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

1.0 OBJECTIVE:

To lay down a procedure for recall of product from the market.

2.0 SCOPE:

The SOP is applicable to ensure that any product not meeting the accepted standards of quality, shall be withdrawn from the customer/market, after a thorough review by QA. This procedure shall be applicable to all the products manufactured in ……

3.0 RESPONSIBILITY:

Manager- QA

Corporate – QA

4.0 DEFINITION(S):

NA

5.0 PROCEDURE:

The procedure for Product Recall shall be as depicted in the flow diagram (Annexure – I).

This procedure covers:

a) Voluntary Recall :

This is recall of product from the market or distribution network of entire quantity, based on decision by QA. This could be because of :

- quality complaint from market, or
- discovery of some deficiency, or
- stability problem subsequent to dispatch, or
- unsold stocks

b) Forced Recall:

This is recall forced by a regulatory agency upon discovery / reporting of violation or deficiency in the product.

5.1 Recall strategy:

The Product Recall shall be undertaken based on the investigations by QA of:

- any market complaint
- any stability failures, or
- post dispatch discovery of unacceptable non – compliance to cGMP or regulatory requirements.
- visually detected physical deterioration
- Unsold stock, of time expired material, in the regional warehouse.

5.2 The QA Manager shall seek approval for recall from Corporate – QA

5.2.1 Corporate – QA shall consult Head – Regulatory Affairs on recall strategy, which shall include;

- Decision to recall
- Need to inform Marketing, Regulatory bodies and Customers,
- Extent of effectiveness checks for recall (whether all consignees are to be notified)

5.2.2 Incase of domestic product recall, the local FDA shall be informed. Subsequently, intimation shall be sent to stockiest to return the goods to our central warehouse.

5.2.3 Incase of Overseas location, the regulatory authority of concerned country and/ or Contract giver shall be informed. Contract giver shall be responsible to arrange withdraw of product from market.

5.3 Based on the determined recall strategy, Corporate QA shall communicate to Head – Marketing, Distribution Manager, Plant Manager, QA Manager, contract giver as per the format as given in Annexure II.

5.3.1 The Head –Marketing and Distribution Manager shall notify all consignees about the recall details and take appropriate action to;

a) Inform QA – Corporate, QA Manager and Plant Manager of the quantity available with the consignees,

b) Arrange withdrawal of product from the customer / distribution

5.3.2 The Head – Marketing, Distribution Manager as per the advice from Corporate -QA shall ensure that the batch quantity affected is quarantined and returned to the manufacturing location. The recalled batch shall be investigated through the handling of Non conformances as per SOP.

5.3.3 The QA manager and Plant manager shall make a report on progress of product recall

as per Annexure-III.

5.4 The Plant Manager and Distribution Manager and Head – Marketing shall reconcile the total batch (Production) quantity vis–a–vis the returned quantity and quantity if consumed. The reconciliation report shall be sent to QA - Corporate, within 15 days.

5.5 The Corporate-QA and Marketing shall ensure that the process of Recall is over within 30 business days.

5.6 Once the reconciliation report is received, the QA Manager shall inform to the Corporate - QA and the Head–Regulatory affairs about quantity to be recalled.

5.7 The QA Manager in consultation with Corporate–QA and Head–Regulatory shall decide the fate of recalled product.

5.8 In case of critical nature of recall where public health is concerned, a public mass media shall be used like Radio, TV etc for the notifying the public in mass.

5.9 In case of product recall, all concerned people telephone number/fax/e mails shall be used. If it is not possible to content the concerned persons, then concerned field staff members shall personally inform to the concerned people/agents

5.10 Preservation of Records:

5.10.1 All records of recall shall be filed in chronology and preserved with QA for 6 years.

5.11 To check the adequacy & effectiveness of recall procedure, mock recall shall be performed once in a 2 years, preferably batch distributed to international and domestic market shall be selected for recall, otherwise separate recall for domestic and international market shall be performed.

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

6.0 ABBREVIATION(S):

QA : Quality Assurance

PM : Plant Manager

Dept. : Department

FG : Finished Goods

PM : Packing Material

QA : Quality Assurance

QC : Quality Control

RM : Raw Material

SOP : Standard Operating Procedure

7.0 REFERENCE(S):

NA

8.0 ANNEXURE(S):

ANNEXURE - I : Product recall flow diagram

ANNEXURE -II : Product recall Communication

ANNEXURE -III: Product recall progress report

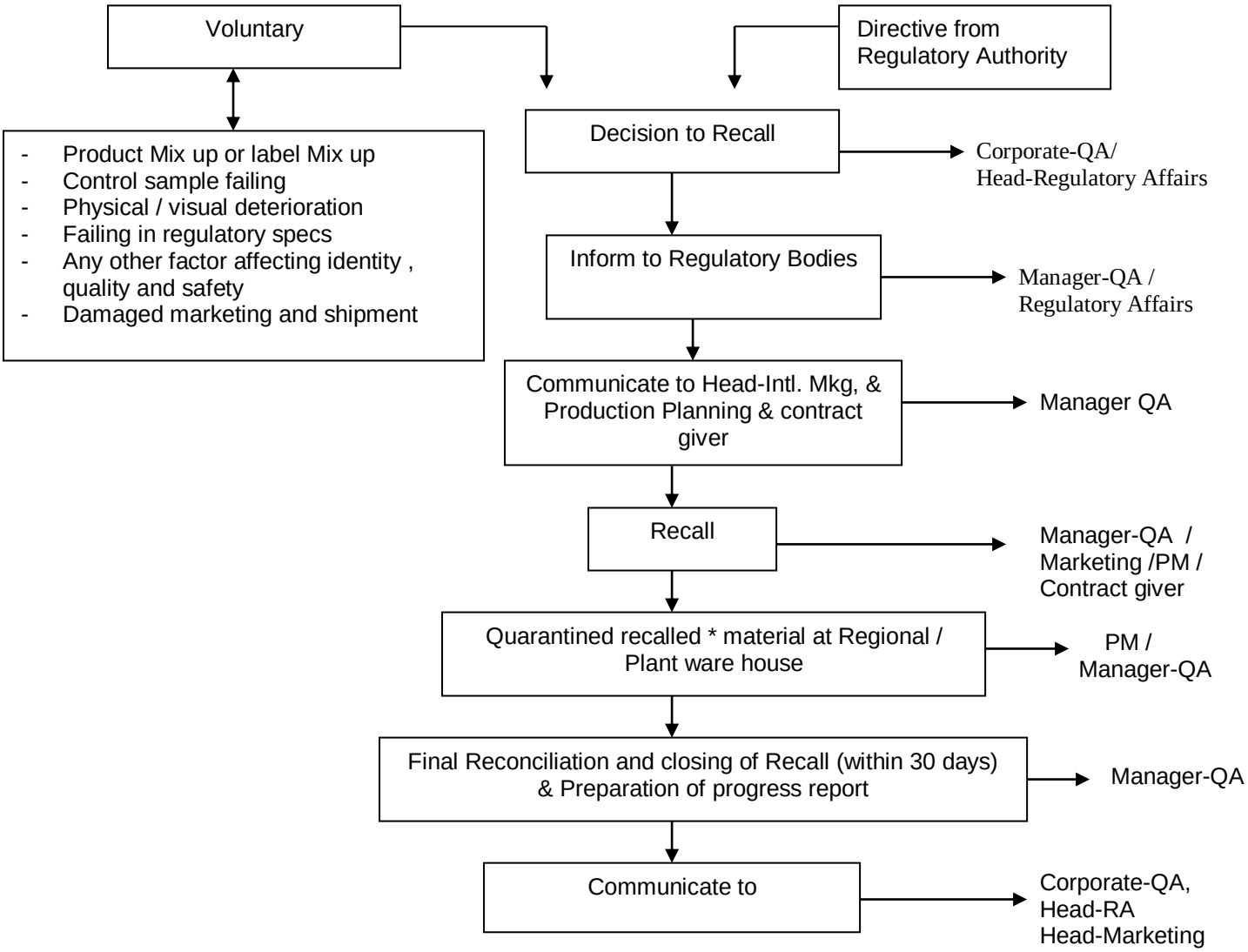
9.0 REVISION CARD:

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

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

Annexure I

Product recall flow diagram



- In case of overseas locations where logistics of transportation, timeless etc. pose impediments, the recalled material shall be disposed off on the Corporate QA recommendation as per environmental / safety, regulatory guidelines applicable in respective country. Method of disposal and a memo certifying disposal shall be sent to Corporate QA by country manager.

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

Annexure II

Product recall Communication

Item	Details
Date	
From	**Quality Assurance**
To	□ **Marketing** □ **Distribution** □ **Regulatory Affairs**
Product	
Batch Number	
Manufacturing Date	
Expiry Date	
Batch size	
Date of Release	
Reason for recall	

	Name	Signature	Date
Prepared By (Manager – QA)			
Approved By (Corporate –QA)			

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

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

Annexure III

Product recall progress report

Product			
Batch No			
Mfg. Date		**Exp. Date**	
Reason for recall			
Quantity dispatched			
Quantity to be received			**(As per report from distribution and marketing)**

Date	Quantity received from market	Balance quantity

Reconciliation of batch:

Quantity to be received: _____ Actual quantity received: _____

Remarks:

_____ _____

Plant Manager **Q.A. Manager**