स्वास्थ्य एवं
परिवार कल्याण मंत्रालय
MINISTRY OF
HEALTH AND
FAMILY WELFARE
सत्यमेव जयते

NATIONAL HEALTH MISSION
राष्ट्रीय स्वास्थ्य मिशन

Anemia Mukt Bharat

Operational Guidelines on Intravenous Iron Treatment in Pregnant Women and Lactating Mothers

Ministry of Health and Family Welfare,
Government of India

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आराधना पटनायक, भा.प्र.से.
अपर सचिव एवं मिशन निदेशक
(रा.स्वा.मि.)

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भारत सरकार
स्वास्थ्य एवं परिवार कल्याण मंत्रालय
Government of India
Ministry of Health & Family Welfare

Message

Anemia continues to be a significant public health challenge in our country, especially among pregnant women. With over half of women suffering from anemia during pregnancy, there are risk associated with both maternal and foetal health. Anemia undermines our efforts to reduce maternal mortality and improve birth outcomes.

Anemia Mukt Bharat (AMB) programme under the National Health Mission (NHM) has made commendable progress through proactive interventions and multisectoral convergence. However, to further intensify our efforts and address moderate to severe anemia in pregnant women more effectively, particularly where oral iron is poorly tolerated or ineffective—the use of intravenous (IV) iron therapy has emerged as a scientifically sound and alternative to restore iron levels and improve outcomes.

The Operational Guidelines on Intravenous Iron Treatment in Pregnant Women and Lactating Mothers, including the use of Ferric Carboxymaltose (FCM), are grounded in robust national and international evidence. These guidelines are an add-on and advancement to the Guidance Note on use of Intravenous Iron among Pregnant Women, offering expanded implementation protocols and refined clinical recommendations. FCM with higher and faster rise in hemoglobin, shorter infusion time and fewer side effects, make it especially beneficial in the second and third trimesters of pregnancy and during the postpartum period.

I urge all States and Union Territories to adopt and implement these guidelines in routine service delivery, making our health system more responsive and effective in managing anemia among pregnant and lactating women. Strengthening service delivery at Primary Health Centres and higher-level facilities, ensuring uninterrupted availability of intravenous iron, and building the capacity of healthcare providers are key to the success of this initiative.

Our collective commitment will ensure that no woman is left behind in our journey toward achieving Sustainable Development Goals and a healthier India.

(Aradhana Patnaik)

Meera Srivastava, IRS
Joint Secretary

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Foreword

Anemia, during and after pregnancy has been frequently associated with maternal fatigue, reduced work capacity, delayed recovery, and poor infant growth and development. In severe cases, it contributes to postpartum hemorrhage, low birth weight, stillbirths, and maternal mortality. Addressing this critical challenge is essential to improving maternal and child survival and strengthening our healthcare delivery system.

While the Anemia Mukt Bharat (AMB) strategy under the National Health Mission (NHM) has made considerable progress in promoting the use of oral iron and folic acid supplementation, limitations in adherence and absorption, especially in cases of moderate to severe anemia calls for multi-pronged strategies to improve the same.

The Operational Guidelines for Intravenous Iron Treatment in Pregnant Women and Lactating Mothers have been provided to serve as a practical and easy to understand resource for program managers and healthcare providers. They outline evidence-based protocols for the use of intravenous iron, including Ferric Carboxymaltose (FCM) and Iron Sucrose (IS), supported by robust clinical research and expert consensus. We hope that these guidelines will provide support and guidance across States/UTs to strengthen the quality of maternal care services.

(Meera Srivastava)

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The Operational Guidelines on Intravenous Iron Treatment in Pregnant Women and Lactating Mothers, including the use of Ferric Carboxymaltose (FCM), have been prepared following extensive technical deliberations and collaborative consultations between the Ministry of Health and Family Welfare, domain experts, and supporting partner agencies working in the field of maternal health and nutrition.

I would like to sincerely acknowledge the leadership, strategic direction and unwavering support of Ms. Aradhana Patnaik, Additional Secretary & Mission Director (NHM), and Ms. Meera Srivastava, Joint Secretary (RCH), whose vision and guidance were pivotal in the conceptualization and finalization of these guidelines.

I am also thankful for the many-many detailed contributions from the National Technical Expert Committee on FCM, Dr Pawan Kumar, Additional Commissioner (Maternal Health), Dr Neena Malhotra, Dr Bindu Bajaj and Dr Reena Yadav, Heads of Departments of Obstetrics and Gynaecology from AIIMS, Safdarjung Hospital and Lady Hardinge Medical College respectively, Dr Nuzhat Aziz from Fernandez Hospital, Hyderabad, Dr Rishi Dhawan and Dr Pankaj Malhotra from the Departments of Hematology at AIIMS and PGI Chandigarh respectively, as well as Dr Bharati Kulkarni and Dr Reema Mukherjee from ICMR and Dr Kapil Yadav from NCEAR-AIIMS, all of whom provided timely and very useful inputs. Contribution of the Jhpiego team in coordinating the development and printing of this guideline is also acknowledged.

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(Dr. Zoya Ali Rizvi)

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List of Abbreviations

AAM	Ayushman Arogya Mandir
ABHA ID	Ayushman Bharat Health Account ID
ADR	Adverse Drug Reaction
AE	Adverse Event
AMB	Anemia Mukt Bharat
ANC	Antenatal Checkup
ANM	Auxiliary Nurse Midwife
ASHA	Accredited Social Health Activist
BP	Blood Pressure
CBC	Complete Blood Count
CDSCO	Central Drugs Standard Control Organisation
CHC	Community Health Center
CoA	Certificate of Analysis
DH	District Hospital
EU	Endotoxins Units
FCM	Ferric Carboxymaltose
FHR	Fetal Heart Rate
FRU	First Referral Unit
GSTIN	Goods and Services Tax Identification Number
Hb	Hemoglobin
IEC/BCC	Information, Education, and Communication/Behaviour Change Communication
IFA	Iron Folic Acid
IM	Intramuscular
IP	Indian Pharmacopoeia
IS	Iron Sucrose
IV	Intravenous

List of Abbreviations

LM/LW	Lactating Mother/Lactating Women
LMP	Last Menstrual Period
MC	Medical College
M&E	Monitoring and Evaluation
MH	Maternal Health
MoHFW	Ministry of Health and Family Welfare
MO	Medical Officer
MW	Molecular Weight
NABL	National Accreditation Board for Testing and Calibration Laboratories
NFHS-5	National Family Health Survey - 5
PHC	Primary Health Centre
SBP/DBP	Systolic Blood Pressure/Diastolic Blood Pressure
VAT	Value Added Tax
WHO-GMP	World Health Organization’s Good Manufacturing Practices

Contents

1. Introduction

Anemia is a condition in which the number of red blood cells or their oxygen-carrying capacity is insufficient to meet the body's physiological needs.

Anemia is caused by several factors:

- Nutrient deficiencies
- Inadequate diet (or the inadequate absorption of nutrients and poor bioavailability of iron)
- Low iron stores
- Soil Transmitted Helminths (STH) infestations
- Infections (malaria, tuberculosis, HIV)
- Inflammation
- Chronic diseases
- Gynaecological and obstetric conditions (maternal blood volume expansion during pregnancy, hemorrhage associated with childbirth, menstrual loss)
- Inherited red blood cell disorders.

Anemia is a significant public health problem globally and is associated with adverse health effects, and far reaching social and economic impacts. It leads to reduced physical work capacity, poor maternal and perinatal health outcomes, delayed growth, cognition and motor development in children.

Anemia during pregnancy is associated with postpartum hemorrhage, neural tube defects, low birth weight, premature births, stillbirths and maternal and neonatal mortality. It can continue to affect the women in their postpartum period which may worsen due to blood loss during and after delivery. It further leads to intergenerational cycle of poor health and suboptimal growth.

Iron deficiency is considered the most common nutritional deficiency leading to anemia. Iron deficiency anemia develops due to lack of adequate intake of iron in diet, impaired absorption in body, excessive loss or impaired RBC production. Deficiencies in Vitamin A, Folate, Vitamin B12 and Riboflavin can also result in anemia due to their specific roles in the synthesis of hemoglobin and/or erythrocyte production.

Globally, absolute iron deficiency (absent or reduced body iron stores that do not meet the need for iron of an individual and responds to iron supplementation) contributes to almost half of all cases of anemia. Functional iron deficiency (adequate or increased iron stores that cannot meet the need for iron because of the effects of infection or inflammation and does not respond to iron supplementation) is also responsible for anemia in low and middle income countries.

1.1 Anemia: A Major Public Health Concern in India

According to National Family Health Survey (NFHS-5) Anemia is a major public health issue in India affecting:

52.2% Pregnant Women

60.6% Lactating Mothers

Anemia during pregnancy and postpartum period may be detected by testing the hemoglobin concentration frequently at both community and healthcare facility level. A hemoglobin (Hb) concentration of less than 11 g/dL is regarded as anemia in pregnancy while Hb less than 12 g/dL indicates anemia in women in reproductive age including lactating mothers.

A diagnosis of iron deficiency can be confirmed by the serum ferritin concentration falling to less than 30 µg/L in pregnant women and less than 15 µg/L in non-pregnant women. Pregnant women and lactating mothers with any anemia and those at risk of iron deficiency anemia should be identified and treated as per protocols, to prevent them from developing adverse effects of anemia.

1.2 Use of Intravenous Iron in Treating Anemia

Iron deficiency anemia can be effectively treated with oral iron supplements and is recommended as the first line of treatment. However, poor adherence to oral iron treatment remains a persistent challenge, primarily due to associated gastrointestinal adverse effects. For women who have severe gastrointestinal side effects or are non-responsive to oral iron, intravenous iron may be given.

> Intravenous (IV) iron is an effective alternative to oral iron as it circumvents the natural gastrointestinal regulatory mechanisms to deliver non-protein bound iron to red blood cells. IV iron helps in achieving rapid correction of hemoglobin, replenishing iron stores and is better tolerated than oral iron in treating iron deficiency anemia.

It is important to confirm iron deficiency by testing hemoglobin level and/or serum ferritin using venous blood sample. (Details are given in Service Delivery Algorithm on page 10-11)

Table-1 lists the indications and contraindications for the use of the IV iron among the pregnant women and lactating mothers.

Table 1: Indications and Contraindications for use of IV iron

Indications	Contraindications
Severe anemia due: • Iron deficiency Hb 5-6.9 g/dL[1] at 13-34 weeks of pregnancy • Hb 5-7.9 g/dL in lactating mothers Moderate anemia (Hb 7-9.9 g/dL) due to iron deficiency In pregnant women (after 13 weeks) and lactating mothers (of 0 to 6 months child) if - • Oral iron not tolerated[2] • Non-compliance to oral iron[3] • No improvement in Hb or improvement <1 g/dL after 1 month of Oral IFA	Known hypersensitivity to iron preparation or excipients of Iron Sucrose or FCM Anemia not caused by iron deficiency Liver disorder like jaundice, cirrhosis Acute cardiac failure Known case of transfusion dependent thalassemia, sickle cell anemia disease or hemolytic anemia Serum ferritin >150 µg/L Fever, Acute infection/Illness

The most commonly used IV iron preparations for the management of anemia in pregnancy and postpartum period are Iron Sucrose (IS) and Ferric Carboxymaltose (FCM). IV-IS is already in use for treatment of moderate and severe anemia in pregnant women.

IS is a non-dextran iron with a complex structure comprising a polynuclear iron (III) hydroxide core surrounded by sucrose. It is recognized for its relatively short half-life of 5-6 hours, facilitating rapid erythropoiesis and a swift increase in hemoglobin levels, typically seen within 5 to 7 days.

With emerging time and evidences, the use of Ferric Carboxymaltose (FCM) as single dose IV iron infusion for treating iron deficiency in severe and moderately anemic pregnant and postpartum women has been recommended.

FCM is a macromolecular ferric hydroxide carbohydrate complex with a ferric hydroxide core stabilised by a carbohydrate shell.

In the bloodstream, the iron from the iron carbohydrate complex is released and is either taken by ferritin or serum transferrin. The iron-transferrin complex binds to receptors on erythroblasts situated in the bone marrow providing essential iron for hemoglobin synthesis. Thus, FCM is rapidly cleared from plasma and largely distributed to the bone marrow.

Evidence from national and international studies have shown that both FCM and IS are safe and effective for treatment of anemia in pregnancy and postpartum period. The Table 2 below compares IV-IS and FCM.

1 For severely anemic pregnant women with haemoglobin less than 5 g/dl **at any gestation**,or severe anemia at gestation of over 34 weeks , immediate hospitalization irrespective of period of gestation where round-the-clock specialist care is available.

2 Patients may experience adverse effect from iron supplements, but these usually settle down with time. Adverse effects of iron include constipation, diarrhoea, epigastric pain, faecal impaction, gastrointestinal irritation and nausea. Intolerence to Oral Iron to be assessed by Medical Officer/Treating Physician based on clinical history and examination

3 Non compliance will not have any specific symptoms and will be decided only after detailed history and examination

Table 2: Comparison between Iron Sucrose and FCM

Iron Sucrose (IS)	Ferric Carboxymaltose (FCM)
Lower stability; relatively short half-life of 5-6 hours	Higher stability, longer half-life of about 16 hours
Rapid increase in hemoglobin levels, typically seen within one week of completion of the final dose of the treatment	Rapid replenishment of iron stores with significantly higher Hb rise typically seen within one week and sustained upto 3 to 6 weeks. FCM brings greater and faster hemoglobin increase in treatment of anemia as compared to IS
The expected increase in hemoglobin level for pregnant women with severe and moderate anemia is approximately 2.5 gm/dL and 1.6 gm/dL, respectively 3 weeks after complete calculated dose of IV-IS treatment	The expected increase in hemoglobin level for pregnant women with severe and moderate anemia is approximately 3.6 gm/dL and 2.74 gm/dL, respectively 4 weeks after complete calculated dose of FCM treatment
Antigenicity higher	Antigenicity much lower
Dose: Need of multiple visits to deliver the required iron dose Maximum dose in one sitting: 200 mg Maximum dose in one week: 600 mg Maximum dose in one pregnancy to avoid overload and associated complications is 1000 mg i.e 5 doses of 200 mg Inj. Iron Sucrose over 2 weeks	Dose: Maximum dose and total replacement dose can be given in a single infusion, allowing for efficient delivery of substantial amount of iron in one administration Maximum dose in one sitting: 1000 mg Maximum dose in one pregnancy to avoid overload and associated complications is 1500 mg
Administration: After preparation using 0.9% Normal Saline, the initial phase of the infusion should be at a rate of 20-30 drops per minute for the first five minutes, subsequently increasing to 80-90 drops per minute	Administration: After preparation using 0.9% Normal Saline, the initial phase of the infusion should be of 20-30 drops per minute for the first five minutes and after that drop rate can be increased to 100-120 drops per minute
Time for administration: Iron Sucrose administration takes around 30 minutes	Time for administration: FCM requires a shorter administration time, approximately 15 minutes

The drug monographs[1] of Ferric Carboxy Maltose Injection and Iron Sucrose Injection are not available in The Indian Pharmacopoeia (IP)[2]. The Indian regulatory bodies like Central Drugs Standard Control Organisation (CDSCO)[3], State Drugs Controller emphasize the importance of assessing key physical and chemical parameters such as particle size, molecular weight (MW), iron and carbohydrate content, osmolality, zeta potential, density, and pH levels since these factors impact bioavailability, pharmacokinetics, patient safety and therapeutic efficacy.

States/UTs may refer to draft monograph for Ferric Carboxy Maltose Injection (under consideration of inclusion in IP 2026) and the United States Pharmacopoeia (USP) monograph for Iron Sucrose Injection for ease in procurement and ensuring the quality standards.

Technical specifications for Ferric Carboxy Maltose Injection and Iron Sucrose Injection are given in Annexure VII and VIII respectively.

To ensure efficacy as well as maintaining safety profile and quality, States/UTs may refer to criteria given in Annexure IX for IV iron procurement.

The Operational Guidelines for Intravenous Iron Treatment in Pregnant Women and Lactating Mothers, aim to standardize the administration and provision of safe and effective treatment protocols for moderately and severely anemic women during and after pregnancy, thereby, improving maternal and neonatal health outcomes across the country. These guidelines are a crucial step toward achieving the goals of the Anemia Mukt Bharat (AMB) programme.

The States/UTs may plan to implement the use of IV iron, especially FCM, in a phase wise manner beginning with district hospital and above to ensure that moderate and severely anemic pregnant women and lactating mothers (of 0-6 months child) are prioritized in the first phase, considering their greater vulnerability to morbidity and mortality as well as adverse pregnancy outcomes.

1 Monograph is scientific document of detailed parameters of a drug including its physical and chemical properties that are used to determine whether a medicine meets key quality attributes.

2 The Indian Pharmacopoeia (IP) is the official, legally enforceable book of drug standards in India, published by the Indian Pharmacopoeia Commission (IPC) under the Ministry of Health & Family Welfare

3 Central Drugs Standard Control Organisation (CDSCO) under Directorate General of Health Services, Ministry of Health & Family Welfare, Government of India

2. Implementation Plan

Effective and safe implementation of IV iron needs robust institutional mechanisms with defined roles and accountability within the public health system.

The implementation framework for IV iron roll out is placed at Figure 1. At the National level, the Nutrition Division of the Ministry of Health and Family Welfare will be the nodal division while at the States/UTs, it will be anchored within the Maternal Health/ AMB division.

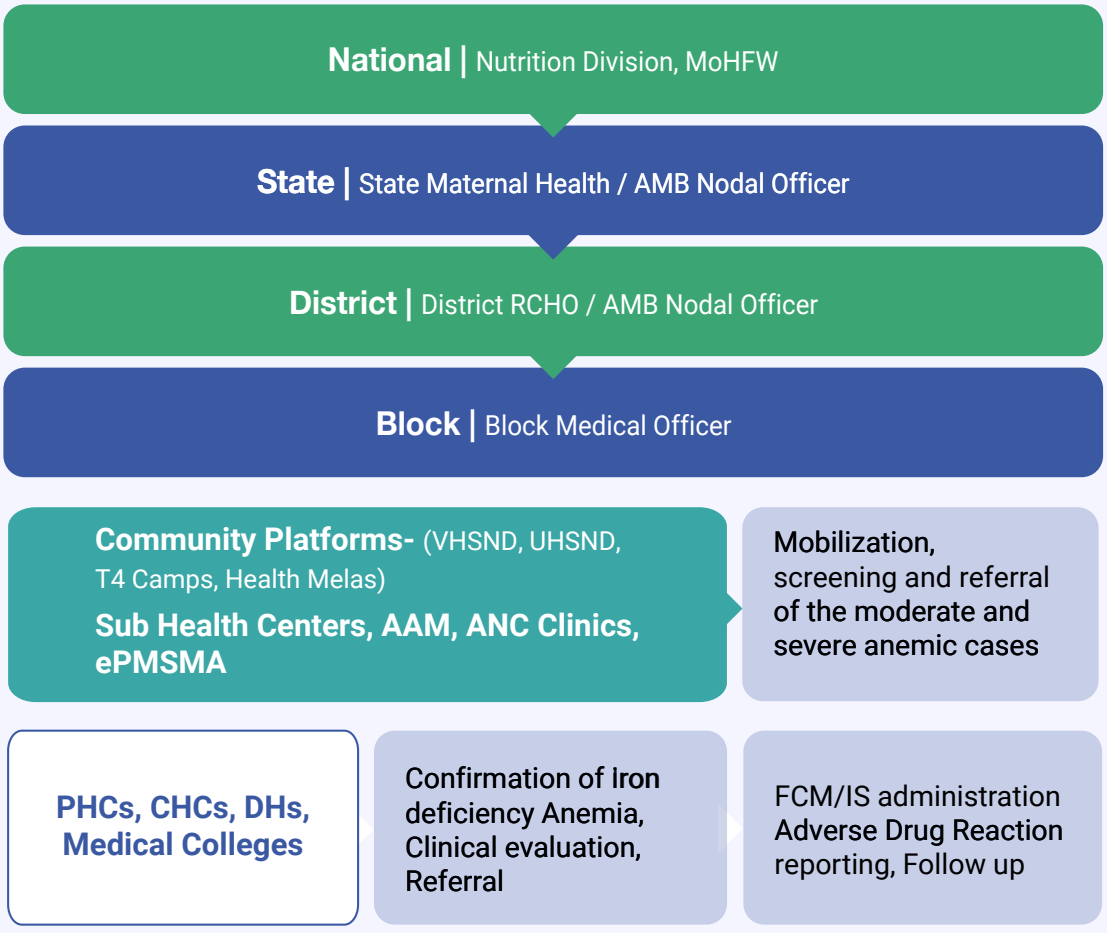

Figure 1: Implementation framework for IV iron roll out

States and UTs will utilise the existing framework of SUMAN to ensure effective implementation[4]. The SUMAN Committees at State and District levels will be responsible for the effective roll out and regular review of the IV iron interventions.

The State/UT should review the progress and suggest the corrective actions to strengthen the intervention in quarterly SUMAN meeting. Similarly, District SUMAN Committees should include the review of implementation and action points for resolving field level issues as agenda items during monthly meetings.

4. SUMAN (Surakshit Matritva Aashwasan) Standard Operational Guidelines
nhm.gov.in/New_Updates_2018/NHM_Components/RMNCHA/MH/Guidelines/SUMAN Guideline 2020 Web Version.pdf

Designated Maternal Health/AMB nodal officers at State and District level will be responsible for the overall review and capacity building of the staff at their respective levels. They will also provide recommendations and suggestions for improving the implementation.

Table 3 summarises the roles and responsibilities of nodal officers and health care workers in roll out of IV iron intervention.

IV iron administration should take place at a Community Health Centers (CHC), First Referral Units (FRU), District Hospitals (DH), Medical Colleges, and Primary Health Centers equipped with trained MBBS Medical Officer, emergency kits and functional referral transport.

To ensure the safe administration of IV iron, it is essential to record detailed patient information including clinical and personal history and to monitor vital signs every 30 minutes, till 2 hours post infusion, reporting of adverse events as per the formats provided in **Annexures (I-VI)**. Post training follow-up and mentoring visits should be conducted to ensure the adoption and maintenance of standardized practices.

Table 3: Roles and responsibilities of various stakeholders for IV iron implementation

Nutrition Division, Ministry of Health and Family Welfare

- Nodal division for policy and strategy formulation
- Technical support to States/UTs in roll out of IV iron, monitoring, procurement and IEC/BCC material development
- Resource allocation and monitoring the expenditures
- Programme review and supportive supervision

State Nodal Officer

- Ensure the effective roll out of IV iron across the State/UT
- Capacity building of health care workers
- Supportive supervision of IV iron roll out
- Timely procurement and strengthening of supply chain
- Ensure the roll out of IEC/BCC strategies
- Monitor and review the Adverse Drug Reaction cases
- Ensure the convergence with line departments
- Regular programme review during State Committee meeting

District Nodal Officer

- Effective roll out of IV iron at public health facilities
- Ensure the capacity building of health care workers
- Ensure the availability of IEC/BCC materials at community and facility level
- Supportive supervision of the implementation at community and facility level
- Supply chain management to ensure the adequate supplies at health facilities
- Regular programme review during District Committee meeting
- Monitoring, investigating and reporting Adverse Drug reaction cases

Block Medical Officer

- Effective roll out of the IV iron at public health facilities
- Reporting and supportive supervision at block level
- Ensure the availability of adequate IV iron supplies at public health facilities
- Monitoring, investigating and reporting and the Adverse Drug reaction cases

Medical Officer

- Ensure facility preparedness for IV iron administration and adverse effect management.
- Clinical assessment of severe/moderate anemic pregnant women or lactating mothers for IV iron administration
- Ensure the correct dose calculation for IV iron administration
- Supervise patients receiving IV iron
- Ensure the timely management of adverse drug reaction/complication
- Ensure the referral and follow up of the patients having severe adverse reactions/complications
- Review the updates of eligible beneficiaries during monthly or sector meetings
- Ensure records and registers are maintained, and monthly reports are submitted

Staff Nurse

- Ensure the availability of drugs and consumables for IV iron administration
- Ensure the availability of drugs and consumables for managing severe adverse drug reactions
- Maintain records and documentation for IV iron administration

ANM

- Identify and create a list of pregnant women suitable for intravenous iron treatment
- Refer the women with moderate or severe anemia due to iron deficiency for IV iron

ASHA

- Sensitize and mobilize identified anemic mothers to Primary Health Centres or higher health facilities for injectable iron treatment
- Ensure the follow-up visit of the beneficiaries to the facility after one month

Service Delivery Algorithm for IV iron

Screening at VHSND / AAM /SC /Health facilities and Referral of eligible moderate and severe anemic PW/LM (Refer AMB Op. Guidelines 2018) to PHC /CHC / SDH / DH / MC for IV iron	Immediate hospitalization is recommended for severely anemic pregnant women in the third trimester of pregnancy or PW with hemoglobin <5 g/dl, irrespective of period of gestation
Evaluation by MO of referred Health Facility	IV iron is contraindicated in fever, known/suspected cases of Sickle Cell Anemia, Thalassemia. Extra vigilance for women with h/o previous allergies, Rheumatoid Arthritis, Systemic Lupus Erythematous and other inflammatory diseases. Any co existing medical disorder to be ruled out e.g. Cardiac illness.
Clinical Examination and Investigations [Investigations: Hb, Weight (Pre-pregnancy/1 st ANC weight), Temperature, Pulse, Respiratory Rate, Pedal Oedema, Fetal Heart Rate, Blood Pressure, SpO2] Counselling of PW/LW and family on benefits, complications of IV iron infusion Informed verbal consent of the beneficiary	To confirm the Iron deficiency, CBC (Complete Blood Count) and/or serum ferritin is recommended, if the testing facilities are available. Absence of the facilities for testing CBC/Serum ferritin should not be a limiting factor for IV iron administration
Calculation of required dose of IV iron using Ganzoni's formula. Preparation of IV iron solution using 100 ml of 0.9% Normal Saline	Iron Sucrose- Maximum dose should not exceed 200 mg in one session and 1000 mg in a period of 14 days. (5 doses of 200 mg each) FCM- Maximum dose should not exceed 1000 mg in single session and 1500 mg in one pregnancy period.
IV iron administration under MO/SN observation Iron Sucrose- Start with 20-30 drops/min for first 5 minutes, increase gradually 80-90 drops/minutes to complete over 20 to 25 minutes FCM- Start with 20-30 drops/minute for first 5 minutes, increase gradually to 100-120 drops/minutes to compete calculated dose over 15 minutes.	Ensure the availability of fully equipped Emergency Kit stocked with Adrenaline and Hydrocortisone at the bedside before IV infusion. Stop IV iron infusion immediately in case of perivenous leakage Ensure the availability of trained Staff for the analphylaxis management
Post-infusion management Ensure client's safety following IV iron administration	Flush the infusion line with 10 ml of 0.9% NS at the same rate to clear any residual medication and maintain infusion line patency. Observe for every 30 minutes till 2 hours post infusion for post-IV iron adverse events, infusion and anaphylactic reactions for prompt management

Documentation of administered dose, date and formulation of IV iron for accurate records and tracking of progress

Discharge advice

- Advise to seek medical attention promptly in case of any reactions such as nausea, vomiting, dizziness, fever, myalgia or injection site reactions.
- Advice serum phosphate testing in case of persistent weakness, fatigue, myalgia, bone pain 1 week following FCM administration**
- Maintain a balanced diet, rich in iron-containing foods.
- If needed, schedule visits for the next IV iron administration.
- Schedule a follow-up visit 4 weeks after completing IV iron dose

Follow up

Four weeks after first dose of IV iron

Examine for persistent weakness, fatigue, myalgia, bone pain 1 week following of FCM administration**

Refer pregnant woman nearing expected date of delivery (EDD) to treating physician/specialist for further clinical evaluation.

If improved

continue with the prophylactic/therapeutic oral IFA doses.

If no improvement

in Hb level by > 1g/dl after 4 weeks, refer refractory and unresponsive cases to higher centers.

Refer the refractory and unresponsive cases to treating Physician/Specialist for further investigation and management

IV iron should only be administered in a health facility* setting

*Public Health Facilities at level of PHCs and above

SCAN ABOVE QR CODE TO GET THE SERVICE DELIVERY ALGORITHM FOR IV IRON

3. Adverse Events

An Adverse Event (AE) is any undesirable experience associated with the use of IV iron in a beneficiary. Although administration of IV iron is safe, adverse events may be experienced in some cases.

Adverse events may occur due to the drug, or due to the process of administration. They may also occur coincidentally around the time of iron infusion but are unrelated to it and are hence known as coincidental adverse events. Identifying, prompt management, and reporting of AEs is crucial for taking appropriate actions to address safety concerns. Table 4 summarizes common adverse events and their management.

Table 4 : Management of Common adverse events associated with IV iron

MILD ADVERSE EVENTS	
Signs and Symptoms	**Management**
• Transient facial flushing • Pruritus, urticaria, rashes • Headache • Nausea/diarrhoea • Myalgia/arthralgia/ lumbar pain • Slight chest tightness • Metallic taste	1. Stop iron infusion for 15 min and observe 2. Check vital signs (BP, pulse, respiratory rate, SpO2) 3. Immediately alert supervising provider 4. Watch for symptom progression or resolution 5. Treat symptomatically 6. Consider oxygen for hypoxia 7. If unstable or symptoms worsen in 5-10 minutes, treat as a moderate-to severe reaction 8. If the patient remains stable after 15 minutes of total observation, consider completing iron infusion at 50% of the previous rate 9. Observe for 2 hours after infusion and document reaction

MODERATE ADVERSE EVENTS

Signs and Symptoms	Management
• Transient cough • Shortness of breath • Hypotension (a drop of SBP of ≥ 30 mmHg from baseline or SBP ≤ 90 mmHg) • Tachycardia (HR >100/min) • Infusion site reaction, extravasation • Hypophosphatemia[5]	1. Stop iron infusion 2. Check vital signs (BP, pulse, respiration rate, O2 saturation), immediately alert supervising provider 3. Watch for symptom progression or resolution 4. Consider oxygen for hypoxia 5. If required, IV fluid may be given, after assessing for hypovolemia 6. Consider IV corticosteroid (eg, hydrocortisone) 7. If unstable or symptoms worsen, treat as a severe reaction 8. Do not rechallenge or resume current iron infusion 9. Observe for ≥1-4 hours after infusion attempt and document reaction

SEVERE ADVERSE EVENTS

Signs and Symptoms	Management
• Anaphylaxis • Wheezing, Bronchospasm • Stridor • Periorbital edema • Arrhythmia • Cardiovascular collapse • Seizures • Unconscious or nonresponsive • Respiratory arrest	1. Stop iron infusion immediately 2. Initiate immediate rapid response 3. Vasopressor- Inj. Epinephrine IM (1:1000); Give 0.5 mg if there is no need of resuscitation; Repeat the dose for one time if needed; Give 1mg in 10 ml 0.9% NaCl, if resuscitation needed 4. Corticosteroids (Inj. Hydrocortisone 200 mg IV) 5. Administer antihistamines (Inj. Pheniramine Maleate 2 ml, IV/IM) 6. 100% High Flow Oxygen through mask or reservoir bag 7. If unstable or symptoms worsen, transfer to intensive care unit 8. Do not rechallenge or resume current iron infusion 9. Observe for 4-24 hours after infusion attempt

Refer to Annexure VI for the drugs used in management of reaction with IV iron infusion

5. Hypophosphatemia is rare and asymptomatic manifestation

Reporting and Investigation of Adverse Events:

Robust governance mechanism needs to be established to manage, report and investigate AEs related to IV iron administration. Adverse events will be reported by the treating physician to Block nodal officers and District nodal officers of Maternal Health within 24 hours of occurrence for further actions. AEs should be reported in the prescribed format as given in Annexure V.

All reported severe AEs (SAEs) will be investigated by the District Nodal Officer for Maternal Health within 7 days of reporting. They will discuss the investigated SAEs in detail in the monthly District SUMAN Committee meeting for preventive action to avoid AEs in future.

4. Special Considerations

4.1 Overdose

Administering IV iron over and above the required amount to correct iron deficiency can result in iron accumulation within storage sites. If facilities are available, monitoring iron parameters such as serum ferritin and transferrin saturation can aid in identifying iron buildup. Clinicians should be vigilant to prevent iron overdose by calculating required IV iron dose using Ganzoni Formula (Annexure III), thorough clinical evaluation and testing Serum Ferritin, if facilities are available.

Regular monitoring and appropriate management are essential to ensure patient safety during IV iron therapy.

Clinicians should also be vigilant to avoid using mixed drug dosage schedules and should avoid using Iron Sucrose and FCM as alternate/ subsequent infusions. A single formulation should be used for the entire treatment dosage for each patient.

4.2 Hemoglobinopathies

Pregnant women and lactating mothers should be investigated for Sickle Cell Disease, Thalassemia and other hemolytic anemias during Antenatal Checkup (ANC) and Postnatal Checkup (PNC) visits, respectively. IV iron is contraindicated in these conditions to avoid potential complications due to iron overload.

Before proceeding for the IV iron administration, thorough clinical history and relevant blood tests must be conducted to rule out the hemoglobinopathies. Any known and suspected case of these conditions should be referred to higher centers for further clinical evaluation and management.

4.3 Hypophosphatemia

Hypophosphatemia, a condition with reduced serum phosphate level, may occur as treatment emergent side effects of FCM administration. It is typically mild, transient, and subclinical, seen in about 40-60% of cases. However, severe persistent hypophosphatemia (<2 mg/dL serum phoshphate) is rare with single dose FCM.

Only repeated FCM transfusion may lead to severe persistent hypophosphatemia. The lowest serum phosphate levels occur around 2 weeks after FCM transfusion and usually return to baseline within 12 weeks.

Mild and moderate hypophosphatemia is a asymptomatic and self limiting condition. In severe hypophosphatemia, symptoms such as fatigue, proximal muscle weakness, mylagia and bone pain are usually seen. Patient should be advised to seek prompt medical attention in case of persistent clinical signs and symptoms following FCM infusion.

During follow up visits, treating physician should clinically evaluate the patients for symptoms of hypophosphatemia and suspected patients should be referred to higher centers for the serum phosphate level assessment and further management.

5. Capacity Building

The objective of capacity building is to empower healthcare providers at all service delivery points to effectively screen, diagnose, and manage iron deficiency anemia in pregnancy and post partum period.

IV iron therapy is crucial for managing moderate to severe anemia, making it essential to have a thorough understanding of its administration, indications, contraindications, and potential adverse effects.

States/UTs should plan for capacity building of all healthcare providers as well as programme managers. Training will be done for two cadres: (a) medical officers/staff nurses and (b) nodal officers/ programme managers from health, WCD, and related line departments, at all levels in the State.

One day training programme should be planned to inform medical officers and staff nurses on the technical aspects of IV iron administration along with the sensitization on AMB strategy. Programme managers and nodal officers will be specifically oriented on programme implementation, with focus on supply chain management of IV iron, IEC/ BCC activities, monitoring, linkages between line departments, review and reporting mechanisms for 'Anemia Mukt Bharat'.

A detailed plan will be developed by the State, outlining specifics such as training dates, batch divisions, names of facilities included in each batch and the agenda. Resource materials developed by the National Team or modified/ translated in regional/local languages should be utilized for training and advocacy purposes across different platforms.

6. Monitoring and Evaluation

Monitoring and Evaluation (M&E) of IV iron intervention is essential to ensure its efficacy and safety in managing iron-deficiency anemia. Effective M&E processes involve regularly tracking patient outcomes such as hemoglobin levels and overall health status, to assess the therapeutic impact of the treatment.

Additionally, M&E helps to evaluate adherence to treatment protocols and guidelines, ensuring that patients receive the appropriate care tailored to their specific needs. Collecting and analyzing data through M&E contributes to evidence-based practices, helping to refine and optimize treatment regimens over time.

Robust M&E frameworks should be set up at State, District and Block level to support the continuous improvement of healthcare services, enhance coverage, and ensure the effective treatment of iron deficiency to improve the maternal and neonatal health outcomes.

The coverage of IV iron among pregnant women and lactating mothers should be monitored at the State/UT and District levels against the targeted number of beneficiaries and reported on a quarterly basis to the National level. Regular review meetings at State and District levels, field visits to monitor the IV iron implementation and regular analysis of programmatic data should be done to ensure the positive outcomes of IV iron intervention.

7. Monthly Reporting Format

Appropriate documentation of patient information with name, age, gestation period, ABHA ID, medical record/registration number, date and time of administration, hemoglobin level, dose and formulation of Iron administered, relevant medical history, concomitant medications, allergies, or other factors is to be done.

In case of any adverse events, describe the events in detail and include any medications administered, dosage, and route of administration as per the format.

A. Patient Information

Name:	
Age:	Weight (Kg):
ABHA ID:	
Address:	
Referred from:	
LMP/Gestational Age:	Pre-pregnancy weight (in Kg)
Fetal Heart Rate	Pedal Oedema (Y/N)
H/o Following conditions (put a Tick (✓) mark): If any of following conditions is present, DO NOT GIVE injectable Iron and refer patient to higher centers/ specialist for further investigation and treatment.	
1. Known case of thalassemia disease, sickle cell disease or hemolytic anemia.	
2. Family H/o hemoglobinopathies	
3. Jaundice or Cirrhosis	
4. Anemia other than Iron Deficiency	
5. Hypersensitivity to injectable Iron formulations	
6. Acute Cardiac Failure	
7. Serum ferritin >150 µg/L (Please mention NA if facilities are not available)	
Whether informed consent taken from the patient/husband/caretaker for IV iron administration (Y/N)	

B. Vitals to be monitored before, during and after IV iron infusion:

Vitals Monitoring	Temperature	Blood Pressure	Pulse Rate	Respiration Rate	SpO2	FHR	ADR, if any
Before IV infusion							
During IV infusion							
Post Infusion							
After 1/2 hr							
After 1hr							
After 1 1/2 hr							
After 2 hr							
At discharge							

A. Record format for IV FCM

S. No. :	Name of Beneficiary	ABHA ID	Phone number	Weight (Kg)	Gestational age (Mention 'NA' for Lactating mothers)	Hb (g/dL) (Before administration)	Required dose of FCM (mg)	Dose of FCM given (mg)	Date of administration of doses					Hb (g/dl) after 1 month of completion of dose/s (Please mention date of testing)	Complications if any
									I	II	III	IV	V		
1															
2															
3															
4															
5															
6															
7															
8															
9															
10															

B. Record format for IV Iron Sucrose

S. No. :	Name, Address and Phone number of Beneficiary	ABHA ID	Phone number	Weight (Kg)	Gestational age (Mention 'NA' for Lactating mothers)	Hb (g/dL) (Before administration)	Required dose of Iron Sucrose	Date of administration of IS doses					Hb (g/dl) after 1 month of completion of doses (Please mention date of testing)	Complications if any
								I	II	III	IV	V		
1														
2														
3														
4														
5														
6														
7														
8														
9														
10														

Dosage Calculation for IV iron (IS and FCM)

IV iron doses required to replenish the patient's total body iron deficit can be calculated by using Ganzoni formula as given below.

Where,

Total iron deficit (mg)

$$2.4 \times \text{Body weight}^{a}\ (\text{kg}) \times (\text{Target Hb in g/dL}^{b} - \text{Actual Hb in g/dL}) + 500^{c}$$

a: Pre-pregnancy weight in kg. If pre-pregnancy weight is not available, weight recorded during the first visit of first trimester to be used.

b: Target Hb for pregnant women = 11.0 gm/dL.

c: The allowance for reserve iron is 500 mg in pregnant women weighing > 35 kg.

If the pregnant women's weight is <35 kg, allowance for iron store is 15 mg/kg body weight

Preparation of IV iron solution

Process	Iron Sucrose	FCM
1.Vial Selection	Choose the appropriate vial size based on the required dose	
	Iron Sucrose is available in a 5 ml packaging, contains 100 mg of elemental Iron vial (20 mg/ ml)	Inj. FCM is available in 50 mg iron/ml concentration with the preparation of 500 mg (10 ml vial); 750 mg (15 ml vial); 1000 mg (20 ml vial) and 100 mg in 2 ml ampules
2.Visual Inspection	Before use, visually inspect the vials for any sediment or damage, ensuring the solution is homogeneous and free of particles	
3. Dilution	Withdraw the required amount of IV iron from the vial based on the calculated dose	
	The maximum dose of iron in the form of Iron Sucrose to be administered in one session is 200 mg. Mix the Iron Sucrose with 100 ml of 0.9% Normal Saline Solution for IV administration. *The maximum dose of Iron Sucrose should not exceed 600 mg (3 doses of 200 mg each) in a week and 1000 mg in one pregnancy period.*	The maximum single dose to be administered in one session should not exceed 1000 mg of iron. Mix the FCM with 100 ml of 0.9% Normal Saline Solution for IV administration. *The maximum dose of FCM should not exceed 1500 mg in one pregnancy period.*

Single-Use Principle: Each vial is intended for single use only. Discard any unused product and do not reuse vials.

Compatibility and dilution solution: Ensure IV iron is only mixed with sterile 0.9% Normal Saline solution for dilution. Avoid using other intravenous dilution solutions or therapeutic agents to prevent potential interactions or precipitation.

Immediate Use: Use the prepared IV iron solution immediately after dilution with sterile 0.9% sodium chloride solution to minimize the risk of contamination and maintain its integrity.

IV iron Adverse Drug Reaction Reporting Form

A. Health Facility Information

Name and address of the facility	
District:	State:
Name of Healthcare provider reporting AE:	
Date of adverse event:	

B. Patient Information

Name	Age
ABHA ID	
Hospital Registration ID	
Gestational Age (in weeks)	Weight (in Kg)
Hb level (pre-infusion)	Date of Hb test
Relevant medical history including known allergy/drug reactions	
Referred from: (Self/Name of the referral facility)	

C. Indication of IV iron

D. Details of IV Infusion

Type of IV iron administered	Iron Sucrose / FCM
Date and time of Admission for IV infusion	
Date and time of Infusion	
Date and time of adverse events observed	
Details of dosages given	

E. Details of drug

Name and brand or generic name	Iron Sucrose / FCM
Manufacturer (if Known)	
Batch no/Lot no	
Date of Expiry	
Visual inspection of vial - (Intact/ turbidity/ fungal growth/ sedimentation) Preserve the vial if any visual contamination observed	

F. Monitoring and Assessment

Vital signs (before, during and after infusion)

Vitals	Before	During	After
Blood Pressure (SBP/DBP)			
Pulse Rate			
Respiratory rate			
SpO_2			
Fetal Heart Rate			

G. Details of Adverse Event

Signs/ Symptoms	
Severity of event – Death/ life threatening/ hospitalisation/ disability /others	
Describe the events in brief (Timing of symptoms onset and course of progression)	

H. Management of Adverse Drug Reactions (Tick the applicable options):

Drug withdrawn	
Dose reduced	
Dose not changed	
Interventions done	
Time and date of patient response	
Time and date of resolution of symptoms	
Client condition at the time of discharge from facility: Fatal/continuing severe illness/ recovering/ recovered/ unknown/ others	
If the patient is referred, then name of referred facility and timing of referral	
In case of death, mention the date and time of death	
Cause of death	

I. Cause of AE (Please tick the options)

Wrong drug to wrong client	
Wrong dose	
Wrong route	
Wrong rate of administration	
Others	
Not a medication error	

J. Overall comments/observations

Drugs used in the management of infusion reactions with IV iron administration

Adverse Events/Complications	Drugs and dosages to be used
Extravasation	Local application of Hydrocortisone cream
Infusion reaction Complement Activated Related Pseudo-Allergy (CARPA)	a. Mild reaction- Specific treatment not required b. Moderate reaction • Ondansetron, 4-8 mg PO, Once • Loratadine, 10 mg PO, Once • Cetirizine, 10 mg PO, Once • Injection hydrocortisone 200 mg IV, Once c. Severe reaction Inj. Epinephrine (1:1000), 0.5 mg IM (If required, repeat for 1 time)
Anaphylactic reaction	Injection Epinephrine (1:1000) • If no need of resuscitation: 0.5 mg IM (If required, repeat for one time) • If in need of resuscitation: 1.0 mg Ephinephrine in 10 ml of 0.9% NaCl Oxygen; 100% high flow oxygen through mask or reservoir bag Injection Hydrocortisone, 200 mg I.V, Once Injection Pheniramine Maleate, 2 mL I.V/IM Once

General note:

A 30-minute post-infusion monitoring of all patients who are administered IV iron should be done.

Vital signs such as blood pressure, heart rate, respiratory rate, and temperature, to be monitored again at the end of the infusion process

Technical specifications: Ferric Carboxymaltose injection

Ferric Carboxymaltose injection is a terminally sterilized colloidal solution of Ferric Carboxymaltose in water for injection. It contains elemental iron in a stable ferric state (Fe+3) as a complex with a carbohydrate polymer that releases iron to bind with the serum transferrin and serum ferritin. Inj. Ferric Carboxymaltose is equivalent to elemental iron Fe+3, not less than 95.0 per cent and not more than 105.0 per cent of the stated amount of Iron, Fe+3. Technical specifications (under consideration of inclusion in IP 2026) are given below:

Parameters	Specifications
Active Ingredient	Ferric carboxymaltose
Category	Haematinic
Dosage Form	Solution
Route	Intravenous
Usual strength	50 mg iron per mL
pH	5.0 to 7.0.
Description/Colour	A brown to dark brown colour non-transparent solution
Weight per mL (Density)	1.05 gram/mL - 1.15 gram/mL, at 25°.
Chloride content	Not less than 0.45% w/w and not more than 0.55% w/w
Dextrin content	5.5 to 8.5% w/w
Limit of Iron (Fe++)	Not more than 0.4% w/w.
Molecular weight	Weight average molecular weight (Mw)- 130000 to 200000 Da Number average molecular weight (Mn)- Not less than 70000 Da Polydispersity index (Mw/Mn)- not more than 1.5.
Osmolality	270 to 390 mOsmol/ kg
Particulate contamination	Particle of more than or equal to 10 µm size should not be more than 3000 particles per vial and particles of more than or equal to 25 µm size should not be more than 300 particles per vial.
Zeta Potential	Positive
Colloidal particle size (Z-Average) nm and not more than 30 nm.	Not less than 20 nm and not more than 30 nm.
Sodium content	Not more than 0.55% w/w.
Sterility	Complies with the test for sterility as given in section 2.2.11 of Indian Pharmacopeia
Bacterial endotoxins	Not more than 0.33 Endotoxins Unit per mg of iron.
Uniformity of dosage unit	Complies with the test for uniformity of dosage unit as given in section 2.5.4.(I) of Indian Pharmacopeia
Storage	• Store protected from light, at a temperature not exceeding 30°. • Do not refrigerate. • Store in the original package.
Labelling	The label states the quantity of ferric carboxymaltose in terms of the equivalent amount of elemental Iron.

Technical specifications: Iron Sucrose injection

Iron Sucrose Injection is a sterile, colloidal solution of ferric hydroxide in complex with sucrose in Water for Injection. It contains not less than 95.0% and not more than 105.0% of the labelled amount of iron.

Technical specifications for the Iron Sucrose injection, as per US Pharmacopoeia, are given below:

Parameters	Specifications
Active Ingredient	Iron Sucrose
Category	Haematinic
Dosage Form	Solution
Route	Intravenous
Iron content	95.0%–105.0%
Sucrose content	260–340 mg/mL
pH	10.5–11.1 at 20°C
Chloride content	0.012%–0.025%
Limit of Iron (Fe++)	Not more than 0.4%
Molecular weight	• Weight average molecular weight (Mw): 34,000 to 60,000 Da • Number average molecular weight (Mn): Not less than 24,000 Da • Polydispersity index (Mw/Mn): Not more than 1.7
Osmolality	1150–1350 mOsmol/L (1 in 10 dilution)
Turbidity	4.4–5.3
Alkalinity	0.5–0.8 mL of 0.1 N HCl per mL Injection
Specific Gravity	1.135-1165 at 20°
Particulate contamination	Meets small-volume injection requirements
Bacterial endotoxins	Not more than 3.7 USP EU/mg iron
Storage	• Single-dose containers, preferably Type I glass • Store at controlled room temperature • Do not freeze
Labelling	• For IV use only • Must be diluted with 0.9% Sodium Chloride to 1.0–2.0 mg/mL iron

ANNEXURE IX

Checklist for ensuring efficacy and maintaining safety profile/quality criteria for IV Iron procurement:

1. Market standing Certificate of 3 years
2. Master drug list
3. Declaration/ Undertaking by Manufacturers/Suppliers-
    - No Case pending in Court- Spurious or adulterated quality
    - No complaint of product "not of standard quality" during last 2 years
    - Commitment of quality (GSTIN[1]- Name of the state where registered/ Monthly- Annual Producing Capacity / Item Code - Name of drugs/ Estimated bid quantity)
    - Must supply minimum 10% of bid quantity on monthly basis & entire bid quantity within the contract period as per purchase order
    - Blacklisted / banned/debarred by Bid Inviting Authority, Government of India / States
    - No conviction (Firm/Company & its proprietor/Partners/Directors/Power of Attorney holders) under Cosmetic Act 1940
    - Permission by State Licencing Authority for manufacturing of quoted product.
    - Experience in manufacturing the product over 3 years or quoted imported product has over 3 years market standing.
    - Have required Human resource/Equipment/ financial resource/ Competence for timely supply
    - Licence from WHO-GMP[2] licencing authority
    - Deposited all VAT[3]/Sale Tax/ GST & filing returns
    - Supply as per designs in bid & as per instructions given in this regard.
    - Acceptance of Rate of Contract of Bid.
    - Penalty of 5 years if any information provided found false in any stage.
    - Manufacturer is not insolvent, in receivership, bankrupt or being wound up, not have affairs administered by a court or a judicial officer, not have business activities suspended and not the subject of legal proceedings for any of the foregoing reasons.

- None of Company/ or Its associates are convicted of Criminal offence related to professional conduct or making false statement or misrepresentation as to qualify to enter into procurement contract within a period of three years proceedings for any of the forgoing reasons or not have been otherwise disqualified pursuant to debarment proceedings.
- No Conflict of Interest as specified in Act, Rules & bidding document.
- Quoted rates of any item not more than the price fixed by Government under current Drugs (Price Control) Order.
- Average Annual turnover Certificate
- Company Details in full
- Verification of all the above.

4. Award notification along with Agreement with terms & conditions:

- Penalty- Delay in supply, Sub-standard product
- Payment- E-payment with Invoice/GST, Payment Schedule
- Same Manufacture- no subcontract
- NABL Certificate of the manufacturing facility
- Goods supplied are integrated in DVDMS (Drugs and Vaccine Distribution Management System)
- Packaging/ Shelf life- Tamper-proof, handle all-weather conditions. Supply of drugs to have at least 70% shelf life from date of manufacture.
- Bar Code of product as per Government of India guidelines
- Quality analysis of the product
- CoA (certificate of analysis) for the drug from a NABL[4] accredited Lab/ Govt lab or Govt approved lab at the time of delivery of consignment.
- Will bear 0.5 % cost for secondary test/verification.

1 GSTIN- Goods and Services Tax Identification Number

2 WHO-GMP- World Health Organization's Good Manufacturing Practices

3 VAT- Value Added Tax

4 NABL-National Accreditation Board for Testing and Calibration Laboratories

Nutrition Division,
Ministry of Health & Family Welfare
Government of India
Nirman Bhavan, New Delhi