



Oral Replenishment of Iron through Synbiotic Hydrogel Formulation

TECHNOLOGY AVAILABLE FOR TRANSFER

UNMET NEED AND OPPORTUNITY

Oral route is the most preferred method to improve iron status during iron deficiency. However, direct addition of iron salt in foodstuffs is impracticable due to its low solubility, bioaccessibility, and bioavailability at physiological pH. Even with supplements, a large portion of the iron isn't absorbed in the small intestine and ends up reaching the colon. This unabsorbed iron can cause a range of unpleasant gastrointestinal side effects like constipation, diarrhea, and stomach pain. On top of that, excess iron in the colon can trigger oxidative damage and inflammation in the gut lining.

This new invention proposes a delivery system for iron supplements. Hydrogels would be used to encapsulate the iron for oral administration. These hydrogels would also contain probiotics, prebiotics, and other dietary components that promote gut health. The idea is that this approach could improve iron absorption while reducing the inflammatory response in the intestine, potentially leading to fewer side effects.

UNIQUE SELLING PROPOSITION

- **Increased bioavailability** of Iron.
- **Targeted Delivery:** Designed to release its contents in lower gut lowering the risk of aggregation of iron in stomach due to acidic conditions.
- **Reduced inflammatory response.**
- **Easy to manufacture.**
- Iron **Fortification of food products** by mixing with curd or juice to meet iron requirements.

STAGE OF DEVELOPMENT

The technology has been compared for efficacy with commercially available supplements and qualifies for a Technology Readiness Level of 5. Scale up data with lab scale reproducibility at 10 L worked out.

INTELLECTUAL PROPERTY

Patent granted in India in the year 2024 with a priority date of 2020.

TECHNOLOGY

A synbiotic hydrogel formulation comprising of iron, prebiotic/dietary fibre and a probiotic bacterium encapsulated in alginate beads. The formulation is intended to maintain iron and gut microbial homeostasis in the human body through oral administration.

- Hydrogel beads comprising of carbohydrate-based material (sodium alginate and potato starch) and water-soluble cross linker (calcium chloride), bead size in the range of 700-900µM.
- The beads co-encapsulate iron dextran and a probiotic bacterium (Bifidobacterium sp.).
- This delivery system utilizes a pH-sensitive mechanism to release iron dextran and probiotic bacteria in 2 hours in the duodenal pH, where the absorption of iron is maximum and the hydrogel continues to slowly release the remaining iron dextran over a longer period, potentially up to 8 hours.

EXPERIMENTAL DETAILS

Two major genes involved in the iron homeostasis were tested for gene and protein expression. During an increase in the body's iron demand the expression of DMT 1 increases in order to absorb more iron and fulfil body's iron requirements. Whereas the expression of ferritin (iron-bound protein) is reduced due to iron deficiency. Changes in the expression level of DMT-1 and Ferritin genes were analyzed in Caco2 cell line.

In-vitro studies

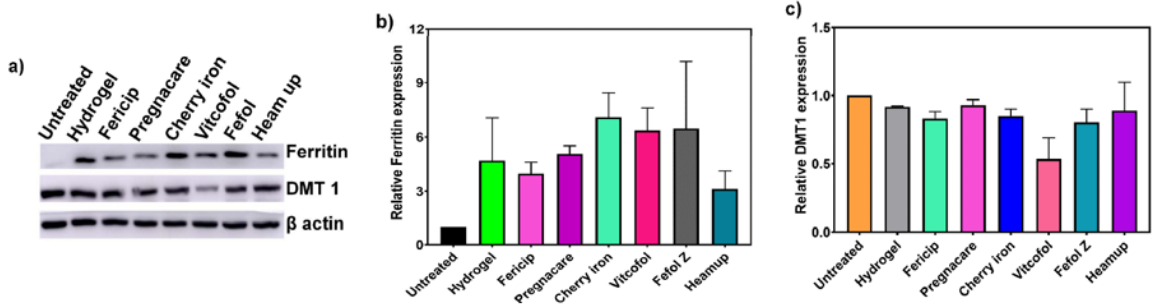


Fig: Relative Protein expression of Ferritin and Divalent metal transporter (DMT1) in Caco2 cell line. The results show that the iron bioavailability provided by synbiotic hydrogels is equivalent to commercially available iron formulations.

In-vivo and ex-vivo studies

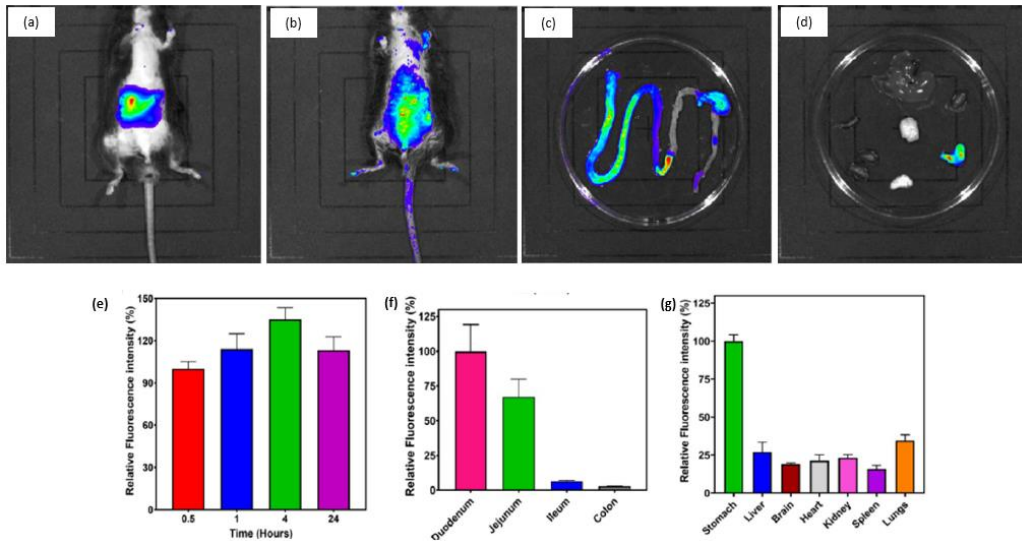


Fig: In-vivo and ex-vivo biodistribution studies of the prepared synbiotic hydrogel: live imaging of animal at (a) 0.5 h and (b) 24h; (c) ex vivo image of the isolated digestive tract; and (d) other harvested organs including stomach, liver, spleen, lungs, kidney, and heart; (e) relative fluorescence of released dye from hydrogel post-administration in the digestive tract ; (f) relative fluorescent intensity of the observed signal in different parts of the intestine; and (g) organ wise relative fluorescence .

APPLICATION

Final Product Application in making iron sachet and capsules, fortified ice-cream, fortified curd and fortified drinks.



Bacteria + iron-dextran-loaded beads

LICENSING OPPORTUNITY

BCIL is looking for an industrial partner involved to license this patented technology for commercialization.

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