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Review Article

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

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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

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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

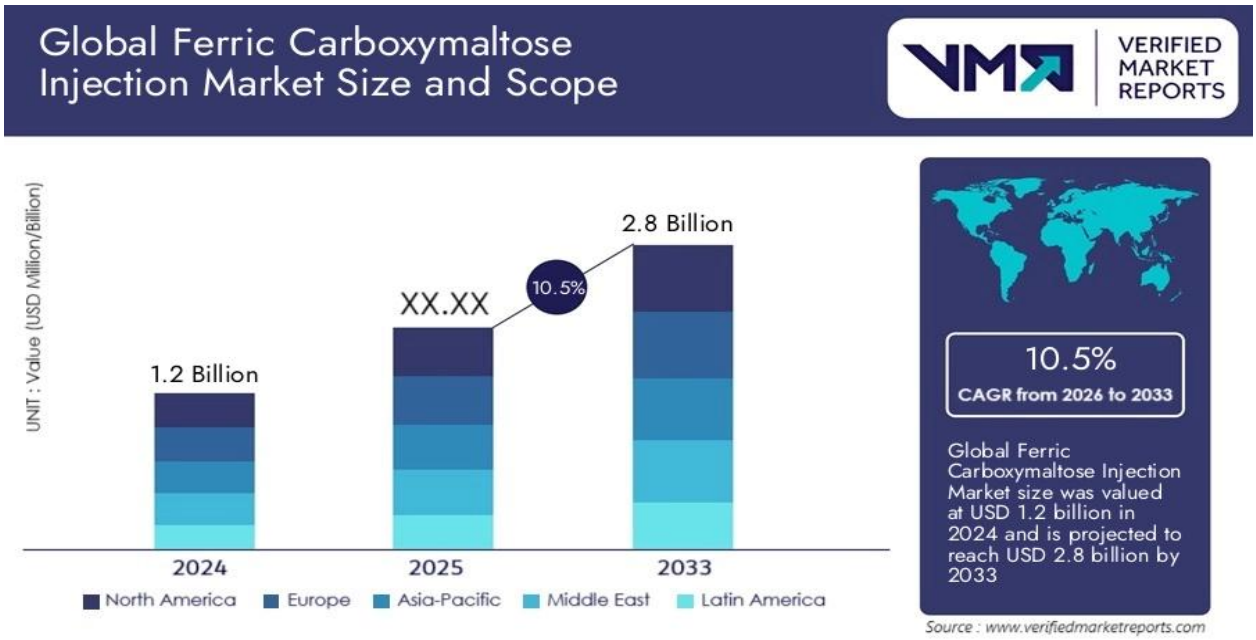


Figure 1. Global Ferric Carboxy Maltose Injection Market Size (1)

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

General Drug Characteristics	Description
Brand Name	Ferinject
Generic Name	Ferric carboxy maltose Injection
Molecular weight	788.4g/mol
ATC Code	B03 (8)
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)
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

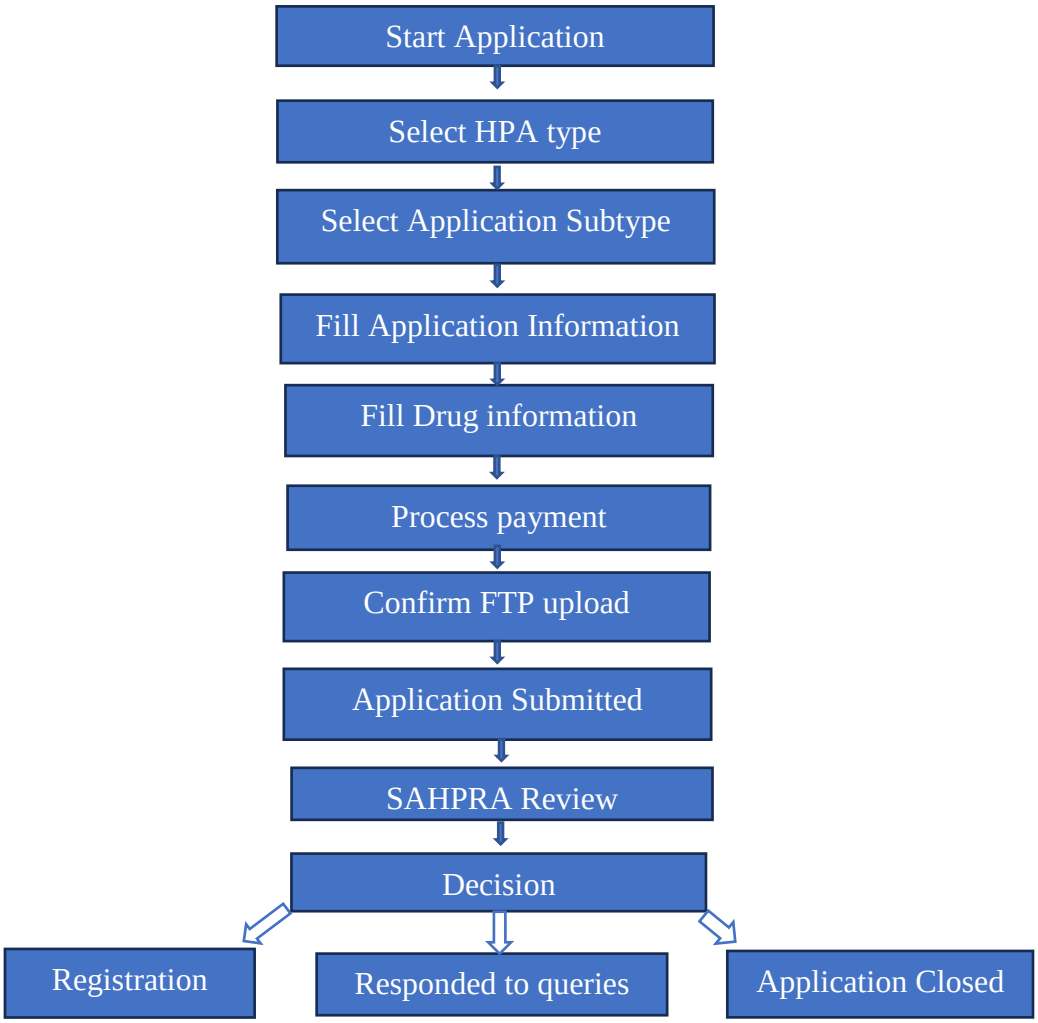


Figure 2. Drug Registration Process Flow Chart (15)

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

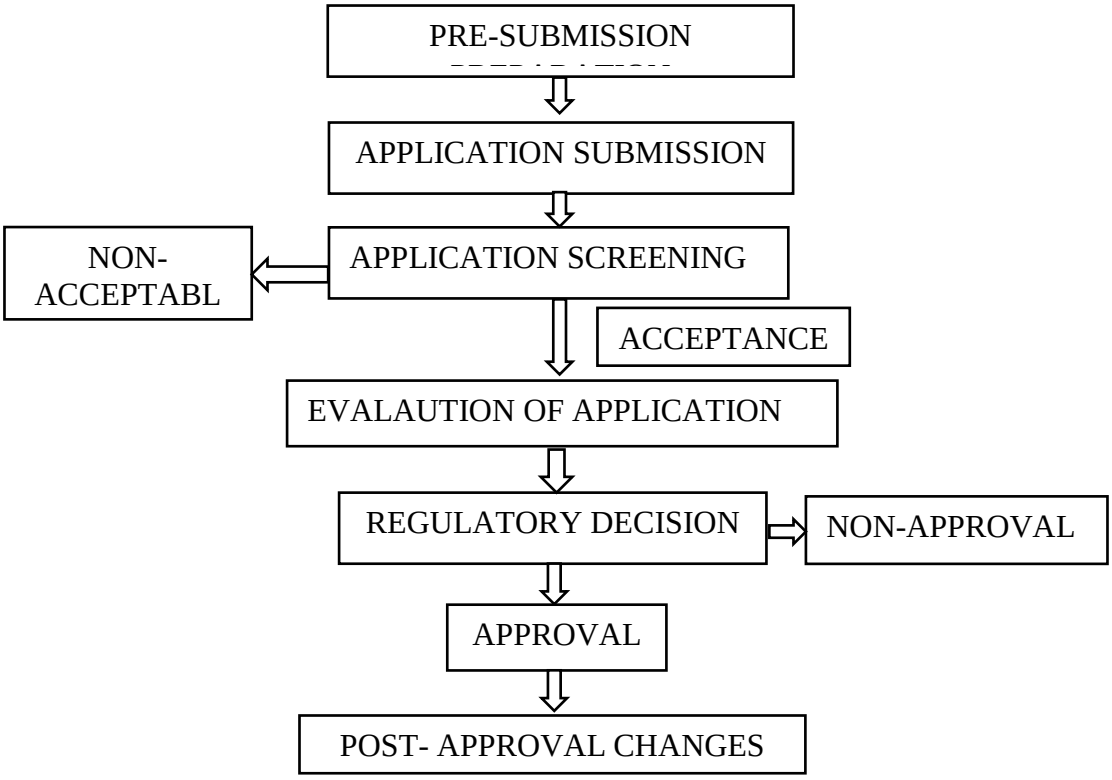


Figure 3. Registration Process overview (17)

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

Parameter	South Africa (SAHPRA)	Singapore (HSA)	Saudi Arabia (SFDA)
Regulatory Authority	South African Health Products Regulatory Authority	Health Science Authority	Saudi Food & Drug Authority
Application Type	New Chemical Entity (NCE/NDA)	(NDA-1, NDA-2, NDA-3)	NDA; Verified; Abridged
Application Submission Route	Verified Route	NDA-2	Verified Route
Submission Format	eCTD	ACTD or eCTD	eCTD
Evaluation Pathways	Full Review, Abridge Review, Verification Review	Full Review, Abridge Review, Verification Review	Full Review, Abridge Review, Verification Review
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
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
Submission Portal	SAHPRA Engagement Portal	PRISM Portal	Saudi Drug Registration System
Local Agent Requirement	Yes	Yes	Yes
Post-Approval Variations	Major (Type II), Minor (Type IA/IB)	Major and Minor Variations	Type IA(Minor) Type IB (Moderate) Type II (Major)
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.

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Conflict of Interest

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

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