PRODUCTION OF ENCAPSULATED IRON FOR DOUBLE FORTIFICATION OF SALT WITH IODINE AND IRON

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Summary: The feasibility of using fluidized bed technology for pilot trials and large scale production of encapsulated ferrous fumarate for the manufacture of double fortified salt containing iodine and iron has been successfully demonstrated.

Introduction and Background:

For centuries, salt has been an essential ingredient of the human diet as a popular food seasoning and as a preservative. Because of its universal and fairly uniform consumption by all segments of population, in the 20th century salt became recognized as the most natural vehicle for food fortification to enhance the nutritional quality of diets. Salt iodization is the most widespread example. The Codex standards for food grade salt recognize its use as a carrier for food additives or nutrients for technological or public health reasons: it specifically gives as examples iodine, iron, vitamins and additives used to carry or stabilize these (Codex, 2001).

With successful salt iodization programs around the world, interest in adding iron, another essential nutrient for human health, has gained attention during the past 20 years. In theory, the combination of iodine and iron in salt can simultaneously combat iodine deficiency disorders and iron deficiency anaemia, which together affect more than one-third of the world's population. However, research efforts had to address a broad array of chemical, technical, and organoleptic problems. The most important of these is the instability of iodine compounds in the presence of iron and other salt impurities. A less-critical problem is the oxidation of ferrous compounds. Some iron compounds are dark in colour, and water-soluble iron compounds, which are the most bio-available, react with moisture and impurities in salt to develop unacceptable colour that is conspicuous in the white salt.

The key to successful double fortification of salt is finding ways to prevent iron and iodine interactions either through the use of stabilizers and/or through encapsulating one or both of the micronutrients in an inert, digestible material. Several research groups have taken up the challenge of solving these technical problems (Brahmam et al, 2000; Zimmermann et al, 2004). The Micronutrient Initiative (MI), in collaboration with the Department of Chemical Engineering and Applied Chemistry, University of Toronto, has been working on developing appropriate technologies for fortifying edible salt with iodine and iron (Yusufali 2001; Diosady et al, 2002; Yuan et al, 2008). Initial efforts focused on identifying suitable iron compounds. After screening more than 10 iron compounds, ferrous fumarate has been selected for further study because of its lower potential for adverse sensory changes and high relative bioavailability similar to that of the standard ferrous sulphate

Ferrous fumarate ($C_4H_2FeO_4$) is a form of iron used in dietary supplements and multivitamin formulations for addressing iron deficiency in humans. Ferrous fumarate is a dark-reddish compound, insoluble in water, and easily oxidized by iodine to ferric fumarate which is somewhat less bioavailable (INACG, 2002). One of the challenges, therefore, was to produce, from red ferrous fumarate, an iron premix that would visually blend in with white salt.

When the chemical problems of interactions between iodine, iron and salt impurities were investigated, the need for separation of iron and iodine by a physical barrier was identified. This physical barrier must remain intact from manufacture through to home usage, but must release the nutrients either during food preparation or in the digestive system. Microencapsulation of iodine using food-grade, digestible ingredients was therefore selected as the most suitable technology for minimizing chemical interactions. A promising approach to double fortification initially tested consisted of adding a premix containing encapsulated potassium iodide and ferrous fumarate to dry table salt. The iodine was encapsulated with dextrin by spray-drying. The coating successfully prevented the iodine and iron from interacting or coming into contact with moisture in the salt (Diosady and Mannar, 2000).

However, since salt iodization programs already have well established procedures for the addition of iodine to salt, subsequent research efforts focused on encapsulating the iron compound to produce a stable premix. This would facilitate adoption of the technology because salt production facilities could easily blend an encapsulated ferrous fumarate premix with locally produced iodized salt, in predetermined proportion, to produce double fortified salt (DFS) of required iron concentration.

To ensure that the double fortified salt will be both effective and acceptable to the consuming public, the premix production must meet the following criteria:

- The particles have to be uniform before encapsulation can take place
- To prevent segregation during distribution, the particle size has to match that of the salt
- The particles have to have sufficient hardness and tensile strength to avoid breakdown during mixing with salt

- Encapsulation should provide a sufficient barrier to prevent iron and iodine interaction
- The premix particles should be about 100 to 200 times more concentrated than the fortification target to allow effective mixing of the premix into the salt.

This paper describes the product development process, with focus on pilot and commercial scale production of an iron premix consisting of encapsulated ferrous fumarate.

Analytical Methods

Iron content, coating integrity, particle size and colour were used as criteria to evaluate the encapsulated ferrous fumarate premix. For DFS, the iron and iodine content were measured.

Total iron was determined by Atomic Absorption Spectrophotometry (AOAC, 1990) modified for fortified salts (Diosady et al 2002). The spectrophotometric method developed by Harvey, Smart, and Amis (1955) was used for determining the iron content of the double fortified salt samples. To ensure the availability of iron within the microcapsules, the soy stearine was first dissolved by hexane or trichloroethylene. Ferrous iron was determined directly, total iron was determined after reduction of all iron to the ferrous form, and finally ferric iron was determined by difference.

Coating Integrity

A simple way of checking the integrity of the coating of the iron premix is to adapt the same experimental procedures as for the *in-vitro* bioavailability test (U.S. Pharmacopoeia, 1995). The mass of iron premix sample used was increased to 0.1 g from the recommended 0.02 g and the pH of the dissolution medium, hydrochloric acid was pH = 4 instead of pH = 1. This test is based on the premise that the active ingredient, namely iron contained in the coated iron premix is dissolved over a period of time due to imperfections of the coating. The objective therefore was to determine the amount of iron in the premix that dissolved in 2 hours. One litre of dissolution medium, 0.0001 N HCl, was prepared and 900 mL transferred into a 1 L Erlemeyer flask and the remaining 100 ml kept in a beaker. A thermal bath using distilled water was preheated to 37ºC. Approximately 0.1 g of iron premix was added to the solution in the Erlemeyer flask which was then placed in the bath at a shaking speed of 90 - 92 rpm. Ten mL samples solution from the dissolution medium were removed every 10 minutes. The 10 mL of sample was replaced with 10 ml 0.0001 N HCl from the beaker. All the samples were subsequently analyzed for iron.

Coating integrity was also examined using Scanning Electron Microscopy.

Particle Size Distribution

Particle size distribution of the premix as well as the salt used to produce DFS was measured.

Particle size distribution analysis was performed using a set of Tyler® screens ranging in size from 50 µm to1000 µm and a sieve shaker. About 100 g of sample were separated with the sieves stacked into the sieve shaker for 5 minutes. The separated particles were then weighed to determine the fraction of particles of the size range of two adjacent sieves.

Colour

The colour of premix was quantified by a Hunter colourimeter, using the CIE 1976 L*a*b* (CIELAB) system. L* is the lightness coordinate, (L* = 0 for black and L* = 100 for white); a* represents the red/green coordinate, with +a* indicating red, and –a* indicating green; and b* represents the yellow/blue coordinate, with +b* indicating yellow, and –b* indicating blue.

Discussion of Results

After a series of laboratory scale tests at the University of Toronto, the formulation in Table 1 was selected for further investigation (Yusufali, 2001):

Table 1: Premix formulation

Compound	%	Function
Granulation:		
Ferrous Fumarate	46.8	Micronutrient
Hydroxy Propyl Methyl Cellulose **(**HPMC)	5.0	Binder
Titanium Dioxide ($TiO_{2)}$	14.9	Colour masking
Sodium hexametaphosphate (SHMP)	3.3	Colour stabilizer
Encapsulation:		
Soya stearine	24.0	Coating
TiO_2	6.0	Colour masking

The functions of the compounds are explained in more detail below:

Ferrous Fumarate: Iron source (micronutrient)

Hydroxy Propyl Methyl Cellulose (HPMC): A widely used functional food ingredient, HPMC is used in the formulation as a binder during agglomeration. It is a water-soluble polymer, based on chemically modified cellulose.

Sodium hexametaphosphate (SHMP): Sodium hexametaphosphate is used as a stabilizer for iron. Although it is a good chelating agent, its primary role in the formulation is to bind water, and thus limit the migration of iron and iodine ions. It is a normal food ingredient, often used as an emulsifying, stabilizing and thickening agent in products such as cured meat products, infant formulae, ice creams and cheese.

Titanium Dioxide (TiO_2): Titanium dioxide is a white colour masking agent. It is a food ingredient used in many processed foods as a white pigment. TiO_2 adds a white coating to the pre-mix particles. Food industry regulations permit the use of TiO_2 in foods at up to 1.0% by weight of the finished product. The TiO_2 content of the DFS is much less than this limit: 0.14% by weight.

Soy Stearine: Soy stearine is the main component of encapsulation, the coating system. It is solid, fully hydrogenated refined soybean oil and a normal food ingredient. As it is pure fat, it is water insoluble, and acts as a water barrier, protecting the encapsulated ferrous fumarate from interacting with the environment outside the microcapsule.

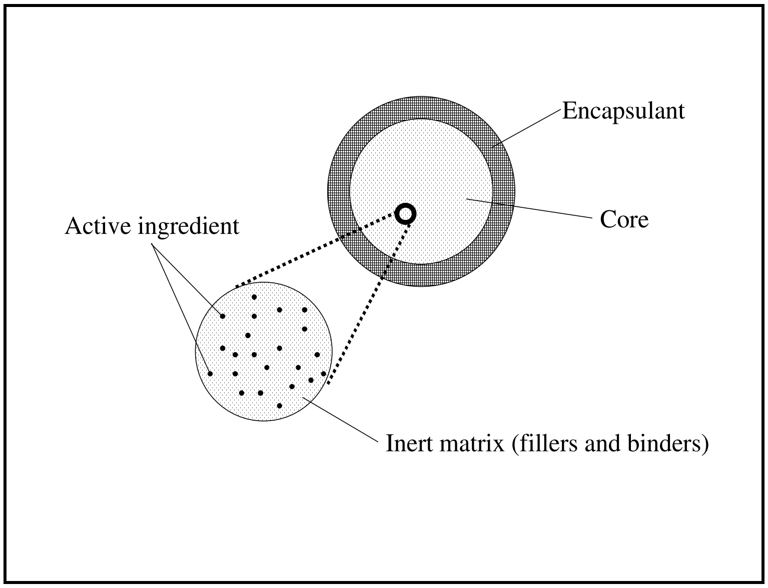
Process Technology:

Agglomeration and encapsulation, commonly used food processing methods, were adapted to produce a stable iron premix.

Agglomeration (Granulation): The premix must have a particle size similar to that of salt grains to prevent segregation (300-800µm). Binding, stabilizing and colour masking ingredients were used to produce agglomerated granules.

Encapsulation (Coating): Microencapsulation technology encloses the active ingredient – ferrous fumarate – in an inert matrix, which prevents the reactions of the encapsulated materials with the environment during processing, distribution and retail. A number of industrial processes are available for microencapsulation, including spray drying, fluidized bed coating and pan coating. The typical structure of an agglomerated, encapsulated particle is shown in Figure 1.

Figure 1 Cross section of a typical agglomerated and encapsulated particle.



Pilot and scale-up trials with fluidized-bed technology:

In the laboratory pan agglomeration and coating were the simplest and most inexpensive technique for the production of a stable iron premix. On a pilot scale this technique is not readily controllable and accordingly we selected fluidized bed agglomeration and coating for pilot scale testing. The advantage of this approach is that a high yield of premix particles can be initially formed, and then coated in the same equipment, without use of organic solvents. Using the formulation and process parameters developed in the lab trials we conducted pilot scale trials at Glatt Air Technologies, Inc., Ramsey, New Jersey, USA using Fluid Bed Processing under the supervision of our research team.

Fluid bed processing has been used in the food and pharmaceutical industry for the past 30 years. The technology is versatile for applications such as granulation, agglomeration and encapsulation.

In the Würster type fluidized bed processors of Glatt Air Techniques Inc. particles are suspended in an air stream of controlled velocity, forming a fluidized bed of particles, which behave like a liquid. A solution containing binders can be sprayed up into the bed from below, forming ever larger particles by agglomeration. When the particles reach the desired size, they can be coated in the fluidized bed, by spraying the coating material downwards into the bed.

To ensure the scalability of the process a series of tests were carried out in successively larger equipment, culminating in tests on full size commercial equipment. The processors employed in these trials are listed in Table 2.

Table 2: Fluid Bed Processors of Glatt Air Techniques Inc

Processor	Bowl Insert	Batch Size	Application
GPCG-5	22 Litre	5 – 20 kg	Process Development
GPCG-60	220 Litre	50 – 200 kg	Scale-up Trials
GPCG-300	1100 Litre	300 – 550 kg	Scale-up Trials & Commercial production

Product Development with Fluid-bed Technology

Product development with the GPCG-5 processor, the smallest of the processors listed in Table 2 was directed towards investigating the feasibility of using the fluid-bed technology to make a stable iron premix and to identify the process parameters while GPCG-60 and GPCG-300 were used to scale up the process. The key product parameters were:

- Bulk density: should be close to that of salt.
- Particle size distribution, PSD: similar to that of salt to avoid segregation
- Surface morphology: coating integrity,
- Colour masking: ideally white.
- Iron content: ~15%.

- Reproducibility of process and product

Process Technology

Agglomeration (Granulation)

The granulation process consisted of fluidizing a weighed quantity of ferrous fumarate in the bowl with warm air. The fluidized ferrous fumarate particles were then bottom-sprayed with the granulating solution shown in Table 3.

Table 3: Composition of the Granulating Solution

Ingredients	Weight Ratio
Water (purified)	43.0
HPMC (Methocel®)	1.5
SHMP	1.0
TiO_2	4.5

A solution was prepared by mixing HPMC in the water at 75ºC. Once the HPMC was well dispersed, the SHMP was mixed into the solution for about 5 minutes to ensure that all the materials were well dispersed. Titanium dioxide was then added slowly and the suspension was mixed until it was free of lumps. Fluidization was continued for about 10 minutes after spraying all the granulating solution in order to dry the granulated ferrous fumarate.

During granulation, the fluid bed processor operated under continued fluidization and during the filter shakedown only one filter bag section was shaken at a time. To enable continuous fluidization and spraying, airflow was channeled through another filter section.

The process variables for the three processors are summarized in Table 4.

Table 4: Process variables for granulation

Item	Setting		
	GPCG-5	GPCG-60	GPCG-300
Inlet Air Temperature, ºC	55 (50 - 70)	55 (50 – 70)	55 (50 - 80)
Atomization Air Pressure, bar	2.0 (1.5 - 3.0)	2.0 (1.5 – 3.0)	3.0 (2.5 - 4.5)

Air Volume, cfm	130 - 280	500 – 3000	2300 - 5500
Spray Rate, g/min	70	200 – 800	1500 - 3500
Port Size	1.2 mm	1.2 mm	1.2 mm
Shake Interval	30 sec / 3 sec	30 sec / 3 sec	30 sec / 3 sec
Filter Bag	3/5 micron	3/5 micron	3/5 micron
Nozzle:			
Type	1 nozzle with 3 ports	1 nozzle with 6 ports	1 nozzle with 6 ports
Port, mm	1.2	1.2	2
Position	Flush	Flush	Flush
Inlet Flap	None	100%	100%
WSG mode	First 35 minutes	First 35 minutes	First 35 minutes
GPCG mode	Remainder of process	Remainder of process	Remainder of process
Approx. Process Time, mins.	270	270	420

Atomization air volume was a key variable monitored by the atomization air pressure. At the completion of granulation, the granules were sieved to remove oversize particles and fines, retaining the fraction between 150 and ~ 600µm.

Encapsulation (Coating)

The objective in this process was to coat the granulated ferrous fumarate, with a suspension of the colour masking agent, TiO_2 in a hot melt of soy stearine (melting point ≅ 65^{O}C) in ratio of 1:4. In this process, a weighed amount of soy stearine was melted and kept at about 98^{o}C. While the soy stearine was being stirred, a requisite amount of TiO_2 was slowly added. Mixing of the suspension was continued for until all the titanium dioxide was dispersed. The suspension of soy stearine and TiO_2 was heated and the temperature of the suspension was maintained at close to but below 105^{o}C. The heating tube for the solution tubing was set at 120^{o}C. The suspension was then circulated through the solution lines for about 10 minutes to ensure that the lines were hot and that no clogs due to fat solidification could occur. The spray pump was calibrated to deliver a known amount per minute. Once the process conditions and settings outlined in Table 5 for the coating operation have been verified, a known quantity of granulated ferrous fumarate was put into the product bowl of the processor and the fluidization was commenced.

Table 5: Settings for the Coating Process

Item	Setting
T165 P Filter	#282/283
Nozzle: Type Configuration Position/Angle Nozzle Height	 937 Series 6 head x 1.2 mm ports Flush Lowest Position
Inlet Temperature	45 ~ 55^{o}C
Atomization Air Pressure	3.0 bar (2. ~ 3.5 bar)
Atomization Temperature	95 ~ 115^{o}C
Shake Interval/Duration	15 sec / 4 sec
Inlet Air Volume	1500 ~5000 cfm
Dewpoint	10^{o}C

The hot melt of soy stearine, with some TiO_2 for colour masking, was then top-sprayed on the fluidized bed of already granulated ferrous fumarate. Formation of an acceptable layer of film on the substrate is attained by:

- formation of adequate size droplets
- appropriate contact of these droplets with substrate
- spreading and coalescence of the droplets

For the coating material to adhere and coalesce properly with the surface of the substrate, steady state equilibrium must be established. Simultaneously the coating material must solidify rapidly in order to minimize core penetration and prevent agglomeration of wet particles (Mehta, 1989). In our process hot, melted soy stearine containing dispersed TiO_2 was directly sprayed on the fluidized bed of ferrous fumarate particles. Top-spraying of the coating solution was started as soon as the bed temperature reached 44^{o}C. After the coating process was complete the bed was cooled down while still fluidized. The process followed current good manufacturing practices, cGMP, for foods and pharmaceuticals.

Iron Content

The expected values of ferrous fumarate and ferrous iron based on the batch composition were 46.8% and 15.4% respectively. There was good agreement between actual and expected percentage of iron in the premix. Ferric iron content was found to be less than 1.0% indicating that no oxidation occurred during premix preparation.

Typical results are presented in Table 6 below

Table 6: Iron Content of Premixes

Batch No.	Ferrous Iron, Fe++, %, (g/g)	Total Iron %, (g/g)	Ferrous Fumarate %, (g/g)
PD030430	15.30(15.4)[a]	15.34(15.44)[b]	(46.8)[b]
PD030431	15.10 (15.4)[a]	15.29 (15.59)[b]	46.53 (46.8)[b]

[a] Theoretical value of iron in Ferrous Fumarate

[b] Expected fraction of Ferrous Fumarate in Iron Premix

The iron content of samples of double fortified salt was consistent with the amount expected. This indicated adequate blending with no segregation.

Coating Integrity

It is difficult to determine the uniformity or thickness of the coating on an iron premix particle. However, the measure of the integrity of soy stearine coating on the iron premix can be evaluated by a simple dissolution test, since at pH 4 the soy stearine is not affected, while ferrous fumarate in contact with the solution would dissolve Figure 2 shows the percentage of total iron dissolved in the dissolution medium (HCl) at pH of 4.0, in a typical product made in a commercial production run (Batch PD050213).

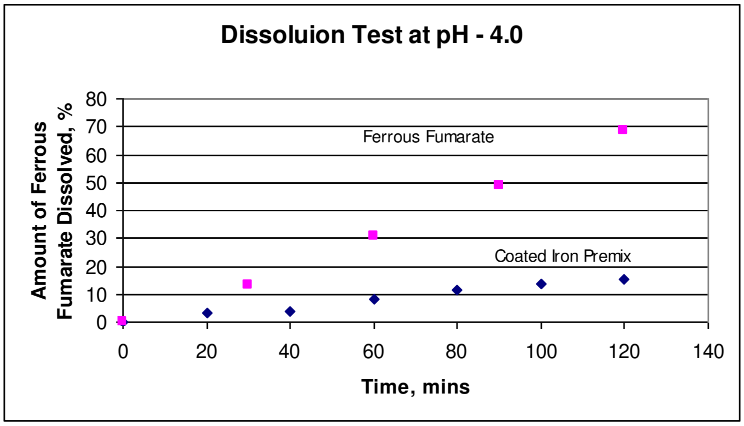


Figure 2: Results of Dissolution Test on Iron Premix

Less than 10% of the iron dissolved in the first hour. This result shows good coating integrity and that the iron nutrient is well protected. Scanning electron microscope (SEM) photographs, shown in Figure 3, also did not reveal any pores thus confirming acceptable coating integrity.

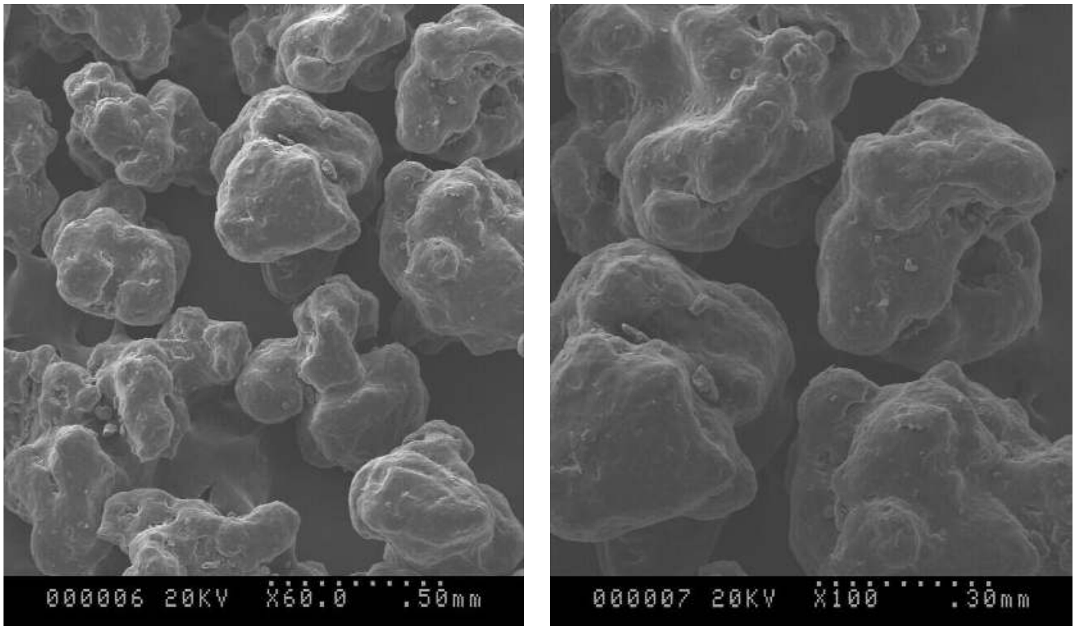


Figure 3: (A, B): Scanning Electron Microscope (SEM) Photographs of Iron Premix, (Batch PD 040375)

Particle Size Distribution

The particle size distributions (PSD) of most of the refined salts from developing countries are centred on particle size of 300 µm or 50 mesh. Figure 4 shows the PSD of a local salt from Nigeria.

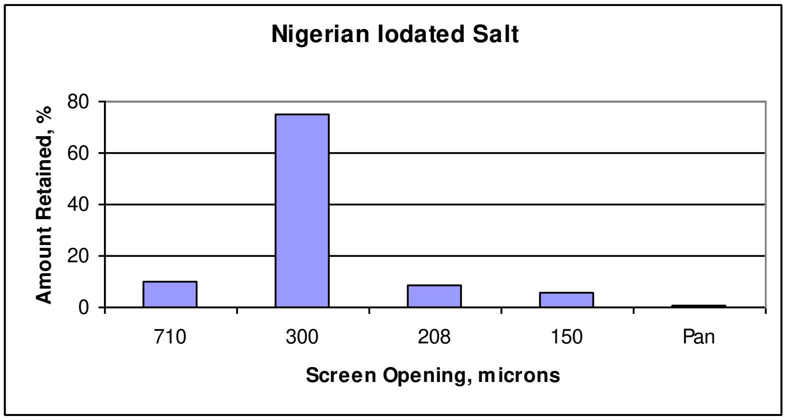


Figure 4: Particle Size Distribution of Salt Iodized with KIO3 by Royal Salt Ltd., Nigeria

It is important that the particle size distribution of the iron premix be close to that of the salt to be fortified. If the iron premix is finer than the salt, it could segregate out of the DFS resulting in uneven distribution. On the other hand larger sizes of iron premix particles than the salt could create an aesthetic problem and reduce consumer acceptability. Accordingly particles greater than 841 µm (16-mesh) and smaller than 150µm were removed from the final product.

The particle size distributions of iron premixes from representative batches produced in the pilot trials with three processors are shown in Figure 5.

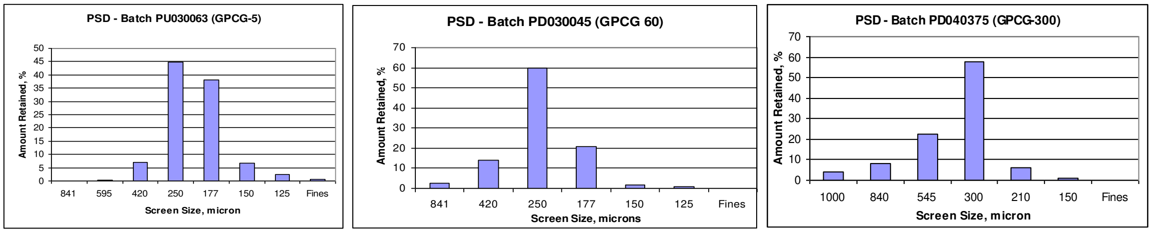


Figure 5: Effect of processor size on premix particle size distribution

In all the pilot runs the particle size distributions of the iron premix were centered on 300 µm, and about 90% of the particles were in the size range of 150 ~ 710 µm. The agglomeration process was readily scaled from the small pilot unit to the large commercial machine. In commercial scale operation the particle size of the products was highly reproducible (Figure 6)

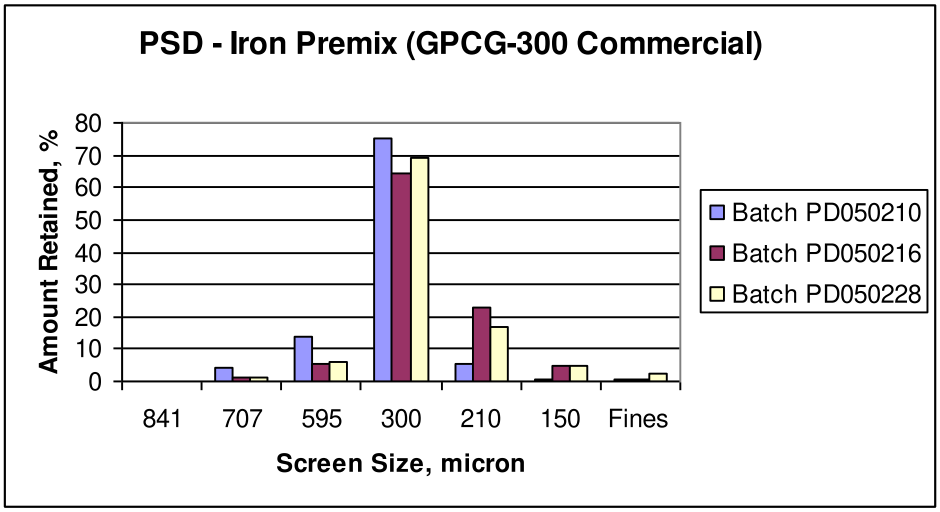


Figure 6: Particle size distribution of ferrous fumarate premixes sampled at the start, middle, and near the end of the commercial production runs with GPCG-300.

Iron Premix Colour

All the iron premixes produced were light grey in colour. A dramatic change of colour of ferrous fumarate occurred during the granulation process from dark red to light grey. The light grey granulated ferrous fumarate was made even lighter in the encapsulation process, resulting in an iron premix that was not readily visible in DFS. The average values obtained for the iron premix samples produced in the pilot trials were as follows:

- Lightness coordinate → $L^* = 82.14$,
- Yellow/Blue coordinate → $b^* = 0.585$,
- Red/Green coordinate → $a^* = 1.258$.

Reproducibility

The process variables and settings summarized in Table 4 show that only the fluidization air volume and the spray rate, respectively for granulation solution and encapsulation, increased with increased capacity of the processor. Consequently, materials handling difficulty also increased with capacity and the product yield decreased with capacity due to material losses. It was found expedient during granulation with GPCG-300 to recirculate the granulating suspension with a pump so as to maintain fluidity of the suspension in order to minimize formation of lumps and reduce foaming caused by HPMC. The amount of soy stearine required for encapsulation was 0.343 kg per kg of granulated ferrous fumarate in all the processors. This provided an adequate level of protection for the iron compound from potassium iodate resulting in a DFS stable for at least twelve months. The average bulk density of the iron premix was 0.78 $g.cm^{-3}$. This value increased with thinner coats of soy stearine as expected, but protection of iron from the iodine also decreased. The colour of the iron premix was also slightly darker when less coating was used.

Production of Double Fortified Salt

The premixes were used in making double fortified salt using iodized salt from Nigeria.

The target iron content of the iron premix was 15.4%, or about 154,000 ppm Fe. Hence the dilution ratio required for making DFS containing 1000 ppm of iron is 1 part of iron premix to 150 parts of salt. DFS was prepared by dry blending 150 parts of iodized salt from Nigeria with 1 part of iron premix resulting in a fortified salt containing 50 ppm of iodine and 1000 ppm of iron. It is important to note that the ratio of premix to salt can be adjusted depending on the salt consumption. This shows that DFS is a viable option even if population's salt consumption is reduced based on revised recommendations for lower salt intake.

The in-vivo bioavailability of the iron premix was tested, and was it was not significantly reduced from the pure ferrous sulphate (Wegmüller, 2004). The stability of DFS was successfully tested in several countries (Oshinowo et al, 2004 and 2007).

We have performed a series of large-scale runs to produce 5 tons of iron premix, which were used to make 750 tons of double fortified salt for field trials in Nigeria, Kenya and

India. Subsequently the premix production technology has been successfully transferred to India through industry partners Pam Glatt Pharma Technologies and Umang Pharmatech, two manufacturers of fluidized bed equipment similar to those used in the pilot and scale up trials reported in this paper. Efficacy trials using DFS produced using local salt resulted in dramatic reduction in iron deficiency anemia and improved iodine status among children in India, confirming the viability of this approach for the simultaneous reduction/prevention of iron deficiency anemia and iodine deficiency disorders in the developing world (Andersson et al, 2008). Currently school lunch programs throughout the State of Tamil Nadu, India have been using DFS produced by Tamil Nadu salt Corporation.

5. Conclusions

Early in the project we decided to use local salt iodized with potassium iodate and encapsulated iron to achieve a stable DFS. Ferrous fumarate was selected for its bioavailability, bland taste, stability and high iron content. Iron premix was made by first granulating the ferrous fumarate with a binder, hydroxypropylmethylcellulose (HPMC), a stabilizer, sodium hexametaphosphate (SHMP) and titanium dioxide (TiO_2). The result was a dramatic colour change from reddish brown to light grey. This was followed by encapsulation of granulated ferrous fumarate with a hot melt of soy stearine with more titanium dioxide at 98ºC. The product was a light grey iron premix that was not too conspicuous when blended with iodized salt to produce double fortified salt. Soy stearine is an inexpensive, heat stable vegetable fat, easily digestible, and not likely to conflict with the social or religious customs of the consumer.

The results have confirmed that the fluidized bed technology is a viable option for commercial scale production of iron premix for double fortified salt (DFS). In this program we have progressed from laboratory scale production of 50-100g batches of iron premix, using a pan granulator, to full scale processing of 550kg batches using Wurster type fluidized bed technology. Successful pilot trials were done with processors of incrementally increased sizes, with 7, 200 and 550 kg capacity. We achieved processing conditions that resulted in high quality products with very good reproducibility in terms of both yield and quality.

Less than 10% of iron in the premix dissolved in HCl at pH = 4.0 in one hour indicating good coating integrity. The bulk density of the iron premix, at the present level of satisfactory coating, was 0.78 $g.cm^{-3}$.There was very good reproducibility of particle size distribution (PSD) of the iron premix, tailored to that of free flowing refined salt. It was consistently centered on particle size of 300 µm (50 mesh) with about 90% of the particles were in the size range of 150 to 710 µm (100< premix <25 mesh).

Large scale production of 5 tons of iron premix, enough to make 750 tons of DFS with an iron content of 1000 ppm, and 50 ppm of iodine was completed with the 550 kg processor. Technology was successfully transferred to India and the DFS locally produced by Tamil Nadu Salt Corporation is currently being used in a successful school meal program in the state of Tamil Nadu, India

Acknowledgements

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