD OPERATING PROCEDURE	
Department: Quality Assurance	**SOP No.:**
Title: Documentation & Data Control	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

INVALID COPY

CQA Sign & Date:

LOGO	***X-----** **LOCATION **DEPARTMENT#**	
	TITLE	

CONTROLLED COPY
Sign.....
Date.....

MASTER COPY
Sign.....
Date.....

Left Upper Corner of the Page, Stamp in Red Ink, Signed by Black Ink Ball Point Pen

Right Upper Corner of the Page, Stamp in Green Ink, Signed by Black Ink Ball Point Pen

Left corner of the Page, Stamp in Red Ink.

Below Right Upper Corner of the Page, Stamp in Blue Ink, Signed by **Blue Ink** Ball Point Pen

Right Corner of the Page, Stamp ir Violet Ink

Below Footer in center of the Page, Stamp in Violet Ink, Signed by Black Ink

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DISPLAY COPY

ADDITIONAL PAGE
Issued By CQA
Sign & Date:-

Note:
**Location: It is the location of the plant and place.
#: It is the respective Department name.

STANDARD OPERATING PROCEDURE	
Department: Quality Assurance	**SOP No.:**
Title: Documentation & Data Control	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

ANNEXURE–X (Specimen Copy)

LOGO	***X-----** **LOCATION **CORPORATE QUALITY ASSURANCE#**
ISSUANCE RECORD OF UNCONTROLLED COPY/ REFERENCE COPY OF SOP / FORMAT / DOCUMENT	

Year:

S.No.	Date	Department	SOP / Format / Document Title	SOP / Format / Document No.	Revision No.	Uncontrolled Copy / Reference Copy	Purpose	Issued By (Sign & Date)	Issued to	Remarks

Note: #In case of QA documents Word CQA (Corporate Quality Assurance) shall be replaced with QA (Quality Assurance) in format.
**Location: It is the location of the plant and place.

STANDARD OPERATING PROCEDURE	
Department: Quality Assurance	**SOP No.:**
Title: Documentation & Data Control	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

ANNEXURE–XI

LOGO	*X----- **LOCATION **CORPORATE QUALITY ASSURANCE#**
	DOCUMENT DESTRUCTION RECORD

S. No.	Document Title	Document No.	Date of Destruction	Destruction Done By (Sign & Date)	Destruction Checked By (Sign & Date)	Remarks

Note: #In case of QA documents Word CQA (Corporate Quality Assurance) shall be replaced with QA (Quality Assurance) in format.
**Location: It is the location of the plant and place.