



ORIGINAL

SOP #	VC-NQA-034	TITLE:	Effective:	08/26/16
Revision #	03	Product Recall Procedure	Status:	APPROVED
Superseded By:	Manav Shah		Total Pages:	07

REVIEWED BY/DATE:	QUALITY APPROVAL/DATE:
<i>P. Patel</i> . 08/30/22	<i>M. Shah</i> = 08/30/22

1. Purpose:

To outline a written and an effective procedure for product withdrawal and/or recall

2. Scope:

This SOP applies to all dietary supplements manufactured by VitaCare Pharma and requires to be recalled due to defective and contaminated product that may pose or cause public health & safety risk. This SOP outlines all aspects of product recalls, including all corrections and removals. Recalls may be undertaken voluntarily or at the request of the FDA. FDA provides guidance to assign product recall into 3 classifications.

- Class-I Recall: A serious emergency recall situation involving product which may have an immediate or long term serious adverse effects on the life or health of human consumers. (Involved wholesale, retail and consumer levels)
- Class-II Recall: A priority situation involving product which may cause temporary or medically reversible adverse health hazards or where the probability of the serious adverse effects to human life or health is remote. (Involved wholesale and retail levels)
- Class-III Recall: A situation involving product which does not pose a health threat, but which may have serious or wide-spread customer or public relations implications. (Involved wholesale level)

3. Responsibility: Quality Control Director

4. Reference: 21 CFR Chapter 7 Subpart C, Reportable Food Registry (RFR)

5. Procedure:

- a. A recall committee will be formed, headed by either President or Director of Quality Control, which is responsible for directing all company communication regarding the recalled product, ensuring that all recalled product has been picked up, and responding to all customer questions, concerns and complaints.
- b. In the event of a Product Recall affecting product distributed by VitaCare Pharma, the following will take place if deemed necessary:
 - Must report as soon as practically possible, but in no case later than 24 hours after a responsible party determines that an article of food is a “reportable food”
 - Must submit certain data elements in the initial report of Reportable food registry (RFR), such as Food registration number, Date on which article of food was determined to be reportable, description of food, including quantity and amount, extent and nature



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- of the adulteration, results of investigation, disposition of the article of food, product packaging information for easy identification, contact information for the responsible party, the contact information for parties directly linked to the supply chain, etc.
- Must investigate the cause of the adulteration, if the reportable food originated at the responsible party
 - May be required to provide notification to immediate previous sources and immediate subsequent recipients of the reportable food after consultation with FDA
 - Must provide amended reports as necessary
 - Must consult with FDA to follow up as necessary
 - Must maintain records related to each report received, notification made, and report submitted to FDA for 6 years
- c. If recall is related to product complaints, fill out product complaint report as per relevant SOP-VC-NQA-019.
 - d. If recall is related to serious Adverse Events, follow instructions as per relevant SOP-VC-NQA-020.
 - e. An evaluation and complete assessment will be conducted by recall committee (Appendix – B), which includes identification of the problem and health hazards associated with it, class and depth of the recall, population at risk, degree of seriousness and long or short term consequences.
 - f. A letter of recall notification (Appendix – A) is issued to all responsible parties, including customers, distributors and packaging contractor, as early as possible with all completed information such as, Name of the Product, Batch #, Date of Shipments, Reason for Recall, Contact information and/or Action required indicating proper instructions and procedure, as to what to do with the recalled product.
 - g. An internal task committee will gather all necessary information related to the particular product as early as possible by reviewing batch production records, samples for additional analytical tests, quarantine remaining or recalled product and accountability, etc. and relay that information to the committee immediately.
 - h. Recall Coordinator will also inform local regulatory agencies about product recall and outlining the recall strategy and measures taken. Execution of the recall plan should proceed while waiting for regulatory confirmation of the plan. Closely follow specific advices and instructions provided by agencies to facilitate the process of product recall.
 - i. If required and advised by agencies, general public warning will be issued by using general news media, either national or local as appropriate.
 - j. Committee will also follow up and check status and/or effectiveness of the recall notification or warning overall, to determine whether additional extent of measures are being made or not.
 - k. All recall related communication will be issued in the form of email/fax or any other written form and have it recorded, as necessary.
 - l. Once, start receiving recall product within the facility, it should be identified properly with pasting “**REJECTED**” labels on each box/container and moved to the designated Rejected or Quarantine area until further notice.



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- m. All returned documents are to be submitted to purchasing department for further accounting action.
- n. A recall committee will meet to gather all necessary information and review the effectiveness of the recall procedure. Meeting minutes are to be kept on file up to date.
- o. A recall Coordinator will issue recall status report and any further updates to FDA, as required and requested.
- p. On completion of the execution of the recall strategy the Recall Coordinator will submit a written recommendation to FDA that the recall is now to be terminated. The recall is not considered over until the Agency sends official notice that the recall is terminated. Product shall not be destroyed without inviting an Agency representative to be present at the event.
- q. All manufacturing documents for affected product and communication reports both to the third party and/or to the regulatory agencies are archived by QA and kept in secure locked cabinet in the office for 6 years.

r. **RECALL COMMITTEE CONTACT INFORMATION:**

- **Dr. Manav Shah – President & CEO**
 Phone: 908-754-1792 (Office)
 732-991-1116 (Cell)
 908-754-1793 (Office-Fax)
manav@vitacarepharma.com
- **Amrita Gupta – Director of Quality Control**
 Phone: 908-754-1792 (Office)
 848-248-9242 (Cell)
 908-754-1793 (Office-Fax)
amrita@vitacarepharma.com

s. **LOCAL AGENCY CONTACT INFORMATION:**

- **Recall Coordinator**
FDA-New Jersey District
 10 Waterview Blvd, 3rd Floor
 Parsippany, NJ 07054
 Phone: 973-331-4917
 Fax: 973-331-4969



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- Health Products and Food Branch Inspectorate**
Health CANADA
 Graham Spry Building, 3rd Floor
 250 Lanark Avenue
 Address Locator # 2002B
 Ottawa, Ontario
 K1A 0K9
 Fax: 613-952-9805
DCVIU UVCEM@hc-sc.gc.ca

6. Archiving SOP:

All original documents are to be archived by QA & controlled copies are to be submitted to concerned departments.

7. Revision History:

Rev. No.	Revision Details	Reference/CCF No.	Effective Date:
00	New Procedure	N/A	11/13/12
01	To Comply NSF Guidelines, Contact information added for Recall Committee members and Local Agency (FDA).	13/QA/008	09/16/13
02	Health CANADA contacts information added.	14/QA/005	08/11/14
03	As per NSF requirement, Appendix = A & B added. Details of data elements (b) for reportable food registry added.	16/QA/047	08/26/16
03	Periodic Review	SOP # VC-GEN-001	08/27/18
03	Periodic Review	SOP # VC-GEN-001	08/27/20
03	Periodic Review	SOP # VC-GEN-001	08/30/22

8. APPENDIX:



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APPENDIX-A:-

LETTER OF PRODUCT RECALL NOTIFICATION

DATE:

Dear Valued customer,

Please review the detail information for the product that has been recalled recently. If you have this specific product in your premises, contact or return to VitaCare Pharma immediately for further action. You may take and follow immediate action(s) as described below.

Name of the Product:	
VC Code:	Batch #
Date of Shipment:	Quantities Shipped:
REASON FOR RECALL:	
HEALTH RISK INVOLVED:	
ACTION REQUIRED:	
ADDITIONAL REMARK:	

If you have any further questions or concerns, please contact us at 908-754-1792, you will be directed to Recall Coordinator.

We thank you, in advance, for your immediate attention and prompt action to this notification.

Sincerely,

Director of Quality Control



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Name:

APPENDIX-B:-

PRODDUCT RECALL REPORT:

RECALL PRODUCT INFORMATION:					
PRODUCT NAME:					
VC CODE #			VC BATCH #		
MFG. DATE:			QUANTITY/BATCH SIZE:		
REASON FOR RECALL:					
HEALTH RISK INVOLVED:					
ACTION REQUIRED:					
ADDITIONAL REMARK:					
PRODUCT RECONCILIATION:					
QUANTITES PRODUCED:					
QUANTITIES SHIPPED:					
QUANTITIES IN INVENTORY:					
SHIPPING HISTORY:					
SHIPPED DATE:	CUSTOMER	PO #	# OF UNITS	CARRIER	FINAL DESTINATION
CUSTOMER CONTACT INFO:					
CUSTOMER	NAME OF CONTACT	PHONE #		FAX #	E-MAIL:
DONE BY/DATE:					



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REVIEWD BY/DATE:					
PRODUCT RECALL HISTORY:					
Sr.	RECEIVED DATE	CUSTOMER	QTY. SHIPPED	QTY. RECEIVED	REMARK
PRODUCT RECALL RECONCILIATION:					
QUANTITES SHIPPED:					
QUANTITIES RECEIVED:					
% YIELD:					
PRODUCT RECALL STATUS: <input type="checkbox"/> CLOSED <input type="checkbox"/> NOT CLOSED					
INVESTIGATED & MONITORED BY:					
NAME & DESIGNATION:				SIGNATURE:	
1.					
2.					
3.					
4.					
QA APPROVED BY/DATE:					