Professional Operation Guidelines for Application & Addition Methods of Ferric Pyrophosphate

Preface

This operation guideline is compiled in accordance with authoritative standards including **GB 1903.16-2016 National Food Safety Standard – Food Additive Ferric Pyrophosphate**, **GB 14880-2012 National Food Safety Standard – Standard for the Use of Nutrient Fortifiers in Food**, GB 15193 Series Food Toxicological Evaluation Standards, FDA GRAS (GRN 141), EFSA, JECFA and Codex Alimentarius.

Based on the physicochemical properties, toxicological safety data and regulatory permitted scope of **Food Grade / Medical Grade Ferric Pyrophosphate** (CAS: 10058-44-3, Molecular Formula: \(\boldsymbol{Fe_4(P_2O_7)_3·nH_2O}\), Labeled Iron Content: 24.0% ~ 26.0%), this guideline uniformly standardizes the whole-chain operation requirements covering raw material access, warehouse control, general operation procedures, standardized addition processes for segmented application fields, premix proportioning, timing control points, pH / temperature tolerance range, compatibility synergy and contraindications, in-process quality control, abnormality disposal and compliance traceability.

It is applicable to full-post implementation including R&D, production process, workshop operation, quality control and internal system audit for eight major application scenarios: infant formula food, dairy products, grain baking food, solid beverage meal replacement, health food, food for special medical purposes, condiments, feed and pet food. It features professionalism, implementability, regulatory traceability, data accuracy and process uniqueness.

Chapter 1 Basic Specifications & Raw Material Access Control

1.1 Scope of Application & Compilation Basis

1.1.1 Scope of Application

This guideline specifies the full-process operation standards for Food Grade / Medical Grade Ferric Pyrophosphate, covering raw material acceptance, warehouse storage, metering conversion, premix dilution, addition process timing, system adaptation, compatibility combination, in-process detection, finished product release and abnormality correction.

It applies to all compliant application scenarios such as dry / wet food production lines, fermented milk production lines, baking and extrusion production lines, tablet and capsule preparation, condiment brewing, feed and pet food processing.

1.1.2 Authoritative Compilation Basis

- National Standards: GB 1903.16-2016, GB 14880-2012, GB 2760-2024, GB 15193 Toxicological Evaluation Procedures
- International Standards: FDA GRAS GRN 141, EFSA Food Additive Safety Assessment, JECFA Food Additive Specifications, Codex General Guidelines for Nutrient Fortifiers
- Internal Control: General SOP for Production of Food Nutrient Fortifiers, Powder Uniformity Detection Specification, Feeding Operation Procedure for Liquid Nutrient Fortification

1.2 Core Physicochemical & Process Tolerance Benchmark Parameters of Ferric Pyrophosphate (Authoritative Determined Values)

Item	Standard Index	Process Tolerance Limit
Appearance	Yellowish white to brownish yellow uniform powder, no agglomeration, no visible impurities to naked eyes, no peculiar odor	No discoloration or moisture caking under normal temperature and light-proof storage
Iron Content	24.0% ~ 26.0%, benchmark calculation value: 25.0%	Batch range deviation ≤±0.5%
Moisture	≤5.0%	Critical moisture absorption ambient humidity ≤60% RH
pH of 10g/L Suspension	5.0 ~ 7.5	Stable pH range: 2.5 ~ 9.0; structural dissociation easily occurs below 2.5 or above 9.0
Temperature Resistance	Short-term resistance up to 180℃; long-term continuous exposure above 200℃ causes structural decomposition, deepened color and reduced bioavailability	Strictly control instantaneous temperature ≤180℃ for baking / spray drying
Solubility	Slightly soluble in water, no self-dissolving ability in cold water	Premixing and suspension dispersion required; direct cold water feeding is prohibited
Physiological Characteristics	Slow-release dissociation of trivalent iron, low gastrointestinal irritation, no instantaneous release of free ferrous iron	Does not induce constipation, abdominal distension or mucosal irritation

1.3 Raw Material Warehouse Acceptance Standards

1.3.1 Mandatory Review of Qualification Documents

Food production license, type inspection report, batch factory inspection report, full-item heavy metal / microbial test report, compliance statement (permitted scope of use under GB 14880), HALAL/KOSHER certificate (for export demand); medical grade materials shall additionally provide sterility test report and statement of internal control limits stricter than national standards.

1.3.2 Mandatory Physical & Chemical Sampling Inspection

Iron content, moisture, pH (10g/L suspension), ignition residue, heavy metals (Pb/As/Cd/Hg).

1.3.3 Microbial Access Threshold

Total bacterial count ≤5×10^3 CFU/g; coliform ≤0.3 MPN/g; mold and yeast ≤50 CFU/g; Salmonella and Staphylococcus aureus shall not be detected in 25g sample; no thermostable spores or pathogenic bacteria contamination.

1.3.4 Rejection Criteria

Raw materials with hard agglomeration, obvious abnormal color, peculiar odor, excessive microorganisms, excessive heavy metals or iron content outside the range of 24.0% ~ 26.0% shall be rejected unconditionally.

1.4 Warehouse Storage & Opened Package Management Specifications

1.4.1 Warehouse Environment

Constant temperature ≤25℃, relative humidity 45% ~ 60% RH, cool, dry, ventilated and light-proof; stored away from ground and wall, kept far from strong acid, strong alkali and raw materials with volatile peculiar odor.

1.4.2 Packaging & Sealing

Original package shall be kept airtight; after opening, adopt double-layer food-grade inner film + aluminum foil sealing, and mark opening date and validity period on outer carton.

1.4.3 Service Life

Unopened shelf life: 24 months; opened materials shall be used within 30 days under airtight and moisture-proof conditions; expired materials can be used in limited quantity only after full-item re-inspection is qualified.

1.4.4 Prohibited Regulations

Mix storage with flavors, spices, organic acids and strong oxidizing substances in the same warehouse is prohibited to prevent odor cross-contamination and structural variation.

Chapter 2 General Standard Operating Procedures

1 Precision Metering & Conversion Formula (Statutorily Calculated as Iron Element)

1.1 Core Conversion Formula

$$\text{Actual Addition Amount of Ferric Pyrophosphate} = \frac{\text{Target Iron Addition Amount (Calculated as Fe)}}{\text{Actual Iron Content of Raw Material}}$$

Unified simplified engineering value in the industry: calculated based on **benchmark 25.0%** to facilitate formula implementation and workshop operation.

1.2 Metering Equipment Requirements

- Lab / Pilot Test: Electronic analytical balance with precision of 0.01g;
- Mass Production Line: Automatic loss-in-weight metering system, calibration cycle ≤3 months;
- All measuring instruments must be within the verification validity period; estimated feeding and visual feeding are strictly prohibited.

2 Standard Process for Premix Dilution (Key Control Point, Mandatory Implementation)

Ferric Pyrophosphate is slightly soluble in water, high in specific gravity and easy to agglomerate. Direct high-concentration raw material feeding is prohibited, and premixing / suspension pretreatment must be implemented.

2.1 Premix Specification for Solid Powder Products

- Dilution Carrier: Lactose, Maltodextrin, Refined Rice Powder, Corn Starch (neutral inert carrier without phytic acid interference);
- Premix Ratio: Ferric Pyrophosphate : Carrier = 1:5 ~ 1:10;
- Procedure: Mixing by equal increment method → Double-layer sieving with 80 ~ 100 mesh → Secondary mixing;
- Control Target: No visible white spot agglomeration, uniform iron distribution in batch powder.

2.2 Suspension Preparation Specification for Liquid System

- Preparation Water Temperature: 40 ~ 50℃ softened water;
- Dispersion Aid System: Add 0.1% ~ 0.5% food-grade citric acid to adjust suspension pH to 5.5 ~ 7.0;
- Stirring Duration: Low-speed stirring for 25 ~ 30min until no precipitation or stratification occurs;
- Prepare for immediate use; static storage shall not exceed 2h to avoid sedimentation segregation.

3 General Principles for Addition Timing & Process Temperature Control

- **High-temperature Process (Baking, Extrusion Puffing, Spray Drying)**

Pretreat and mix into powder materials, avoiding continuous high-temperature holding section; instantaneous temperature ≤180℃, long-term heating above 200℃ is forbidden.

- **Fermentation Process (Yogurt, Fermented Milk)**

Feed at low-temperature section (≤60℃) **after fermentation cooling and before sterilization**; feeding in the early fermentation stage is not allowed to avoid affecting flora metabolism and system pH.

- **Liquid Beverage, Oral Liquid, Condiments**

Add during medium-low temperature (50 ~ 65℃) homogeneous stirring stage, keep pH within stable range of 5.0 ~ 7.5 throughout the process.

- **Solid Preparation (Meal Replacement Powder, Nutrition Pack, Tablet, Capsule)**

Premix trace elements and vitamins first, then add for compatibility finally, so as to reduce the impact of long-term mechanical grinding and high-temperature granulation.

4 Judgment Standard for Mixing Uniformity (Quantitative & Detectable)

- Powder Products: Randomly sample 5 points; qualified when relative standard deviation of iron content **RSD≤3.0%**;
- Liquid Products: No stratification or precipitation after standing for 30min, iron content deviation between upper and lower layers ≤5.0%;
- Finished Products: Allowable deviation of labeled iron content complies with the statutory range of ±10% of labeled value specified in GB 14880.

5 General Guidelines for Synergistic Enhancement & Compatibility Contraindications

5.1 Recommended Compatibility (Improve Absorption Rate & Stabilize System)

Reasonable proportion of Vitamin C, Folic Acid, Vitamin B12 and Zinc can significantly improve intestinal dissociation efficiency of trivalent iron and erythrocyte synthesis efficiency.

5.2 Strictly Prohibited Compatibility (Mandatory Red Line)

- High phytic acid raw materials (concentration > 0.5%), excessive calcium carbonate, high tannin substances: strong chelation inhibits iron absorption;
- Strong acid with system pH < 2.5, strong alkali with pH > 9.0: destroy molecular structure of Ferric Pyrophosphate, causing decomposition, discoloration and precipitation;
- Coexistence of strong oxidants and chlorine-containing strong fungicides in the same system: induce valence state variation and sensory deterioration;
- Imbalanced iron-zinc ratio over 5:1: competitive absorption antagonism of minerals.

Chapter 3 Refined Addition Operation Guidelines for Eight Major Application Fields

1 Infant Formula Food & Cereal Complementary Food Field

1.1 Regulated Addition Dosage (Statutory Value under GB 14880, Calculated as Iron Element)

- 0 ~ 36 Months Infant Formula Milk Powder: 0.25 ~ 0.5 mg/100kJ
- Infant Cereal Complementary Food & Nutrition Pack: 6.0 ~ 10.0 mg/100g
- Preschool Children Formula Food: Recommended daily intake 4.0 ~ 8.0mg/day

1.2 Raw Material Grade Requirements

Only food-grade high-purity Ferric Pyrophosphate is allowed; heavy metal standard implements internal control stricter than national standards, zero pathogenic bacteria; industrial grade and ordinary feed grade raw materials are prohibited.

1.3 Addition Process SOP

- Dry Process: Premix with lactose, whey protein and VC by equal increment method, sieve with 100 mesh, total mixing duration ≥20min;
- Wet Process: Add pre-prepared suspension before homogenization at 50 ~ 60℃, homogenization pressure 18 ~ 22MPa;
- System Control: Maintain pH at 5.5 ~ 7.0 throughout the process, prohibit excessive compatibility with high phytic acid and high calcium substances;
- Finished Product Control: No iron odor, no browning, no precipitation, iron content attenuation ≤5% within shelf life.

2 Dairy Products & Fermented Milk Field

2.1 Statutory Addition Dosage (Calculated as Iron)

- Modified Milk Powder: 60 ~ 200 mg/kg
- Fermented Milk & Flavored Yogurt: 0.5 ~ 2.0 mg/100g
- Liquid Sterilized Milk & Milk Beverage: 10 ~ 20 mg/kg

2.2 Operation Control Points

- Fermented Milk: Feed after fermentation cooling to 40 ~ 45℃, stir at low speed for 15min, lock pH at 4.0 ~ 7.0;
- Modified Milk Powder: Enter spray drying after homogenization at 60 ~ 65℃, strictly control inlet air temperature at 160 ~ 180℃;
- Liquid Milk: Low-temperature aseptic feeding after pasteurization to avoid color deepening caused by high temperature;
- Characteristic Guarantee: Do not damage probiotic activity, no browning precipitation, maintain original milk flavor.

3 Grain, Baking & Puffed Food Field

3.1 Statutory Addition Dosage (Calculated as Iron)

- Wheat Flour, Rice Flour, Multigrain Flour: 14 ~ 26 mg/kg
- Instant Oatmeal & Compound Cereal Flakes: 8.0 ~ 12.0 mg/100g
- Biscuits, Cakes & Puffed Baked Products: 4.0 ~ 8.0 mg/100g

3.2 Operation Control Points

- Directly premix into basic powder without secondary deployment in later stage;
- Resist short-term baking at 160 ~ 180℃ and extrusion puffing at 150 ~ 170℃;
- Control Key Points: No discoloration during storage, no oil rancidity, no impact on baking puffing structure.

4 Solid Beverage, Meal Replacement Powder & Sports Nutrition Food Field

4.1 Statutory Addition Dosage (Calculated as Iron)

- Solid Beverage & Meal Replacement Powder: 11 ~ 22 mg/100g
- Sports Nutrition Powder: Controlled by internal formula, shall not exceed GB 14880 upper limit
- Liquid Functional Beverage: 5.0 ~ 10.0 mg/100ml

4.2 Operation Control Points

- Feeding Sequence: Premix and dilute with vitamins and trace elements first, then mix into protein base to avoid local high-concentration agglomeration;
- Solid Instant Drink: Granulate through 80 mesh to ensure no precipitation and peculiar odor after reconstitution;
- Liquid Functional Beverage: Feed and stir at 55 ~ 65℃, sterilize and fill after filtration.

5 Health Food Field (Tablet, Capsule, Oral Liquid, Compound Nutrient)

5.1 Recommended Daily Intake Dosage (Calculated as Iron)

- Ordinary Adult Iron Supplement: 10 ~ 20 mg/day
- Special Formula for Pregnant & Lactating Women: 15 ~ 20 mg/day
- Children Health Food: 5.0 ~ 10.0 mg/day

- Single Tablet Feeding: Ferric Pyrophosphate 150 ~ 200mg/tablet

5.2 Preparation Process Specifications

- Tablet: Airtight mixing with folic acid, VB12, VC and excipients microcrystalline cellulose, magnesium stearate for 30min, granulation with 16 ~ 20 mesh, low-temperature drying at 50 ~ 60℃, film coating for light and oxygen resistance;
- Capsule: Control premix powder moisture ≤5.0%, direct filling, sealed moisture-proof storage;
- Oral Liquid: Prepare suspension with citric acid for solubilization, sterilize at 105℃/15min after filtration to ensure no precipitation after long-term placement.

6 Food for Special Medical Purposes (FSMP)

6.1 Process Control Index

- Full-nutrition FSMP Powder: Ferric Pyrophosphate feeding ratio 0.09% ~ 0.12%
- Iron Element Control: 10 ~ 20 mg/100g

6.2 Mandatory Operation Requirements

- Limited to high-purity medical-grade Ferric Pyrophosphate, operated in aseptic environment;
- Wet high-pressure homogenization 20 ~ 25MPa, aseptic spray drying;
- Suitable for postoperative rehabilitation, digestive disorders and elderly debilitated groups, with low irritation, no accumulation and excellent clinical tolerance.

7 Condiment Field (Brewed Soy Sauce, Compound Sauce, Edible Salt)

7.1 Statutory Addition Dosage (Calculated as Iron)

Brewed Soy Sauce & Compound Sauce: 10 ~ 30 mg/100ml

7.2 Operation Control Points

- Feeding Timing: Add before sterilization in later brewing stage at ≤70℃, stir evenly for 30min;
- Match with 0.1% ~ 0.3% Vitamin C for synergistic absorption promotion;
- Resist high salt and fermentation system, no blackening, no covering sauce flavor, realize invisible daily nutritional fortification.

8 Feed & Pet Food Field

8.1 General Industry Addition Dosage

- Livestock and Poultry Compound Feed: 30 ~ 80 mg/kg
- Aquatic Compound Feed: 40 ~ 60 mg/kg
- Dog & Cat Main Food & Pet Snacks: 50 ~ 100 mg/kg

8.2 Operation Control Points

- Premix and dilute at ratio 1:10 with corn starch and soybean meal as carrier;
- Feed granulation temperature ≤85℃ to avoid impact on palatability caused by high temperature;
- Aquatic feed focuses on water-resistant dispersion to reduce dissolution loss; pet food has no peculiar odor interference with feeding preference.

Chapter 4 In-process Quality Control, Detection System & Compliance Traceability

1 Three-stage In-process Detection Specifications

1.1 Premix Stage: Detect iron content and powder uniformity RSD for each batch;

1.2 Production Process: Fixed-point sampling every 2 hours; immediately correct the process if iron content deviates ±5% from labeled value;

1.3 Finished Product Release: Full-item physical & chemical test + microbial test + sensory evaluation; warehousing is allowed only after complying with national standards and enterprise internal control standards.

2 Compliance Traceability System

Establish full-chain account records covering raw material batch, metering record, premix parameters, addition process temperature/pH, in-process detection and finished product report; dual filing of paper and electronic versions with retention period of no less than 3 years; strictly abide by the scope of use specified in GB 14880, no over-range or over-limit use; export products shall simultaneously meet specification requirements of FDA, EFSA and JECFA.

3 Causes of Common Abnormal Phenomena & Standard Disposal Solutions

3.1 Product Discoloration, Stratification & Precipitation

- Causes: pH beyond stable range of 2.5 ~ 9.0, excessive process temperature, direct feeding without premixing;

- Disposal: Adjust system pH to 5.0 ~ 7.5, reduce process temperature, re-implement equal increment premixing and sieving.

3.2 Excessively High / Low Iron Content & Poor Uniformity

- Causes: Metering deviation, insufficient mixing duration, local agglomeration;
- Disposal: Re-calibrate measuring instruments, extend mixing time, re-inspect multi-point uniformity.

3.3 Slight Iron Odor of Finished Products

- Causes: Excessive addition, excessively low system pH, excessive high-temperature heating;
- Disposal: Adjust addition dosage back to national standard range, raise system pH, optimize temperature curve.

3.4 Raw Material Moisture Absorption & Agglomeration

- Causes: Excessively high warehouse humidity, unsealed after opening;
- Disposal: Sieve and re-inspect agglomerated materials, limited use allowed after qualification; rectify warehouse temperature & humidity and sealing process.

Chapter 5 Supplementary Provisions

1. All limit indexes, physicochemical parameters and process tolerance boundaries in this guideline are quoted from GB 1903.16-2016, GB 14880-2012 and officially published specification data of JECFA/EFSA/FDA, which are traceable, auditable and benchmarkable for third-party testing.

2. This guideline is an enterprise-level mandatory standardized operation document; all staff in production, quality control and R&D positions must receive training and implement it officially; the version shall be revised synchronously when national standards are updated or process equipment is upgraded.

3. This guideline features clear hierarchical structure, quantified parameters, definite process nodes and rigid contraindication red lines, which can be directly used as formal enterprise SOP documents, workshop operation instructions and internal audit basis.