

National Dairy Development Board

For Efficient Dairying

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MILK POWDER FORTIFICATION

This bulletin includes technical information based on latest developments on products, systems, techniques etc. reported in journals, companies' leaflets and books and based on studies and experience. The technical information in different issues is on different areas of plant operation. It is hoped that the information contained herein will be useful to readers.

The theme of information in this issue is **"MILK POWDER FORTIFICATION".** It may be understood that the information given here is by no means complete.

In this issue: Introduction Methods of Milk Powder Fortification Technical considerations for Milk Powder Fortification Finished Product Evaluation: Quality Assurance Blender Performance Evaluation/Testing Retention of Vitamin A & D in Fortified Milk Powder Reference

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INTRODUCTION

There are several potential solutions to mitigate hidden hunger. The popular approaches are promotion of dietary change (requiring education, advice and incentives), dietary supplementation and fortification of food. Food fortification is one of the potential solution, deliberately increasing the content of essential micronutrients in a food so as to improve the nutritional quality of food and to provide public health benefit. Food fortification has increased recently, as it has been recognized that fortification is a public health intervention for nutritional deficiencies, which has a wider and more sustained impact than supplementation. However, food fortification should be used in combination with promotion of dietary change and dietary supplements.

Milk is widely consumed; thus, the fortification of milk and milk products could provide vital nutrition to a large proportion of the world's population. Milk is a natural highly nutritious food that contains all ten essential amino acids, as well as fats, and important minerals and vitamins. However, milk has low concentrations of some important vitamins and minerals naturally and some are lost during processing. Increasing the quantity of some of these micronutrients could improve dietary balance and health in malnourished individuals. Many countries have a mandatory provision to add back the vitamins removed lost during processing, as it is easily doable.

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Milk is one of the staple food in India which is consumed by almost all age groups. Fortification of milk with Vitamin A and Vitamin D is required in India because of the widespread deficiencies present in the population. National Nutrition Monitoring Bureau (NNMB) survey and a Report of the expert group of ICMR in 2012 has stated that India has very high burden of Vitamin A and D deficiencies, amongst both young children and adults particularly in urban areas are physically less active and have a very limited exposure to sunlight. Vitamin D promotes and aids in calcium absorption. Therefore, to make the best absorption of calcium from milk, it is important to have Vitamin D in it (FFRC-FSSAI).

Technology of liquid milk fortification is already published in the *Technews* 'Fortification of Milk and Milk Products', Issue no 93 in 2017. Current issue of *Technews* provides technology of milk powder fortification (MPF) and other operational details.

Methods of Milk Powder Fortification

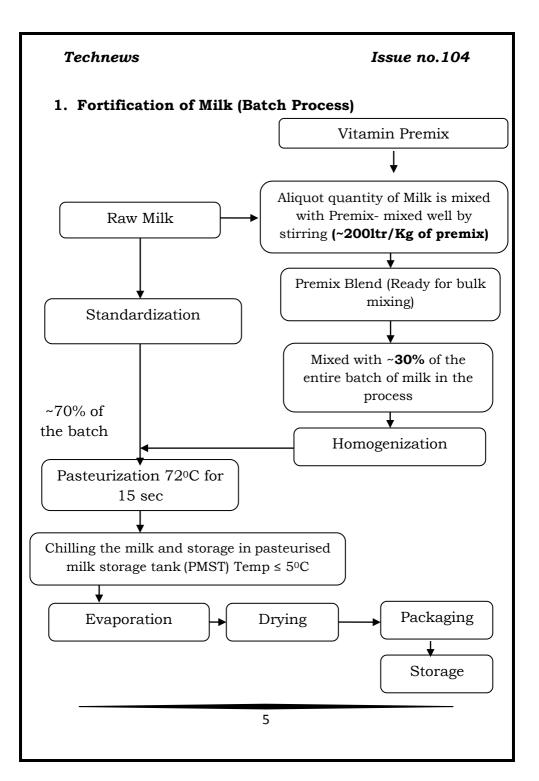
The fortification of milk powder has been achieved by two general types of processes:

- Wet mixing (spray drying process)
- Dry blending process

and some cases combination of the process can also be used (basically in Infant Milk Foods).

Wet mixing process/Spray drying process:

In the wet process, vitamins are added to milk at different steps, like addition of fortificant in to milk (batch method) or continuous dosing to standardized milk used for drying or addition after concentration of milk (to concentrated tank or dosing to drier feed line). This process involves heat treatment, hence required overage of the vitamins to be considered while adding vitamins and necessary measures also to be taken for proper mixing of the vitamins in milk/concentrated milk. This process has the advantage of ensuring a uniform distribution of nutrients throughout the batch compared to dry process. The detailed manufacturing steps of wet mixing process used for fortification are shown in process flow chart no 1 to 4 mentioned below.



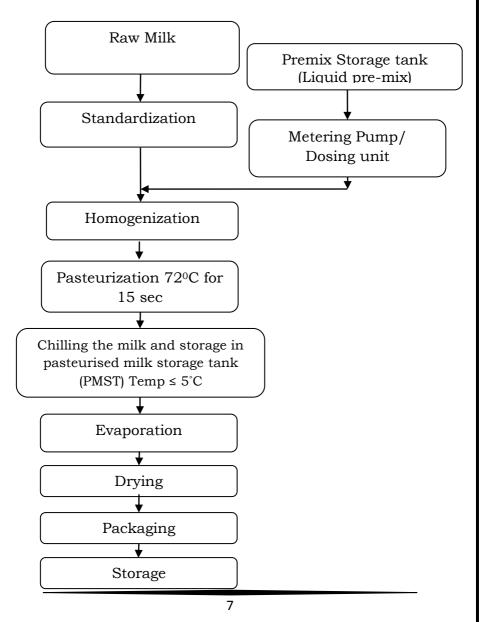
Operational Details

- 1.1.Take aliquot quantity of milk (~200ltr/Kg of fortificant/ as per supplier's recommendation).
- 1.2.Add pre-weighed quantity of premix. Care must be taken for accurate measurement of vitamins for addition, avoid add back of concentrates to bottles.
- 1.3. Mix the entire quantity by stirring and this Pre-mix blend is ready for bulk fortification.
- 1.4. Mix the above Pre-mix blend to 30% of the total batch of fortified milk to be processed.
- 1.5. Homogenize the above quantity and add this homogenized premix to the total milk (rest of the 70%) up on standardization.
- 1.6.Pasteurize entire quantity of milk by heating min 72°C/ 15 sec and immediate chilling of milk to 4°C.
- 1.7.Storage of milk in pasteurized milk storage tank (PMST) Temp \leq 5°C.
- 1.8.Pasteurized milk is subjected to evaporation and drying. Work instruction and SOPs of the plant shall be strictly followed.
- 1.9.Packaging of milk powder in 25 kg bags or in suitable stock keeping units (SKUs) and storage.



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2. Fortification of Milk (Continuous Process)



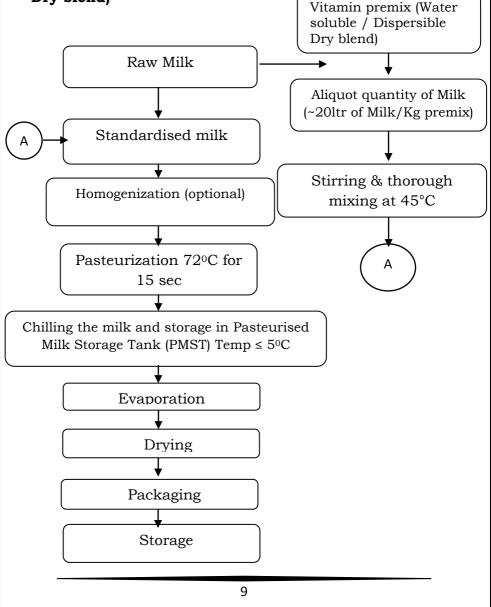
Operational Details

- 2.1. In the continuous process premix shall be stored in closed containers at suitable temperature condition.
- 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 required in the final product.
- 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).
- 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.
- 2.5. Check the meter calibration regularly, including both the pump and the tubing, by determining delivery rate accuracy.
- 2.6. Storage vessels used for supplying vitamin concentrate to metering pumps should be emptied on a regular basis.
- 2.7. A regular systematic cleaning and sanitizing schedule must be maintained for these vessels, pumps and tubing.
- 2.8. Homogenization of milk by applying required pressure is essentially required for uniform mixing of premix.
- 2.9. Pasteurization of milk of milk by heating min 72°C/ 15 sec and immediate chilling of milk to 4°C.
- 2.10. Pasteurized milk is subjected to evaporation and drying. Work instruction and SOPs of the plant shall be strictly followed.
- 2.11. Packaging of milk powder in 25 kg bags or in suitable stock keeping units (SKUs) and storage.



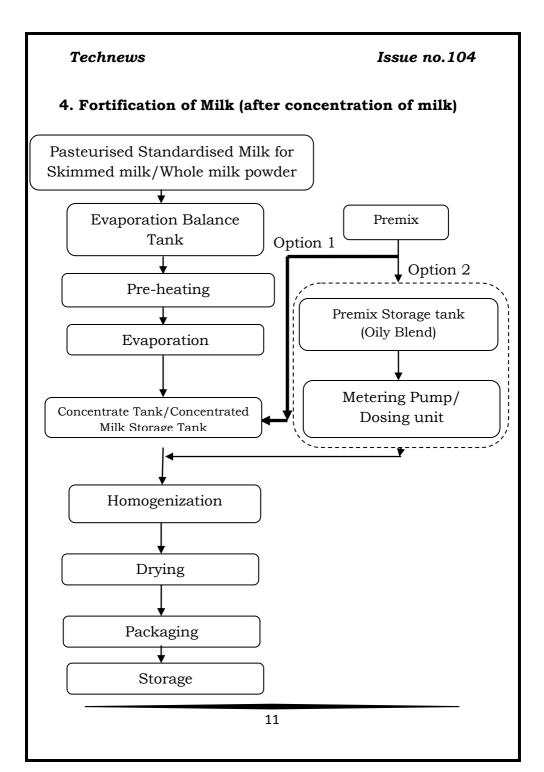
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3. Fortification of Milk with (Water soluble/ Dispersible Dry blend)



Operational Details

- 3.1. Take aliquot quantity of milk (~20ltr/Kg of fortificant/ as per supplier's recommendation).
- 3.2. Add pre-weighed quantity of premix. Care must be taken for accurate measurement of vitamins for addition, avoid add back of concentrates to bottles.
- 3.3. Mix the above blend properly at 45°C or as per supplier's recommendation by stirring and ensure complete solubility/mixing of the vitamin blend.
- 3.4. Add this pre- mix blend to the total milk by batch or continuous process mentioned in flowchart 1 & 2 respectively.
- 3.5. Homogenization is optional in case of aqueous based mix.
- 3.6. Pasteurize milk by heating min 72°C/ 15 sec and immediately chill the milk to 4°C.
- 3.7. Pasteurized milk is subjected to evaporation and drying. Work instruction and SOPs of the plant shall be strictly followed.
- 3.8. Packaging of milk powder in 25 kg bags or in suitable stock keeping units (SKUs) and storage.



Operational Details

- 4.1.In this process fortification of milk powder can be done after evaporation of milk.
- 4.2.Addition of vitamins to concentrate can be achieved by using batch method (option-1) or by continuous method (Liquid premix: oil/water base as mentioned in Option-2).
- 4.3.
 - a. In Batch method (Option-1):
 - ✓ Preparation of vitamin pre-blend: Pre-weighed content of vitamin premix to be mixed with milk or concentrated milk. Description on mixing of vitamin premix (for both liquid and dry) with milk is described under operation details of flow chart 1 & 3.
 - ✓ Mix the above blend properly at 45°C or as per supplier recommendation by stirring and ensure complete solubility of the vitamin blend.
 - ✓ Addition of above blend to concentrated milk tank and mix properly. Ensure proper mixing of the vitamin blend.
 - ✓ Above concentrated milk to be fed to drier by subjecting to homogenization.
 - ✓ Work instruction and SOPs of the plant shall be strictly followed.
 - ✓ Packaging of milk powder in 25 kg bags or in suitable stock keeping units (SKUs) and storage.
 - b. Continuous method (oil based/liquid premix-Option-2):
 - ✓ The metering device/ dosing unit shall be installed in concentrate feed line (before homogenizer) to

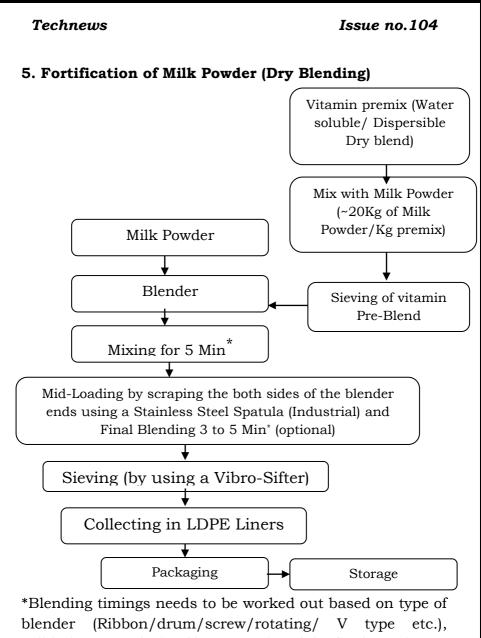
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pump the exact quantity of fortificant by adjusting its flow rate based on the level of fortificant required in the final product.

- ✓ The other operational conditions described under flowchart 2 (point no 2.3 to 2.7) shall be followed for smooth operation of dosing/metering devices.
- ✓ Work instruction and SOPs of the plant shall be strictly followed for drying operation.
- ✓ Packaging of milk powder in 25 kg bags or in suitable stock keeping units (SKUs) and storage.

Dry blending process: In the dry blending process, the ingredients like milk powders, vitamins and other ingredients are in a dehydrated powdered form. These ingredients are weighed as per formulations/batch size, mixed together to achieve a uniform blend of the complete product. The better homogeneity of the final product can be achieved by initial mixing of the vitamin mixture with a suitable quantity of milk powder and followed by mixing quantity (to blender/mixer). this into the bulk Consideration of particle size and density are important to prevent separation of the components on storage. This process is relatively simple and efficient, but requires extra mixing equipment (blender).

The microbiological quality of a dry-blended product is largely determined by the microbiological quality of the dry ingredients. It is advised to practice stringent quality inspection of ingredients for its acceptance. The detailed manufacturing steps of dry blending process used for fortification is mentioned in process flow chart no 5.



validation & analysis of homogeneity of the final powder.

Operational Details

- 5.1 Receiving of milk powder and fortificant/premix for blending up on QC clearance.
- 5.2Preparation of pre-blend:
 - The amount of vitamin premix required for batch needs to be weighed accurately.
 - Take aliquot quantity of milk powder (~20Kg/Kg of fortificant as per supplier's recommendation).
 - Mix the above content by hand mixing in poly ethylene bags (can be divided in to 5Kg +250 gram premix) for minimum 5 minutes.
 - Sieving of mixed powder and collecting in polythene bags.

5.3Blender clearance:

- Ensure proper cleaning and sanitation of blender before loading. Air blow/air drying of the blender surface is highly preferable before loading.
- QC clearance must be done for blender cleaning and visual clearance.

5.4 Loading and Blending:

- Load the blender with half of the quantity of the powder.
- Add pre-blend (5.2) to the blender by distributing all over the powder.
- Add second half quantity of the milk powder to blender. Loading of powder shall take minimum time as possible and there should be no exposure of milk powder to environment.
- Properly close the lid of the blender.
- Mix the entire content for 5 minutes and ensure proper homogeneity/blend of the mix.

- Mid loading of the batch may be practiced by unloading half quantity of the batch when capacity of the blender and batch size is more.
- Scrape both sides of the blender ends using a spatula (Industrial-Stainless Steel Spatula).
- Add back the unloaded powder to blender and mix for another 3 to 5 minutes.
- Note: Blending timings, mid loading needs to be worked out based on type & capacity of blender (Ribbon/drum/screw/rotating/ V type etc.), validation & analysis of homogeneity of the final powder/ as per blender manufacturer recommendations.
- 5.5 Unload the entire quantity up on blending and collect the powder in polyethylene bags.
- 5.6 Sieve the powder through vibro-sifter.
- 5.7 Collection in polyethylene bags, packaging in 25 kg bags or in suitable stock keeping units.
- 5.8 It is better to get QC clearance before converting /packing in to small retail packs.

Technical considerations for MPF

a. Selection of Vitamin Premix

- There should be established mechanism for competitively procuring vitamin and mineral premix from suppliers with proven quality systems and processes. Vitamin premix can be procured from the FSSAI approved suppliers or GAIN (Global Alliance for Improved Nutrition) premix facilities.
- The establishment must have written specifications for vitamin premixes (includes liquid concentrates,

powders) which specify potency, particle size, form and stability details.

- The establishment must ensure that the vitamin premix meets the established specifications either through a certificate of analysis from the supplier or sampling and analysis by the establishment (inhouse/external). Proper sampling plan and testing of premix is necessary to maintain the required concentration of vitamins in the final products.
- The establishment must be sure that the dry blend or wet blend of premixes shall meet the required microbiological requirements and establishment shall also consider these parameter as qualifying criteria for premix acceptance.

b. Stability of fortificant

- Vitamin premixes must be stored according to the manufacturer's recommendations. Once opened, these premixes should be used before the expiry date to prevent loss of potency/assay. Vitamin D is light sensitive and therefore loses potency if stored in clear containers exposed to light.
- Always follow First-In, First-Out (FIFO) and/ First Expiry, Fist-Out (FEPO).
- Stability and sensitivity of the vitamins (refer *Technews* no 93).

c. Stability of fortified milk powder

Its manufacturer's responsibility that a product should meet qualitative and quantitative specifications and label claims throughout the product's shelf life. As a minimum, the following properties should be examined

under the storage conditions stated on the product label, to check stability of the product:

i) Organoleptic properties

- ✓ Appearance, particularly colour;
- ✓ Taste, particularly flavour;
- ✓ Smell.
- ii) Chemical, physical and microbiological properties, in particular:
 - ✓ physical changes on storage (Bulk density, particle size, hardness, lumpiness, agglomeration, solubility etc.);
 - ✓ fat stability (e.g. oxidation/rancidity)
 - ✓ nutritional or physiologically active ingredients in the product are present to the end of the stated shelf life (Assay of individual vitamins or minerals);
 - ✓ change in microbiological growth;
 - ✓ the stability in use of the finished product, i.e. the stability of the product after opening the pack and during the expected consumption period.

FINISHED PRODUCT EVALUATION: QUALITY ASSURANCE

In order to verify the quantity of vitamin(s) in the finished product, the establishment must maintain records and perform laboratory analysis as outlined below

- 1. Records after the production of each product, records must be made of:
 - ✓ name of product, production code and/or best before date of the product
 - ✓ details of vitamin premix used for production (as described in the selection of vitamin premix section)
 - \checkmark the total amount of vitamin solution prepared
 - ✓ the amount of vitamin solution used
 - \checkmark the amount of product produced
 - ✓ the calculated amount of vitamin in the product based on the vitamin solution consumption.
 - ✓ operational details/production log book
- 2. Analysis -
 - ✓ product shall be analyzed for each parameters as per specification.
 - ✓ qualitative test may be performed for vitamin for each lot of fortified powders.
 - ✓ quantitative analysis of vitamin should be performed by an in-house/external laboratory as per FSSAI approved methods.
 - ✓ products must be sampled and analyzed quantitatively at least monthly and more frequently if deviations are encountered. It is recommended that establishments draw three samples, one from the beginning, middle and end of the production run for wet method and dry method follow sampling during unloading of the batch from the blender.

3. Review - on a daily basis, the establishment should compare calculated values and theoretical values to ensure correlation. Significant differences, whether inside or outside legal requirements, should be investigated and corrective action documented.

BLENDER PERFORMANCE EVALUATION/TESTING

The product component uniformity is one important quality measure of the final product. The blending is aimed at creating a homogeneous distribution of each mixture component in the entire volume. The lower the variation of sample composition in the powder mixture, the better the blending quality. Poor blending will greatly affect the suitability of the final product. Homogeneity of powder blends is an important metric for industrial applications in fortified dairy foods including commercial pediatric nutrition products.

There are several main factors that influence the analysis process, the level of homogeneity, and uniformity distribution of the final mixture of products which are grouped into component physical characteristics (size, density, morphology, shape, number of the particle), component chemical characteristics (compatibility between adhesiveness, components, static electric charge. pollutant, and degradation), blending machine (Drum Cross-Flow, Double Cone, Twin shell, Ribbon and Screw), blending method (rotating the blender's shell around a fixed axis and rotate the internal parts of the blender like an impeller or paddle and provide a cutting and shaking

motion continuously) and other process parameters (blending duration, blending speed, flow rate, and volume).

Evaluations of homogeneity should include objective measures of concentrations of nutrients in the final product, after which the level of variation can be deemed adequate or inadequate. A blended batch of dry powder can be separated into numerous sections within the blender, depending on the desired sample size, and then an aliquot can be analyzed from each section to confirm total homogeneity. Since homogeneity testing requires removal of samples from the blend, mixing must be verified through statistical sampling of selected locations throughout the blender. Alternatively, this can be done by capturing subsets of samples at given time intervals while powder is discharged from the blender base. The analytical value used to estimate homogeneity is the coefficient of variation (CV): a ratio of the standard deviation to the mean. Although in certain industries a CV of up to 20% may be permitted, some product categories require CVs as low as 2%.

The following principles should be considered when designing the mixer performance test used in a particular facility:

1. The mixer performance testing procedure

This written procedure should specify:

- ✓ mixing equipment tested
- \checkmark mixing time
- \checkmark batch size

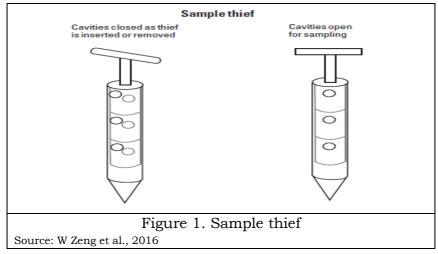
The equipment manufacturer's recommendations should be used as a starting point to establish on-site guidelines for the operation of mixing equipment. The test batch should be manufactured using the facility's current good manufacturing practices.

2. Schedule of tests

Mixer performance must be tested:

- ✓ within a maximum period of 90 days after the installation of a new or replacement mixer
- ✓ after a major repair or modification that could impact on the functioning of the mixer
- ✓ Periodically, but at a minimum once every one to three years depending on the risk profile of the facility.
- 3. Testing Procedures
 - ✓ Mixing operation settings: Sequence of ingredient addition to the mixer, test ingredient inclusion levels, mixing time and batch size should be those used under normal conditions of operation.
 - ✓ Selection of test substance: The test substance is something than can be measured to evaluate mixer performance (its concentration should not be influenced by mixing operations, Should not be air or light sensitive).
- 4. Sampling Procedure
 - ✓ A minimum of nine spot samples should be taken after mixing is completed.
 - $\checkmark~$ These spot samples should represent the full batch.

- ✓ Samples should be taken at, or as close to the mixer discharge as possible
- ✓ Where this is impossible, another option may be to obtain probe samples from different locations in the mixer.
- ✓ A sample thief (figure 1) is commonly used to draw sample from blender, drum, or storage vessels. The thief is a metallic cylinder with one or more recessed cavities that can be opened and closed by twisting a handle.



- ✓ In continuous proportioning systems, samples should be taken with the system running, at even, predetermined time intervals, and as close to the mixer discharge as possible.
- ✓ Use stratified sampling: variation in sampling can be avoided by applying stratified sampling. Instead

of collecting one sample from one location in a blender, extract multiple samples (minimum three) from the same location. Repeat this in several locations in blender, especially in dead zones, such as blender walls, between walls and ribbon gap etc.

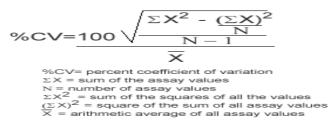
5. Calculation of Coefficient of Variation (CV)

The evaluation of mixer efficiency requires that a minimum of 9 samples of about 100g be taken at equal intervals as the batch passes an access point immediately after discharge from the mixer or completion of blending before discharge by using sample thief.

- ✓ For continuous mixing: for example to take a sample every 15 seconds to obtain a profile.
- ✓ For batch mixing: for example a 250 kg capacity mixer, to take a sample in each of the 25 kg bag to obtain a profile.

Samples must be sent to the laboratory for evaluating one or two key components. Usually those that are easy to assay and are of low concentration in the product, and thus more difficult to distribute evenly throughout the product (e.g. minerals, such as iron or zinc).

Formula



Result evaluation/inference

- ✓ A profile may be considered to be satisfactorily homogeneous if the coefficient of variation is no larger than 10% (i.e. +/- 10% around the average).
- ✓ If CV greater than +/- 10% mixing time should be increased, if it is not sufficient to reduce the CV, then two-step mixing (i.e. use of pre-blend) should be envisaged.
- 6. Corrective Actions
 - ✓ Should the initial mixer test not meet the accepted standards, the results should be re-evaluated and original samples re-assayed.
 - ✓ If the original samples are reanalyzed and indicate that the mixing is adequate, these results should be taken as correct.
 - ✓ If the results of the original test are confirmed and the CV (coefficient of variation) is above the critical limit, a second test must be performed following the same procedures.
 - ✓ Should the second mixer test indicate that the mixing is adequate, these results should be taken

as correct. When the second mixer test verifies that mixing is not adequate, an immediate investigation must be made as to the cause.

✓ Continue corrective action and mixer efficiency testing until adequate mixing uniformity is achieved.

RETENTION OF VITAMIN A & D IN FORTIFIED MILK POWDER

Stability of instantized non-fat dry milk fortified with vitamin A & D has been studied by D.F Owen and J.M.Mcintire by considering various parameter. The study evidenced that no difference in flavor found between samples containing vitamin D2 or D3 when stored at room temperature for 12 months. No loss of vitamin D potency was found on storage through 12 months. Vitamin A levels did not affect flavor although flavor degradation with time was noted. The higher the fortification level for vitamin A, the greater the percentage of loss with time (room temperature). Loss values for vitamin A ranged from 10% (at low level fortification) to 14% (at high level fortification) after 6 months at 37°C; 20 percent for the low A level and 47 percent for the high A level after 15 months at room temperature. Vitamin A is accordingly over fortified in this study by 20 percent to insure the correct potency for at least 1 year.

J. C. Bauernfeind and L. E. Alles studied possible methods for the enrichment of non-fat dry milk. Enrichment accomplished by wet and dry processes. Comparing the two methods of enrichment, both

approaches practical, the dry-stage method tends to yield slightly higher vitamin A retention values under prolonged storage than the wet-stage method. Stability of vitamin D is less of a problem as compared to vitamin A and is very satisfactory in both enrichment processes. This study concludes that Vitamin off-flavor is no longer a primary drawback to enriched nonfat dry milk production after manufacture and following storage. Study also reveals the suitability of packaging materials for packaging enriched non-fat dry milk. Average vitamin A retention percentages for all packs stored 12 months at 24°C is 90% of initial assay, minimum retention observed was 81% for product packed in Polyethylene bags, unprotected from light. Generally, vitamin D in dairy products can be stable during production, storage and the shelf life period.

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