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| <br>Fortification<br>SOP | <b>STANDARD OPERATING PROCEDURE</b><br><b>Liquid Milk Fortification</b> | Document No.  | NDDB/FC/01A |
|   |   | Date of Issue | 29/08/2017  |
|   |   | Version       | 1.00        |
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## Scope and Objective:

Vitamin fortification can be accomplished by the addition of vitamins at various steps in the processing system, preferably after separation, including the pasteurizing vat, to the HTST constant level tank, or on a continuous basis into the pipeline after standardization and prior to pasteurization in accordance with the manufacturer's recommendations. This process covers order of processing and GMP & GHP as per process requirements for production of fortified milk and its storage.

## Process Method:

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| <b>1. Receiving of Fortificants / Premix</b>  |
| 1.1. Collect the required quantities of Fortificants from the store after these have been found fulfilling the QA compliance for specifications and other general requirements.<br>1.2. Store fortificants as per supplier's direction/ Product labelling requirements to get maximum shelf life.   |
| <b>2. Preparation of Premix and Processing</b>  |
| <b>2.1 Batch Process</b><br>2.1.1. Take aliquot quantity of milk (~200ltr/Kg of fortificant)/ as per suppliers recommendation.<br>2.1.2. Care must be taken for accurate measurement of vitamins for addition and weigh required quantity, avoid add back of concentrate.<br>2.1.3. Mix the entire quantity by stirring, this Milk-fortificant premix is ready for bulk fortification.<br>2.1.4. Mix the above Milk-fortificant premix to 30% of the total batch of fortified milk to be processed.<br>2.1.5. Homogenize the above quantity in case of oily fortificants. Homogenization is optional for aqueous fortificants.<br>2.1.6. Add this homogenized premix to the total milk (rest of the 70%) up on standardization.<br>2.1.7. Pasteurize the entire quantity of milk by heating min 72°C/ 15 sec and immediate chilling of milk to 4°C. |
| <b>2.2 Continuous Process (Oily Blend)</b><br>2.2.1. In the continuous process premix shall be stored in closed containers at suitable temperature condition.<br>2.2.2. The metering device/ dosing unit shall be installed after standardization step to pump the exact quantity of fortificant by adjusting its flow rate based on the level of fortificant in the final product.<br>2.2.3. Pump must be installed so as to be activated only when the unit is in forward flow (the pump shall not be operational during the Flow Diversion).<br>2.2.4. Use a check valve on the injection line to prevent milk from being pushed back into the line. This depends on the pump displacement.  |

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- 2.2.5. Check the meter calibration regularly, including both the pump and the tubing, by determining delivery rate accuracy. Use only properly calibrated tubing for peristaltic pump systems and replace the tubing regularly.
- 2.2.6. Storage vessels used for supplying vitamin concentrate to metering pumps should be emptied on a regular basis.
- 2.2.7. A regular systematic cleaning and sanitizing schedule must be maintained for these vessels, pumps and tubing.
- 2.2.8. Homogenization of milk by applying required pressure is essentially required for uniform mixing of premix.
- 2.2.9. Pasteurization of milk of milk by heating min 72°C/ 15 sec and immediate chilling of milk to 4°C.

### **2.3 Continuous Process (Water Soluble/ Dispersible dry blend)**

- 2.3.1. Take aliquot quantity of milk (~20ltr/Kg of fortificant)/ as per suppliers recommendation.
- 2.3.2. Mix the above blend properly at 45°C or as per supplier recommendation by stirring and ensure complete solubility of the dry vitamin blend.
- 2.3.3. Add this blend to the milk which needs to the standardized milk.
- 2.3.4. Pasteurize milk by heating min 72°C/ 15 sec and immediately chill the milk to 4°C.
- 2.3.5. Homogenization is optional in case of aqueous based mix.

### **2.4 Storage of milk**

- 2.4.1. After clearance from the QA for compliance to its chemical and biochemical requirements, pasteurized milk shall be stored in dedicated pasteurized silos / storage tanks.
- 2.4.2. A precise quality control plan must be outlined to determine the level of fortificant(s) in the fortified milk.
- 2.4.3. Analyze finished products at regular intervals. Results should be reported in International Units for vitamins.

### **2.5. Storage of Vitamin Pre-mix**

- 2.5.1. Stability of vitamins, especially Vitamin A, depends on the storage conditions, especially exposure to light.
- 2.5.2. Vitamin A may deteriorate gradually under normal storage conditions. While on exposure to sunlight or fluorescent light, especially in transparent containers, vitamin A can be rapidly destroyed. Generally, no significant loss of vitamin D will occur within expected shelf-life.

*Note: Vitamins A and D are fat soluble and will gradually become more concentrated in the milk fat portion of the milk. Both oil and water base vitamins are susceptible to this migration problem, hence homogenisation for uniform distribution is recommended.*

### **2.6 General Requirements for Premix storage and Handling**

- 2.6.1 Vitamins are sensitive to heat, light, humidity and oxidizing and reducing agents.

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- 2.6.2 Customize the quantity of concentrated vitamins/ premix based on the batch size, it is recommended to use entire quantity of premix up on removing from the container.
- 2.6.3 Assay of premix/vitamin concentrates shall be ensured periodically for bulk containers.
- 2.6.4 The amount of vitamin concentrates used must be recorded and cross-referenced with the amount of product fortified to ensure that the actual amount of concentrate used closely matches what is required for the total product made.
- 2.6.5 The stability of vitamins needs to be monitored as per supplier's directions during storage.
- 2.6.6 The premix shall be stored in amber colored/ opaque bottles in cool and dry place, avoid exposure to direct sunlight.
- 2.6.7 In case of products fortified with vitamins overages may be added appropriately to compensate for the loss during prolonged storage.