STANDARD OPERATING PROCEDURE (SOP) FOR DESTRUCTION/SAFE DISPOSAL OF CONTROLLED SUBSTANCES (FINISHED PRODUCT/API/ PRECURSOR CHEMICAL).

1. Application on letter head duly signed by MD//CEO/Authorized Person of the firm explaining the reasons(s)/justification for destruction of controlled drugs (API & finished products) with the notarized copies of following documented evidence shall be submitted.

i. Allocation and Import Authorization letter of respective controlled substance (s)/drug(s).
ii. Purchase invoice of respective controlled substance (s) cleared from the area Assistant Director, DRAP.

2. Details of controlled drugs (API/ Finished Products) to be destroyed, shall be submitted on **Annexure-G.**

3. The case found complete in all respects will be processed by the Division of Controlled Drugs, DRAP for approval of the Secretary, Ministry of Narcotics Control, Islamabad for destruction by a panel consisting of the following members:-

- Area Federal Inspector of Drugs, DRAP.
- Concerned area Assistant Director, Regional Office, DRAP.
- One representative from Anti-Narcotics Force (ANF).

4. The TORs of the panel for destruction will be as follows:-

i. On site verification of the quantity to be destroyed/disposed of.
ii. Sampling of material/product to be destroyed as per prescribed procedure as per provision of DRAP Act 2012/Drugs Act 1976. Where sampling is not possible due to any reason then justification thereof be mentioned.
iii. Verify QC laboratory testing report in case of spurious, substandard, recalled or rejected batches of the controlled substances to be destroyed.
iv. Verification and evaluation of the reasons for destruction as stated by the firm in their request.

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v. The panel may take decision for safe disposal/destruction of the said material and furnish a detailed report, otherwise may refer back the matter to Division of Controlled Drugs for further course of action.

5. A certificate of destruction will be issued by the panel after completing the destruction / disposal activity as per **Annexure-J** and report of panel proceedings shall be submitted to the Division of Controlled Drugs, DRAP along with certificate of destruction and other supporting documents.

6. The Ministry of Narcotics Control shall be informed by the Division of Controlled Drugs, DRAP regarding the case, accordingly.

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Annexure -G

DETAIL OF QUANTITY OF CONTROLLED SUBSTANCE(S) TO BE DESTROYED/DISPOSED OFF

Name of firm/applicant…….. Address…….DML/or DSL No.....

A. DETAIL OF APIs (RAW MATERIAL/PRECURSOR CHEMICAL(s))

Sr. #	Name of Controlled Substance(s)	Allocation/Import Authorization/NOC # with date	Batch No.	Import Invoice No with Date	Quantity to be destroyed	Date of expiry	Reasons of Destruction	Remarks, if any

B. DETAIL OF FINISHED PRODUCTS (Locally Manufactured/Finished Import)

Sr. #	Brand Name of the Drug with Dosage Form	Registration #	Composition of the Controlled Substance	Batch No.	Date of Manufacture	Import Invoice No with Date (for Finished import)	Pack size	Quantity in hand to be destroyed	Date of expiry	Reasons Of Destruction	Remarks

1	Pack size of the Finish Drug	Strength						
		Pack size						
2	Unit Packs to be destroyed.							
3	Quantity of Controlled Substance in above stated quantity of product							

Name, Seal & Signature
C.E.O/MANAGING DIRECTOR/
AUTHORIZED PERSON

*****_Add rows if required._

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ANNEXURE-J

CERTIFICATE OF DESTRUCTION FOR CONTROLLED DRUGS

(API/FINISHED DOSAGE FORMS)

We, the undersigned, certify that the following quantities of controlled substance(s) in possession of M/s (Name and Complete address) have been destroyed in our presence in compliance to Division of Controlled Drugs, DRAP letter #.....dated……

Sr. #	Name of Controlled Substance/Finished Product Containing Controlled Substance(s)	Quantity Destroyed/ Disposed of.

Method Of destruction:

Date of destruction:

Site of destruction/Disposal Carried out.

Panel Members Signatures with Name and Designation

1. **Name_____ Designation_____ Signature_____Date_____**
2. **Name_____ Designation_____ Signature_____Date_____**
3. **Name_____Designation_____ Signature_____Date_____**

Firm's Representatives Signatures with Name and Designation

1. **Name_____ Designation_____ Signature_____Date_____**

End of Document

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