

SOP #	VC-NQA-011	TITLE:	Effective:	12/16/22
Revision #	04	Guideline about Issuing Unique Code # & Lot # to Materials/Packaging Components and Products/Batches	Status:	APPROVED
Superseded By:	Prerna Patel		Total Pages:	04

REVIEWED BY/DATE:	QUALITY APPROVAL/DATE:
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1. Purpose:

To provide a general guideline about issuing unique Code # & Lot # to received raw materials, packaging components, finished products batches, product development samples and sample bulks.

2. Scope:

This SOP applies to all raw materials (Active and In-active) used in a dietary supplement and each product and each batch of dietary supplement manufactured by Vitacare Pharma. Issuance of a unique Code # to each raw material and to every product will help to identify each one specifically. Issuance of a unique internal Lot# to each raw material shipment will allow to trace the lot to supplier, the date received, the name of the raw material, the status of the raw material (e.g. quarantined, released or rejected), while to each manufactured batch will allow to trace them back to distribution in case of discrepancies.

3. Responsibility: Quality Assurance, Purchasing Department, R & D

4. Reference: 21 CFR 111 Subpart G 111.155 (d)(1); 111.160 (d)(1); 111.180 (b)(1)
21 CFR 111 Subpart I 111.260 (a)

5. Procedure:

a. Issuance of VC RM # and VC RC # to all received raw materials:

- i. Any new raw material received will have a new VC RM #.
- ii. Every shipment of raw material received will be issued a new VC RC #.
- iii. If same raw material is received from two different suppliers with the same mfg. lot# or different lots from same supplier, they should be given two different VC RC # accordingly. Each received lot should have separate VC RC #.
- iv. There are two types of raw materials: Active and Inactive.
- v. All active raw materials shall have VC RM # as 41XXX where X is the sequential No. (e.g. The first Active raw material received will have Code # 41001). If 41XXX series is completed at #41999, new serial # as 61XXX will be used.
- vi. All inactive raw materials shall have VC RM # as 31XXX where X is the sequential No. (e.g. The first In-active raw material received will have Code # 31001).
- vii. Issuance of VC RC # to raw material will be YYMDDXX. "YY" stands for last two digits of the year e.g. 2012 will be 12. "M" stands current month. "DD" stands for current date i.e. 01, 02, 03, -----, 30, 31. "XX" stands for sequential No. of raw materials received on that date (e.g. 12A0101).

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b. Issuance of VC RM # and VC RC # to evaluation sample of raw material:

- i. Any raw material received for R&D purpose will have VC RM # and VC RC #.
- ii. Use the same format as mentioned in (a) to give VC RM # and VC RC # to evaluation samples of raw material with "RD" pre-affix to only VC RC # (e.g. VC RC # RD/YYMDDXX).

c. Issuance of VC RM # & VC RC # to packaging components/ laboratory chemicals:

- i. All packaging components and laboratory chemicals/reagents received will have unique identification number for their easy identity and to avoid mix-up with other components.
- ii. All packaging components (e.g. bottle, seal cap, cotton, desiccant, scoops, poly bags, corrugated boxes, etc.) shall have VC RM # as 51XXX, where X stands for sequential No. (e.g. 51001, 51002, ---- & so on).
- iii. All laboratory chemicals/reagents shall have VC RM # as 21XXX, where X stands for sequential No. (e.g. 21001, 21002, ----- & so on).
- iv. Issuance of VC RC # for packaging components and laboratory chemicals/reagents shall have same format as mentioned in (a) "YYMDDXX". Where YY = Current Year, M = Current Year, DD = Current Date and XX = Sequential No.

d. Issuance of VC Product Code # and Batch # to production batches:

- i. Each unique product will have VC Production code as VC4XXX, where X is the series of sequential No. (e.g. VC4000).
- ii. Each unique powder product will have VC Production code as VCP3XXX, where X is the series of sequential No. (e.g. VCP3000).
- iii. Each unique Organic certified product will have post-affix "OR" after VC product Code (e.g. VC4XXXX/OR VCP3XXXX/OR).
- iv. Each unique Kosher/Halal certified product will have post-affix "KO" or "HL" after VC product Code (e.g. VC4XXXX/KO or VC4XXXX/HL).
- v. Each manufacturing product batch will have unique batch # as YYMXXX where "YY" is for last two digits of the year, "M" is for the month of January and so on as per the sequential alphabetical order and "XXX" is the sequential No. in that month (e.g.12A001).
- vi. If required, product with color/shade difference will be subdivided into smaller batch sizes by using -A, - B, etc. post-affix after original Batch # to differentiate between different color/shade of same batch (e.g. 12A001-A).
- vii. If required, any finished product shipped as split shipments will be subdivided by using -1, -2, etc. post-affix after original Batch # to differentiate between different shipments of same batch (e.g. 12A001-1).

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e. Issuance of Batch # to product development sample batches:

- i. Product sample batches may be made for any R & D purpose or as per customer request for final approval prior to produce any commercial batch.
- ii. The sample batch will have Batch # as RD/YYMXXX, where "YY" is for last two digits of the year, "M" stands for the current month and "XXX" stands for the sequential no (e.g. RD/12A001).

MONTH	ASSIGNED ALPHABET
January	A
February	B
March	C
April	D
May	E
June	F
July	G
August	H
September	I
October	J
November	K
December	L

f. Issuance of VC RM # & VC RC # for finished products received for repackaging or relabeling purpose:

- i. All finished dietary supplements received for repackaging or relabeling purpose and for distribution rather than as a returned product should have unique identification number for their easy identity and to avoid mix up with other products.
 - ii. If received product is soft gelatin capsules (softgels), assign VC RM # with "SG1XXX", where XXX stands for serial no.
 - iii. If received product is in tablet, capsule, or powder form, assign VC RM # with "PR2XXX", where XXX stands for serial no.
 - iv. Issuance of VC RC # will remain in as same format as described earlier in 5 (a) "YYMDDXX".
- g. QA is responsible to assign VC RM # for each raw material/packaging components, VC Product code # for each product and Batch # for each manufacturing batch.
- h. Purchasing department is responsible to assign VC RC # for all received raw materials.

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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	11/07/12
01	Product Code for powder and Organic products added.	16/QA/042	08/02/16
02	Poly Bags, Corrugated Boxes added as Packaging Components.	18/QA/112	10/01/18
03	Removed batch # subdivision due to blender size. Added Batch # subdivision due to color/shade difference and shipment time Point d.	19/QA/047	01/02/20
03	Periodic Review	SOP # VC-GEN-001	01/04/22
04	New serial # for RM added from #61XXX.	22/QA/020	12/16/22
04	Periodic Review	SOP # VC-GEN-001	12/17/24