DECODING PHARMA

QUALITY ASSURANCE DEPARTMENT

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

1.0 OBJECTIVE:

To lay down a procedure for Mock Recall.

2.0 SCOPE:

This SOP is applicable to conduct the mock recall of finished product manufactured of …….

3.0 RESPONSIBILITY:

Officer/Executive-QA: Preparation, Review, Issuance, and retrieval of SOP.

Head -QA: For review, Approval and effective implementation of SOP.

Mock Recall Coordinator (QA): Follow up for meeting to conduct the mock recall and compile the report.

Mock Recall Team committee (Concerned department): To execute the mock recall and provide the information to coordinator to compile with report.

4.0 ACCOUNTABILITY:

Head QA: For Preparation, Review, Authorization, Training & Effective implementation of SOP.

Head -Concern Department (Warehouse/Production/QC/PPIC): For Effective implementation of SOP.

5.0 DEFINITION:

5.1 **Mock Recall:** Mock recalls are used to determine whether the recall procedure is capable of identifying and quickly controlling a given lot of potentially affected product and reconciling the quantities produced quantities in inventory and quantities distributed.

6.0 PROCEDURE:

6.1 A mock recall will identify potential problem and allow the personnel to become familiar with recall procedure. If problem is identified in the recall procedure, they should be corrected.

6.2 Mock recall in order to evaluate the product recall program, periodic mock recall should be carried out at least once in two years for at least one batch of any product, dispatched for sale where maximum distributor are involved to test the effectiveness of arrangement of recall.

6.3 All information obtained during the mock recall shall be documented in simulation Protocol & Report of Mock Recall.

6.4 Also, any corrective action and deficiencies are obtained then it shall be documented in the simulation recall protocol & report.

6.5 **Selection of Product Batch:**

- Selection of other Batch number shall also be included based on the following criteria's:

✓ Product selected shall be manufactured with sufficient number of Batches manufactured at the site.

✓ Batch number selected shall be manufactured latest before 6 month.

✓ Batches manufactured prior to and after the Batch selected for Mock Recall.

6.6 **Initiation of Mock Recall:**

6.6.1 Prepare a Simulation Protocol for Mock Recall as per **Annexure-I**. Mock recall shall be performed at regular intervals of its frequency. The mock recall relevant information shall be reported in respective Simulation Report for Mock Recall as per **Annexure-II**.

6.6.2 Assigning Numbering System of Protocol and Report for Mock Recall

Numbering System for Mock Recall Protocol:

Number shall be assigned as …../**MRP/YY/NNN**,

Where,

….. : Denotes Company name

/ : Separator

MRP : Denotes Mock Recall Protocol

/ : Separator

YY : Last two digit of Year

/ : Separator

NNN : Stands for Serial Number, starting from **001**.

Example: …./MRP/19/001; Denotes first Mock Recall Protocol raised for in year 2019.

Numbering System for Mock Recall Report:

Number shall be assigned as …**/MRR/YY/NNN**,

Where,

…. : Denotes Company Name

/ : separator

MRR : Denotes Mock Recall Report

/ : separator

YY : Last two digit of Year

/ : separator

NNN : Stands for Serial Number, starting from **001**.

Example: …/MRR/19/001; Denotes first Mock Recall Protocol raised for in year 2019.

6.6.3 Initiate the Mock Recall activities with start of date and time.

6.6.4 Set the time goal of 24 hours within which all the stockiest up to the retailer level to which the consignment of the batch is dispatched is retrieved.

6.6.5 The Stockiest shall be identified with the help of the Marketing department of the third party/LL units for retrieval of the information of existing stocks to meet the Critical Recall criteria.

6.6.6 With the confirmation of the effectiveness of the Mock Recall exercised for critical recalls. Recall categorized under Major and minor shall be obviously ensured to be effective.

6.6.7 Before time goal is set for Mock Recall. A meeting shall be organized by Executive/Operating Manager-QA (mock recall coordinator) with the Recall team committee regarding the Mock Recall activities.

6.6.8 Mock Recall Team Committee consists of the concerned personnel of respective function department (PPIC/Warehouse/Production/QC/QA) and its Head QA.

6.6.9 Start the Clock to initiate the Mock Recall, once the Batch number of the product is selected for mock recall with decision by the Recall Team.

6.6.10 Preference shall be provided in the selection of the Batch for Mock recall based on the criteria like conditional release provided if any viz.
Deviation/incident/Rework/Reprocess/Market Complaint.

6.6.11 Products with Batch Numbers to which the Active ingredients/critical excipient of common A.R. No's are dispensed.

6.6.12 Recall Coordinator shall instruct the PPIC department to contact with the Marketing Head of the third party/LL units /Depot ('s) through fast communication to which the consignment was transferred informing about the Mock Recall activities initiated by the organization and seek help for successful execution of the Mock Recall the organization and shall obtain the information about routes of distribution of the consignment to various stockiest up to the retailer level and also get the current stock lying with the individual stockiest.

6.6.13 Meanwhile Recall Coordinator shall collect and review for correct all the related documents related to the Batch Number ('s') viz, but not limited.

- Bach manufacturing & Packing Records
- COA's of all the Raw & Packing Materials.
- COA's of the Bulk and Finished Products.
- Various Log Books of the Recalled Batch,
- Dispatch details and Invoice.
- Any Deviations/Change Control/Rework/Reprocess etc.

6.6.14 If Mock recall activity is exercised for more than one Batch the activity can be captured in a single protocol with justification for including additional batches e.g. due to usage of API's with same A. R. No's & expected adverse impact of the API's being used in the batches.

6.6.15 Check to review for the Control Samples Retained and record for their physical characteristics.

6.6.16 Photocopies of all the reviewed documents shall be enclosed with the protocol and report.

6.7 **The Criteria of the Mock Recall is met:**

6.7.1 Information from the Marketing department of the third party/LL unit is retrieved within 24 hours from the time set for Mock Recall.

6.7.2 If the information of the stocks in units dispatched is successfully tracked with respect to Not less than 98 % of the total units dispatched.

7.0 ABBREVIATIONS:

SOP	Standard Operating Procedure
QA	Quality Assurance
WH	Warehouse
QC	Quality Assurance
LL	Loan License
PPIC	Production Planning and Inventory Control
Ltd.	Limited
COA	Certificate of Analysis

8.0 REFERENCES:

In-house

9.0 ANNEXURES:

ANNEXURE No.	TITLE OF ANNEXURE	FORMAT No.
Annexure-I	Simulation Protocol for Mock Recall	
Annexure-II	Simulation Report for Mock Recall	

10.0 DISTRIBUTION:

- Master Copy — Quality Assurance Department
- Controlled Copy No. 1 — Warehouse Department
- Controlled Copy No. 2 — Production Department
- Controlled Copy No. 3 — Quality control Department

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		

ANNEXURE – I

	SIMULATION PROTOCOL FOR MOCK RECALL	**PROTOCOL No.:**	
		REVISION No.:	
		EFFECTIVE DATE:	
		PAGE No:	

SIMULATION PROTOCOL

FOR

MOCK RECALL

DECODING PHARMA

QUALITY ASSURANCE DEPARTMENT

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6.	TRAINING RECORD	
7.	PRODUCT DETAILS	
8.	CHECK POINTS	
9.	PROCEDURE	
10.	ACCEPTANCE CRITERIA	
11.	FREQUENCY OF MOCK RECALL	

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1.0 PROTOCOL APPROVAL:

PREPARED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
EXECUTIVE/MANAGER (QUALITY ASSURANCE)			
HEAD (PRODUCTION)			
HEAD (QUALITY CONTROL)			
HEAD (WAREHOUSE)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			

DECODING PHARMA

QUALITY ASSURANCE DEPARTMENT

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2.0 OBJECVIVE:

The purpose of this protocol for Mock recall is, conducted to protect public health and safety. A food withdrawal is generally undertaken for quality purposes or as a precautionary measure before an official recall.

3.0 SCOPE:

This Protocol is applicable for the product mock recall for finish goods and to evaluate the effectiveness of recall management to carry out the following.

- Time taken to trace the product dispatched documents.
- Time required for traceability of marketed product for distribution details.
- Retrieval of distribution documents.
- Time required for the retrieval of batch record, control sample and analytical report.
- Time required for the retrieval of raw material and packing material report.
- Documentation of recall.
- Approval of simulation study report and close out.

4.0 RESPONSIBILITY:

Officer/Executive –QA	To Prepare and execution of Mock recall. To prepare the report on basis of data generated during mock recall exercise. Retrieve the distribution data from the client regarding the stock and relevant documents.
HOD-Production	To review the protocol & report
HOD-Quality Control	To review the protocol & report
HOD-Ware House	To review the protocol & report
HOD-Quality Assurance	Co-ordination for approval of Mock recall protocol & report

5.0 PRODUCT RECALL COMMITTEE:

It is important to have a team responsible for traceability (Mock Recall Management Team). The Team is responsible for co-coordinating all aspects of the product recall.

All members must ensure that all procedures are carried out effectively and efficiently

S.No.	NAME	DESIGNATION DEPARTMENT	RESPONSIBILITY	CONTACT No.
1.				
2.				
3.				
4.				
5.				
6.				
7.				

6.0 TRAINING RECORDS:

S. No.	NAME OF TRAINEE	DEPARTMENT	DESIGNATION	SIGNATURE OF TRAINEE
1.				
2.				
3.				
4.				
5.				
6.				

Name of the Trainer: _____

Inference:_____

_____

_____

_____

Reviewed By:
(Sign/Date)
(QA)

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7.0 PRODUCT DETAILS:

PRODUCT NAME:	BATCH NO.:
MFG. DATE:	EXP. DATE:
PACK SIZE:	DOSAGE FORM:
PRODUCT OF COMPANY NAME:	MARKET:
TOTAL NO. OF UNITS ORIGINALLY RELEASED:	TOTAL NO. OF UNITS DISTRIBUTED:
TOTAL NO. OF UNITS IN STOCK:	TOTAL NO. OF UNITS RECALLED:
DATE OF COMMENCEMENT:	DATE OF CLOSURE:

8.0 CHECK POINTS:

S.No.	Check parameter	Mark (✔) after verified	Verification done by (Sign/date)
1.	Product/brand name		
2.	Product code		
3.	Package/case size & specification		
4.	MRP		
5.	Package/case date code		
6.	MFR retrieval & review /Tech Transfer documents(if applicable)		
7.	Art work		
8.	Lot number/Manufacturing date/Expiration date		
9.	Batch record (BMR/BPR) • In process test Parameter & results • Yield reconciliation • Line clearance • Batch coding details & coding proofs • Batch completion date • Other		
10.	Transfer Ticket		
11.	Laboratory test results (COA's) i.e. RM/PM//Bulk/Semi finish/FG		
12.	Specification of RM/PM//Bulk/Semi finish/FG		
13.	Control sample record		
14.	Equipment maintenance logs		
15.	Finish Goods distribution record (i.e. Total qty. Produced , dispatched, distributed in market (whole seller/Retailer)		

S.No.	Check parameter	Mark (✔) after verified	Verification done by (Sign/date)
16.	Invoice No. & details		
17.	Deviation/Market complaint/Non conformance/OOS/Incident (if any)		
18.	Validation Documents/records		
19.	Periodic product review report		
20.	Stability study details (Accelerated & real time)		
21.	Other		

9.0 PROCEDURE:

a. Select a batch of product which was distributed in market, preferably six months old batch review the batch. Review the batch record to verify how much quantity produced and sent to ware house.
b. Review the dispatch details to verify how much quantity sent, to whom, on which date and invoice/ invoice no. (Take a copy of invoice).
c. Once all reply is received, close the traceability time.
d. Record the time taken from date/time of dummy recall latter to all reply letters received.
e. Carry out review of MFR, executed batch records, RM/PM specification, FP specification and COA, stability data and periodic product review/validation review and reports. Record the time taken to retrieve the documents.
f. Prepare a final summary report on product simulation study along with conclusion and recommendations.

10.0 ACCEPTANCE CRITERIA:

10.1 Information from the Marketing department of the third party/LL unit is retrieved within 24 hours to 72 hours from the time set for Mock Recall.

10.2 If the information of the stocks in units dispatched is successfully tracked with respect to Not less than 98 % of the total units dispatched.

11.0 FREQUENCY OF MOCK RECALL:

- Once in Two Years

ANNEXURE – II

	SIMULATION REPORT FOR MOCK RECALL	**REPORT No.:**	
		REVISION No.:	
		REF. PROTOCOL No.:	
		PAGE No:	

SIMULATION REPORT

FOR

MOCK RECALL

DECODING PHARMA

QUALITY ASSURANCE DEPARTMENT

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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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1.0 REPORT PRE- APPROVAL:

PREPARED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
EXECUTIVE/MANAGER (QUALITY ASSURANCE)			
HEAD (PRODUCTION)			
HEAD (QUALITY CONTROL)			
HEAD (WAREHOUSE)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			

DECODING PHARMA

QUALITY ASSURANCE DEPARTMENT

STANDARD OPERATING PROCEDURE	
Department: Quality Assurance	**SOP No.:**
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2.0 OJECTIVE:

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- Time required for the retrieval of raw material and packing material report.
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HOD-Quality Control	To review the protocol & report
HOD-Ware House	To review the protocol & report
HOD-Quality Assurance	Co-ordination for approval of Mock recall protocol & report

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It is important to have a team responsible for traceability (Mock Recall Management Team). The

Team is responsible for co-coordinating all aspects of the product recall.

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S.No.	NAME	DESIGNATION DEPARTMENT	RESPONSIBILITY	CONTACT No.

6.0 TRAINING RECORDS:

S.No.	Name of Trainee	Department	Designation	Acceptance Criteria	Signature of Trainee	Checked by QA (Sign & Date)
1.				All personnel involved in execution of this protocol shall be trained in the required procedure and shall be documented		
2.						
3.						
4.						
5.						
6.						
7.						
8.						

Name of the Trainer: _____

Inference:_____

_____

_____

_____

Reviewed By (QA):
(Sign/Date)

7.0 PRODUCT DETAILS:

PRODUCT NAME:	BATCH NO.:
MFG. DATE:	EXP. DATE:
PACK SIZE:	DOSAGE FORM:
PRODUCT OF COMPANY NAME:	MARKET:
TOTAL NO. OF UNITS ORIGINALLY RELEASED:	TOTAL NO. OF UNITS DISTRIBUTED:
TOTAL NO. OF UNITS IN STOCK:	TOTAL NO. OF UNITS RECALLED:
DATE OF COMMENCEMENT:	DATE OF CLOSURE:

8.0 CHECK POINTS:

S.No.	Check parameter	Mark (✔) after verified	Verification done by (Sign/date)
1.	Product/brand name		
2.	Product code		
3.	Package/case size & specification		
4.	MRP		
5.	Package/case date code		
6.	MFR retrieval & review /Tech Transfer documents(if applicable)		
7.	Art work		
8.	Lot number/Manufacturing date/Expiration date		
9.	Batch record (BMR/BPR) • In process test Parameter & results • Yield reconciliation • Line clearance • Batch coding details & coding proofs • Batch completion date • Other		
10.	Transfer Ticket		
11.	Laboratory test results (COA's) i.e. RM/PM//Bulk/Semi finish/FG		
12.	Specification of RM/PM//Bulk/Semi finish/FG		
13.	Control sample record		
14.	Equipment maintenance logs		
15.	Finish Goods distribution record (i.e. Total qty. Produced , dispatched, distributed in market (whole		

S.No.	Check parameter	Mark (✔) after verified	Verification done by (Sign/date)
	seller/Retailer)		
16.	Invoice No. & details		
17.	Deviation/Market complaint/Non conformance/OOS/Incident (if any)		
18.	Validation Documents/records		
19.	Periodic product review report		
20.	Stability study details (Accelerated & real time)		
21.	Other		

9.0 PROCEDURE:

a. Select a batch of product which was distributed in market, preferably six months old batch review the batch. Review the batch record to verify how much quantity produced and sent to ware house.

b. Review the dispatch details to verify how much quantity sent, to whom, on which date and invoice/invoice no. (Take a copy of invoice).

c. Once all reply is received, close the traceability time.

d. Record the time taken from date/time of dummy recall latter to all reply letters received.

e. Carry out review of MFR, executed batch records, RM/PM specification, FP specification and COA, stability data and periodic product review/validation review and reports. Record the time taken to retrieve the documents.

f. Prepare a final summary report on product simulation study along with conclusion and recommendations.

10.0 MOCK EXERCISE:

List of documents and time required for their retrieval / review;

S.No.	Documents	Date	Started Time	Completed Time	Time Taken	Remarks
1.	Batch record retrieval					
2.	Batch record review					
3.	Control sample retrieval					
4.	Control sample inspection					
5.	Invoice details					

S.No.	Documents	Date	Started Time	Completed Time	Time Taken	Remarks
6.	MFR retrieval & review					
7.	RM & PM specification & reports – retrieval & review					
8.	Bulk & finished specification & reports – retrieval & review					
9.	Distribution records					
10.	Change controls					
11.	Validation documents					
12.	Periodic product review report					
13.	Deviations					
14.	Market complaints					
15.	Stability study					

Start Time:

Completed Time:

Total time taken for Mock activity completion:

Remarks: (If any)

Done By: Sign. & Date	Checked By: Sign. & Date

11.0 ACCEPTANCE CRITERIA:

11.1 Information from the Marketing department of the third party/LL unit is retrieved within 24 hours to 72 hours from the time set for Mock Recall.

11.2 If the information of the stocks in units dispatched is successfully tracked with respect to not less than 98 % of the total units dispatched.

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12.0 FREQUENCY OF MOCK RECALL:

- Once in Two Years

13.0 REPORT POST – APPROVAL:

INITIATED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
EXECUTIVE/MANAGER (QUALITY ASSURANCE)			
HEAD (PRODUCTION)			
HEAD (QUALITY CONTROL)			
HEAD (WAREHOUSE)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			