Available online on 15 Sep, 2026 at https://ijdra.com/index.php/journal
International Journal of Drug Regulatory Affairs
Published by Diva Enterprises Pvt. Ltd., New Delhi
Associated with Delhi Pharmaceutical Sciences & Research University

Review Article Open Access

Regulatory Approval of Ferric Carboxy Maltose Injection 50mg/ml: A Comparison Across South Africa, Singapore and Saudi Arabia

Nikunj Sureliya[a], Maitreyi Zaveri, [a] Zuki Patel, [a] Vinit Movaliya, [a] Niranjan Kanaki [a,*] Nirav Patel [b]

[a] *Department of Drug Regulatory Affairs, Student of Regulatory Affairs, K.B Institute of Pharmaceutical Education and Research, a constituent college of Kadi Sarva Vishwavidyalaya, Gandhinagar Gujarat 382023, India*

[b]*Step up Pharmatech Regulatory Consultant Naranpura Ahmedabad Gujarat India 380013.*

Abstract

The regulatory approval Procedure for iron formulation, like Ferric Carboxy Maltose injection 50mg/ml , differs among international health authorities because to variation in evaluation schedules, dossier requirements, and reliance mechanisms The registration process and legal frameworks controlling the approval of ferric carboxy maltose in South Africa, Singapore and Saudi Arabia are compared in this paper The Common Technical Document Format used in South Africa by the South Africa Regulatory Authority If the product approved by strict regulatory bodies, it may use a reliance approach through an abridge or verified review for items registered by reference agencies , Singapore's through an abridged or verified review for items by reference agencies Singapore's Health Sciences Authority (HSA) allows submission thorough verification or abridged evaluation Route, allowing the faster access. Saudi Regulatory Authority permit dependence FDA or EMA approvals via the Shortened registration procedure and adheres to GCC-CTD Framework the Comparative analysis emphazies regional variation in data expectations, stability circumstances, and labelling requirements while highlighting the growing global harmonisation through dependency models. Improving regulatory convergence and reliance frameworks can improve the patient access to high-quality injectable iron supplements and maximize review efficiency.

Conclusion: South African Regulatory Authority, Health Science Authority and Saudi Food Drug Regulatory Authority show differences in Timelines, dossier formats, and local Requirements for Ferric Carboxy Maltose Injection approval. However, all three are used Reliance Pathways based on approval of reference agencies Despite Regional variation this sifts supports global harmonization Strengthening Reliance Models can improve efficiency and faster patient access.

Keywords: Ferric Carboxy Maltose Injection; Regulatory Approval; Drug Registration; Comparative Regulatory Analysis

Article Info: Received 20 Mar 2026; Review Completed 06 Jun 2026; Accepted 02 Aug 2026

Cite this article as:
Sureliya N, Zaveri M, Patel Z, Movaliya V, Kanaki N, Patel N. Regulatory Approval of Ferric Carboxy Maltose Injection 50mg/ml: A Comparison Across South Africa, Singapore and Saudi Arabia. Int. J. Drug Reg. Affairs [Internet]. 2026 Sep 15 [cited 2026 Sep 15]; 14(3):27-32. Available from: http://ijdra.com/index.php/journal/article/view/882

DOI: https://doi.org/10.22270/ijdra.v14i3.882
*Corresponding author. E-mail address: niranjan.kanaki@kbiper.ac.in (N. Kanaki)

1. Introduction

An Intravenous iron formulation called Ferric Carboxymaltose injection (50mg/ml) is frequently used to treat iron insufficiency when oral therapy is not work because of its complicated composition and parental administration, the medication must pass a stringent regulatory review process to Guarantee safety, efficy, and quality before approved. In spite of global harmonization efforts, regional differences in injectable product regulations The Regulatory approval procedure for Ferric Carboxymaltose injection in south Africa, Singapore and Saudi Arabia are compared in this article, emphazing significant variation in submission specifications, assement, methods, and approval paths to facilate successful international Registration Campaigns. (1)

2. Overview of Iron Deficiency anaemia

Anaemia caused by iron deficiency is a prevalent condition. When there are not Sufficient healthy Red Blood Cells in the blood, is called anaemia. The body's tissues receive oxygen from red blood (2) Lack of iron, frequently brought on by pregnancy or blood loss, results in iron deficiency anaemia. Iron supplements and consumption of foods high in iron are used to treat. (3)

2.1 Causes of Iron Deficiency Anaemia

Diets low in iron: Our diet contains foods that provide iron, but for every 10 to 20 mg of iron consumed, only 1 mg is absorbed. A person may have iron-deficiency anaemia to some extent if they are unable to consume a balanced diet high in iron.

GI Track abnormalities: Following some types of gastrointestinal procedures, iron malabsorption is frequent. The upper small intestine absorbs the majority of

the iron that is consumed through food. Iron-deficiency anaemia could be caused by any anomalies in the gastrointestinal (GI) tract that change the way iron is absorbed. Additionally, iron absorption will be reduced by surgery or drugs that inhibit the creation of stomach acid.

Blood loss: Iron-deficiency anaemia can arise from a reduction in iron due to blood loss. Menstrual bleeding, gastrointestinal bleeding, and injuries are possible causes of blood. (4)

2.2 Symptoms of iron Deficiency Anaemia

- Weakness
- Mood and cognitive changes
- Headache
- Dizziness
- Pica
- Heart palpitation
- Breathlessness
- Feeling Cold (5)

2.3 Treatment of iron Deficiency Anaemia

Ferric Hydroxide core supported by a Carbohydrate shell makes up the innovative dextran-free intravenous iron formulation known as ferric carboxymaltose (FCM). It works well to treat iron deficiency anaemia (IDA) because it permits controlled iron release to the reticuloendothelial system and iron-binding proteins. High doses (up to 1500 mg in two 750 mg doses spaced one week apart) can be administered quickly with FCM, either as a gradual IV push or as a 15-minute infusion. A test dose is not necessary, although hypersensitive reactions must be watched for. According to clinical research, FCM has a good safety record and is not inferior to oral and other IV iron regimens. In certain situations, it is even better. (6)

3. Global Market of Ferric Carboxy Maltose Injection 50mg/ml

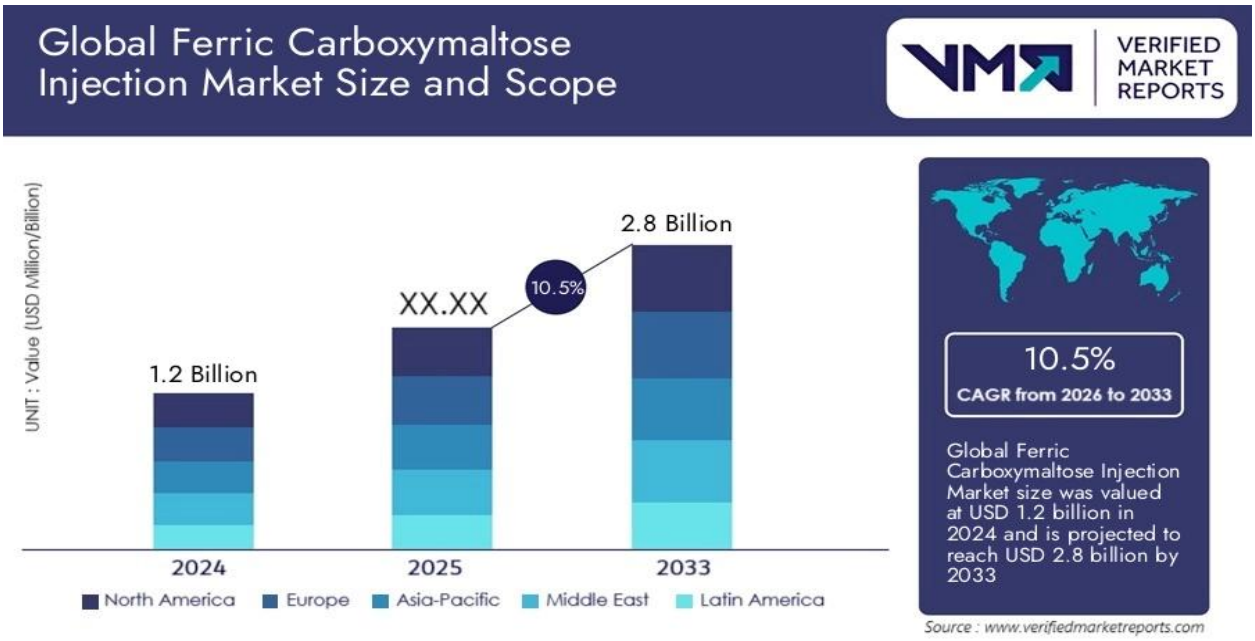

Figure 1. Global Ferric Carboxy Maltose Injection Market Size (1)

4. Comprehensive Drug Profile of Ferric Carboxy Maltose Injection 50mg/ml Injection

It is a medication that replaces iron. It is used to treat iron-deficiency anaemia, a form of anaemia in which your body produces fewer red blood cells as a result of low iron levels. The production of red blood cells, which transport oxygen throughout the body, requires. (7)

Table 1. Physicochemical Properties of the Ferric Carboxy Maltose Injection

Sr no	General Drug Characteristics	Description
1	Brand Name	Ferinject
2	Generic Name	Ferric carboxy maltose Injection
3	Molecular weight	788.4g/mol
4	ATC Code	B03 (8)
5	Mechanism of action	A colloidal solution of the iron complex is ferric carboxymaltose, which can be injected or infused. The complex is designed to provide the body's ferritin and transferrin proteins with usable iron in a regulated way. Red cell utilization of 59Fe from radio-labelled ferric carboxymaltose ranged from 61% to 84% in individuals with renal anaemia and from 91% to 99% in those with iron deficiency (ID) twenty-four days after the dosage. (9)
6	Route of Administration	Intravenous

5. Regulatory Requirements for Ferric Carboxy Maltose injection 50mg/ml Registration as Per SAHPRA

In South Africa, medicine's registration is controlled by the Medicine & Related substance Act,1965(Act No.101 of 1965), its provisions and requirements, & rules and guidelines that are published under it. The information needed to register "medicines" and submit an application to modify a registered medicine is outlined in these guidelines. The provided data will be assessed in light of the Act's. (10)

The South African government established the National Department of Health, which houses the South Africa Regulatory Authority, to make sure that the health & welfare of both humans and animals are its top priorities.

To guarantee that medications, medical equipment, and IVDs fulfil the necessary requirements to safeguard South Africans' health and wellbeing, SAHPRA is built upon three pillars of safety, efficy and quality. The ethos of SAHPRA is defined by these three. (11)

5.1 Ferric Carboxy Maltose Injection 50mg/ml Falls under NDA Category in South Africa, Singapore and Saudi Arabia

- Ferric Carboxymaltose Injection 50 mg/mL, already Approved by European Medicine Agency & FDA, is considered a New Chemical Entity (NCE) in South Africa and Singapore as it has not been previously registered in these markets.
- Ferric Carboxy Maltose Injection 50Mg/ ml Application are Submitted Under Verified Route in SAHPRA. (12)
- Ferric Carboxy Maltose Injection 50mg/ml Application is Submitted in Singapore as NDA-1 Application. (13)
- For SFDA Application is Submitted under the Verification Registration Route.
- So, for Preclinical and clinical study that can only relies on the Reference Agency s Assessment Report of the USFDA So entire Preclinical and Clinical Study are Does not Required.

5.2 Preclinical and Clinical Requirements of Ferric Carboxy Maltose Injection 50mg/ml

Product is alredy approved by FDA and EMA

Instead of submitting the complete preclinical and clinical study reports, only the reference country's assemetment repoert is submiited to to the drug regulatory authorities of South africa, Singapore and Saudi Arabia. (14)

5.3 Application Process overview for Drug Registration

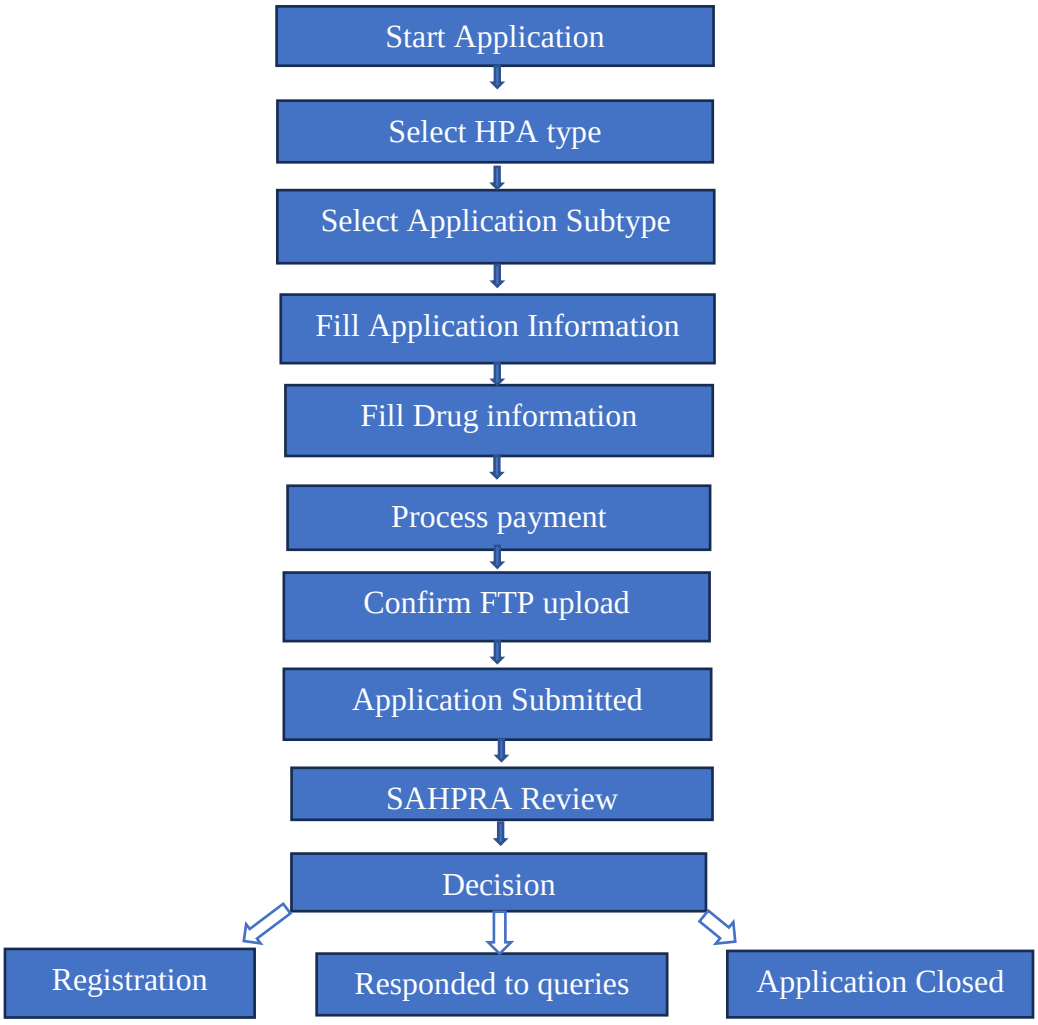

Figure 2. Drug Registration Process Flow Chart (15)

6. Registration Requirements of Ferric Carboxy Maltose Injection 50mg/ml as per HSA

Regulatory Authority: Health Science Authority

In Singapore, the Ministry of Health Oversees Health Sciences Authority (HSA), a government agency. In addition to managing the nation's blood supply, including blood bank and transfusion medicine standards, and providing expertise in fields like forensic medicine, forensic science, and analytical chemistry testing, the HSA's three main functions include serving as the national regulatory approval authority for all health. (16)

6.1 Registration Procedure of Ferric Carboxy Maltose Injection 50mg/ml as per HSA

To market a medicinal product in Singapore, a company must apply for product registration and receive marketing approval from the Singapore Authority

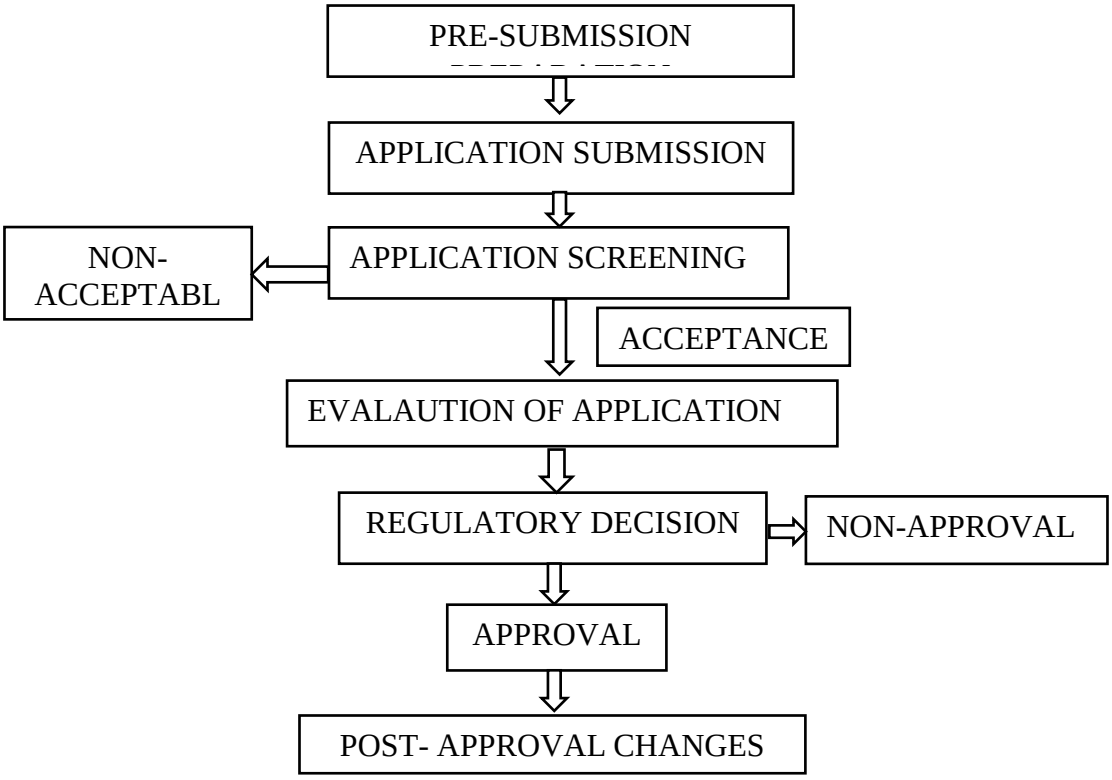

Figure 3. Registration Process overview (17)

7. Registration Requirement of Ferric Carboxy Maltose Injection 50mg/ml in Saudi Arabia

By assuring the food safety medication, medical equipment, cosmetics, pesticides, and animal feed in collaboration with the appropriate Saudi Drug Authority performs a crucial role in servicing Allah's guests, which include Hajj pilgrims and Umrah. (18)

The duties of the authority are extensive and range from reporting adverse events to registering drugs. It has an impact on pharmaceutical businesses all around the world since it is essential to the creation, approval, and tracking of novel treatments. Businesses wishing to do business in Saudi Arabia. (19)

7.1 Registration Requirement for Ferric Carboxy Maltose Injection 50mg/ml in Saudi Arabia

- The Registration Committee of Manufacturers of Pharmaceuticals and their Products approved the updated Registration rules of Pharmaceutical and Health Product Manufacturers and their Products at its meeting No. (1150), dated 9/11/1444 AH, in accordance with Article (20/4) of the Implementing Regulations of the Law of Pharmaceutical and Health Products, which required the registration committees to perform the update tasks.
- Ferric Carboxy Maltose Drug Registration Application Submitted Under Verification Route. (20)

7.2 Procedure for Online Submission

Step 1: online Submission

- The applicant must complete Application Form 2 via the Saudi Drug Registration System and make the required payment.
- File is Uploaded by applicant

Step 2: pre-designation meeting

- Meeting with Executive Director of Regulatory Department is required to verify the applications' eligibility and make sure it satisfies the following

requirements the Applicant Should submit meeting request to Designation. Drug@sfda.gov.sa after completing the checklist.

- Within five business days, the regulatory department will send the applicant email with the meeting's specifics.
- The RA team will thoroughly review the product file in accordance with checklist & guidelines during the meeting.
- For information on target processing timelines for Drug Sector procedures, consult Regulatory Framework for Drugs Approval. When the Drug Sector sends an email approving the desired pathway, the performance targets begin.

Step 3: Waiting for post-meeting decision:

- The Applicant will get SFDA's decision via Designation.Drug@sfda.gov.sa within 5 working days.
- If the product is not eligible, the application moves to regular pathway (Fess not refundable).

8. Comparative Table of NDA Registration Pathways in South Africa, Singapore and Saudi Arabia

Table 2. Comparative overview of NDA Registration Pathways of South Africa, Singapore & Saudi Arabia

Sr no	Parameter	South Africa (SAHPRA)	Singapore (HSA)	Saudi Arabia (SFDA)
1	Regulatory Authority	South African Health Products Regulatory Authority	Health Science Authority	Saudi Food & Drug Authority
2	Application Type	New Chemical Entity (NCE/NDA)	(NDA-1, NDA-2, NDA-3)	NDA; Verified; Abridged
3	Application Submission Route	Verified Route	NDA-2	Verified Route
3	Submission Format	eCTD	ACTD or eCTD	eCTD
4	Evaluation Pathways	Full Review, Abridge Review, Verification Review	Full Review, Abridge Review, Verification Review	Full Review, Abridge Review, Verification Review
5	Approval Timelines	Verification: 236 days Abridged: 303 days Full: 336–792 days	Verification: 60 days Abridged :120 days Full:180 days	Verification:30 Days Abridged :60 days Full: 280 Days
6	Labelling Requirements	Local package inserts (PI), PIL two languages: English and Afrikan	Package insert & label per Appendix 7 of TPB-GN-005	Guidice for Presenting Labelling information, SPC, and PIL
7	Submission Portal	SAHPRA Engagement Portal	PRISM Portal	Saudi Drug Registration System
8	Local Agent Requirement	Yes	Yes	Yes
9	Post-Approval Variations	Major (Type II), Minor (Type IA/IB)	Major and Minor Variations	Type IA(Minor) Type IB (Moderate) Type II (Major)
10	Climatic Zone (Stability)	II	IVb	III & IVa

9. Conclusion

In South Africa, Singapore, and Saudi Arabia, the regulatory approval procedure for Ferric Carboxymaltose Injection 50 mg/mL considers both jurisdiction-specific needs and standardized regulatory standards. Considerable variations exist in review processes, reliance mechanisms, documentation formats, and approval deadlines, despite the fact that all three authorities demand the submission of a Common Technical Document backed by thorough quality, Nonclinical and clinical data Faster approvals may be possible when prior authorization from reputable reference organizations is available, like Singapore and Saudi Arabia offer streamlined or organized verification processes. In South Africa, on the other hand, reliance models are developed gradually and the pathway is mainly full-review. The whole registration strategy is further impacted by additional variances in stability conditions, pharmacovigilance obligations, labelling requirements, and local administrative processes. A successful regulatory strategy for Ferric Carboxymaltose Injection in these jurisdictions therefore requires careful alignment with country-specific technical and administrative requirements while strategically utilizing accelerated or reliance pathways where applicable.

Acknowledgements

I would like to express my sincere gratitude to my guide, Mentor and Head of the department for their valuable guidance and support throughout this work. I also extend my heart fail thanks to my colleagues for their encouragement and cooperation additionally; I want to thank the International Journal of Drug Regulatory Affairs for providing me with the chance to get the article published.

Financial Disclosure Statement:

The authors are not financially connected to any organizations or entities that have a financial interest in or conflict with the subjects or content included in the text. This category includes employment, consulting, honoraria, stock ownership or options, expert testimony, grants or patents received or pending, and royalties.

Conflict of Interest

The authors declare that there is no any Conflict of interest regarding publishing this article.

Reference

1. Verified Market Reports. Ferric Carboxymaltose Injection Market Size, Segmentation, Forecast, Applications [Internet]. India: Verified market reports; 2025 August [cited 2026 Feb 11]. Available from: https://www.verifiedmarketreports.com/product/ferric-carboxymaltose-injection-market/
2. Mayo Clinic. Iron deficiency anaemia - Symptoms & causes. [Internet]. India: Mayoclinic; 2025 September 20 [cited 2026 Feb 11]. Available from: https://www.mayoclinic.org/diseases-conditions/iron-deficiency-anemia/symptoms-causes/syc-20355034
3. nhs.uk. Iron deficiency anaemia [Internet]. UK: Nhs; 2024 January 26 [cited 2026 Feb 11]. Available from: https://www.nhs.uk/conditions/iron-deficiency-anaemia/
4. Hopkins medicine. iron-Deficiency Anaemia [Internet]. EU: Hokinsmedicine health; 2025 July 12 [cited 2026 Feb 11]. Available from: https://www.hopkinsmedicine.org/health/conditions-and-diseases/irondeficiency-anemia
5. Very well Health. 10 Signs Your Iron Levels Might Be Too Low. [Internet]. India: Verywellhealth; 2025 September 12 [cited 2026 Feb 11]. Available from: https://www.verywellhealth.com/low-iron-symptoms-11802492
6. Abraham Bincy P. The role of ferric carboxymaltose in the treatment of iron deficiency anaemia in patients with gastrointestinal disease. Therapeutic Advance in Gastroenterology [Internet]. 2016 January [cited 2026 Feb 17]; 76 (2): 1-6. Available from: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4699280/
7. Drugs.com. Ferric Carboxymaltose Monograph for Professionals. [Internet]. India: Go Drug bank; 2026 March 4 [cited 2026 Feb 11]. Available from: https://www.drugs.com/monograph/ferric-carboxymaltose.html
8. GoDrug Bank. Drug Profile of Ferric Carboxy Maltose [Internet]. India: Go Drug bank; 2024 March 1[cited 2026 Feb 11]. Available from: https://go.drugbank.com/unearth/q?searcher=drugs&query=Ferric+carboxy+maltose+injection+&button
9. U.S. Food and Drug Administration (FDA). Ferric Carboxymaltose Injection Labelling [Internet]. US: U.S. Food and Drug Administration; 2020. September 16 [cited 2026 February 12]. Available from: https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/203565s009lbl.pdf
10. SAHPRA. SAHPRA s' core Business [Internet]. South Africa: SAHPRA; 2025 September 6 [cited 2026 Feb 17]. Available from: https://www.sahpra.org.za/who-we-are/
11. 11 SAHPRA. SAHPRA s' core Business [Internet]. South Africa: SAHPRA; 2025 September 6 [cited 2026 Feb 17]. Available from: https://www.sahpra.org.za/who-we-are/
12. Frpportal. Where the Roads to Accelerated Assessments Converge [Internet]. South Africa: Frpportal; 2025 March [cited 2026 Feb 17]. Available from: https://frpportal.public.erudee.org/FRP/5fff176d88f8d3329a3722d9
13. HSA Pharma Regulatory in. India's Regulatory Knowledge Hub [Internet]. Singapore: Pharma regulatory.in; 2025 DEC 12 [cited 2026 Feb 18]. Available from: https://www.pharmaregulatory.in/hsa-evaluation-routes-full-abridged-and-verification-explained/
14. (CDA-AMC). Ferinject Combined Review Ferric Carboxymaltose [Internet]. Canada: Canda Drug Agency (CDA-AMC); 2025 April [cited 2026 Feb 11]. Available from: https://www.cda-amc.ca/sites/default/files/DRR/2025/SR0842-Ferinject-Combined_Review.pdf
15. Sahpra.org. Sahpra New Application – SAHPRA Engagement Portal Applicants Training Manual [Internet]. South Africa: Sahpra Engagement Portal Sahpra; 2024 April 7 [cited 2026 Feb 14]. Available from: https://portal.sahpra.org.za/user-manual/_site/create_new_hpa.html
16. Pacific Bridge Medical. Singapore's Health Science Authority History and overview [Internet]. Singapore: Pacific bridge Medical; 2023 August 23 [cited 2026 Feb 17]. Available from: https://www.pacificbridgemedical.com/publication/singapores-health-science-authority/
17. HSA. HSA Registration overview. [Internet]. Singapore: Therapeutic Products HSA; 2025 August [cited 2026 Feb 17]. Available from: https://www.hsa.gov.sg/therapeutic-products/register/overview/overview
18. SFDA. The official website of the Saudi Food and Drug Authority [Internet]. Saudi Arabia: Official Website of SFDA; 2025 March 8 [cited 2026 Feb 18]. Available from: http://www.sfda.gov.sa/en/HajjAndOmrah
19. SFDA. Introduction to the Saudi Food and Drug Authority (SFDA) and Its Role and Its Role [Internet]. Saudi Arabia: Introduction to SFDA Authority; 2025 December 18 [cited 2026 Feb 18]. Available from: https://www.pharmaregulatory.in/introduction-to-the-saudi-food-and-drug-authority-sfda-and-its-role-regulatory-executive/
20. SFDA. Information Lists The official website of the Saudi Food and Drug Authority [Internet]. Saudi Arabia: Information List of SFDA; 2022 May 6 [cited 2026 Feb 18]. Available from: https://www.sfda.gov.sa/en/listscategories?keys=drug+registration&tags=2