DECODING PHARMA

QUALITY ASSURANCE DEPARTMENT

STANDARD OPERATING PROCEDURE	
Department: Quality Assurance	**SOP No.:**
Title: Finished Product Control Sample Collection, Storage and Disposal	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

1.0 OBJECTIVE:

To lay down a procedure for finished product control sample collection, storage and disposal.

2.0 SCOPE:

The procedure is applicable to the finished product samples required for control sample collection, storage and disposal.

3.0 RESPONSIBILITY:

Executive/Officers – Quality Assurance, Quality Control

Head – Quality Assurance

4.0 DEFINITION(S):

NA

5.0 PROCEDURE:

5.1 Collection and Storage of Control Samples:

5.1.1 Withdraw control sample from each batch for all products (Refer Annexure-II) from start, middle and end of the packing operation.

5.1.2 If there is more than one type of packing of same batch, withdraw the control sample for all types of packing.

5.1.3 Quantity specified for the sampling is based on the requirement of a minimum of two complete analysis.

5.1.5 Withdraw the required number of blisters / strips and arrange to place in control sample room in the specified rack/location.

5.1.6 Put the control sample stamp on the outer side of each pack with red colour ink and record the detail in control sample register as per Annexure –III.

5.1.7 Lock the control sample room and keep the key under the custody of Head-QA.

5.1.8 Control sample shall be stored for a period of 12 months beyond the expiry date of the

product.

5.1.9 Control samples shall only be removed out from control sample room incase of unavoidable circumstances like re-analysis for market complaint and shall be removed out after written approval of Head-QA.

5.1.10 Requisition for the control samples removed out/used for analysis shall be stored in file as a record.

5.1.11 Record the temperature and relative humidity of the control samples room twice in a day using a calibrated hygrometer as per Annexure –I.

5.1.12 The temperature shall be 25 ± 2°C and relative humidity within 50 ± 5 %.

5.1.13 Incase temperature and relative humidity goes beyond the limit, inform to maintenance department immediately to rectify the problem.

5.1.14 Evaluate the control sample every six months for physical appearance and shall be recorded as per Annexure –IV.

5.1.15 In case of physical discrepancy, sample shall be subjected for complete analysis as per product specifications.

5.2 Destruction of control Samples:

5.2.1 After completion of storage period, segregate the control samples and label them as “Control Samples For Destruction”.

5.2.2 Get the approval from QA-Head for destruction of Control Samples.

5.2.3 Defoil the strips / blisters and dissolve it into water and transfer the disposals into ETP and also transfer the empty strips / blisters into scrap yard for destruction.

5.2.4 Record the destruction of control samples as per Annexure –III

6.0 ABBREVIATION(S):

QA : Quality Assurance

ETP: Effluent Treatment Plant.

7.0 REFERENCE(S):

NA

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8.0 ANNEXURE(S):

Annexure – I: Temperature and Relative Humidity Record

Annexure – II: Control Sample Quantity

Annexure – III: Control Sample Register

Annexure – IV: Control Sample Observation Record.

9.0 REVISION CARD:

S.No.	REVISION No.	REVISION DATE	DETAILS OF REVISION	REASON (S) FOR REVISION

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Annexure I

TEMPERATURE AND RELATIVE HUMIDITY RECORD (CONTROL SAMPLE ROOM)

Frequency : Twice a day
Temperature : 25±2°C **Month/Year:**
Relative Humidity : 50±5%

Date	Time	Temperature (^{0}C)	Relative Humidity (%)	Checked By

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Annexure II

Control Sample Quantity

S.No.	PRODUCT	QUANTITY		
		PHYSIAN SAMPLE	SALE	EXPORT

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Annexure III

CONTROL SAMPLE REGISTER

Product Name:

S.No.	Date	B. No.	Mfg. Date	Exp. Date	Quantity	Quantity withdrawn	Purpose	Authorization	Date of Destruction	Destroyed By/Date	Remark

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Annexure IV

CONTROL SAMPLE OBSERVATION RECORD

Product Name				**Pack Style**	
Batch No.		**Mfg. Date**		**Exp. Date**	
Initial Description					

S.No.	Date	Description (Complies/Does not Complies)	Checked By/Date