National Agency for Food & Drug Administration & Control (NAFDAC)

Public Assessment Report (PAR)

Iron sucrose injection 20 mg/mL

Iron sucrose 20 mg/mL

A4-101953

Joviex Healthcare Limited

This report reflects the scientific assessment for the approval of Iron sucrose injection. The product was licenced in February 2026.

PART 1: ABSTRACT

Iron sucrose injection, manufactured at Kamla Lifesciences Limited, Tarapur M.I.D.C, Maharashtra, India, was granted marketing authorization by NAFDAC for the treatment of iron deficiency anemia on 24 February 2026.

Iron sucrose injection is indicated for the management and treatment of iron deficiency anemia such as in active inflammatory bowel disease and chronic kidney disease when oral iron preparations are ineffective.

For details on the uses of this product and for side effects and warnings, see the summary of product characteristics (SmPC), which can be found in the NAFDAC Greenbook.

The marketing authorization of iron sucrose injection by NAFDAC is based on the review of the Common Technical Document (CTD) dossier submitted to ascertain the quality, safety, and efficacy.

All accepted presentations of iron sucrose injection have been shown in part 2 of this report. The Summary of Product characteristics (SmPC) and the approved labelling have been presented in part 3 and part 4 respectively.

Scientific discussion on the quality, non-clinical and clinical aspects of iron sucrose injection has been presented in Part 5 of this report.

The detailed steps taken to approve iron sucrose injection by NAFDAC have been presented in part 6 of this report.

No action or steps have been taken following the marketing authorization of iron sucrose injection.

PART 2: ACCEPTED PRESENTATIONS

Product Name	Active Ingredients	Pharmaceutical Form/Description	Packaging	Pack size
Iron sucrose injection	Iron sucrose 20 mg/mL	A brown colour liquid filled in 5 mL amber ampoule	5 mL amber ampoule	5 x 5 mL

PART 3: SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

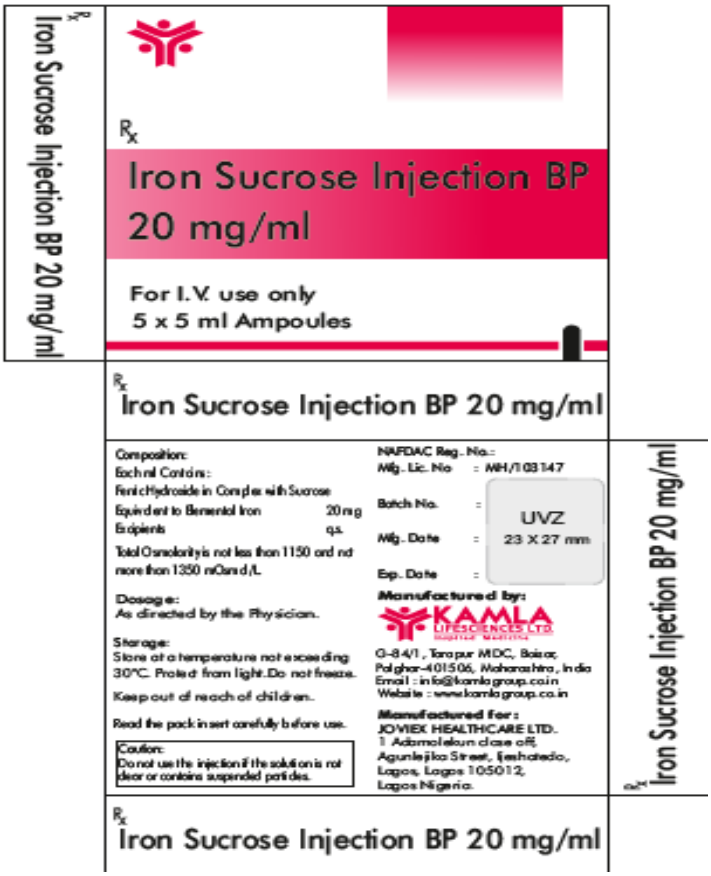
Refer to the NAFDAC Greenbook URL below for the SmPC

See: https://greenbook.nafdac.gov.ng/

PART 4: LABELLING

Primary label

Secondary label



PART 5: SCIENTIFIC DISCUSSION

5.1. About the Product

5.1.1 Name of the product

Iron sucrose injection 20 mg/mL

5.1.2 Therapeutic indication

Iron sucrose injection 20 mg/mL is used for the management and treatment of iron deficiency anemia.

5.1.3 Applicant

Joviex Healthcare Limited, 1 Adamolekun close off, Agunlejika Street Ijeshatedo, Lagos, Nigeria.

5.1.4 Pharmaceutical form

A brown colour liquid filled in 5 mL amber ampoule.

5.1.5 Storage

Do no store above 30^{o}C and protect from light.

5.1.6 Shelf life

24 months

5.1.7 Product presentation

Iron sucrose injection is a brown colour liquid filled in 5 mL amber ampoule. Available as a 5 x 5 mL ampoule.

5.2 Drug Substance

5.2.1 Manufacturer

Iron sucrose is manufactured by SNJ Labs Private Limited, Plot No.5 to 16, Survey No.137, Padavala-360024, Taluka Kotda Sangani, Dist: Rajkot, Gujarat, India.

The API specifications are pharmacopoeial based.

Stability testing was conducted according to the requirements of NAFDAC. The proposed re-test period is justified based on the stability results when the API is stored in line with the storage statement.

5.3 Other ingredients

Other ingredients used in the formulation of iron sucrose injection include sodium hydroxide, water for injection, all being controlled by pharmacopoeia. None of the excipients are derived from human or animal origin. None of the excipients are derived from human or animal origin.

5.4 Drug Product

5.4.1 Drug product manufacturer

Kamla Lifesciences Limited, Tarapur M.I.D.C, Boisar-401 506, Tal. & Dist. Palghar, Maharashtra, India.

Pharmaceutical development

The objective of the pharmaceutical development is to manufacture a generic which is stable, deliver the intended performance, safe and bioequivalent in term of efficacy to the reference product, Venofer (Iron sucrose injection), manufactured by American Regent Inc., USA.

The product is manufactured by an aseptic filtration and filling process following the depyrogenation of the ampoules. All the manufacturing processes were validated.

5.4.3 Specification

The finished product specification is based on in-house standards. The finished product specifications include description, identification, alkalinity, osmolality, clarity of solution, extractable volume and bacterial endotoxin test. The test procedures have been adequately validated.

5.4.4 Stability

Stability studies have been conducted at 30°C/75%RH as long-term storage conditions and for six months at accelerated conditions in the packaging intended for marketing of the product. The product proved to be quite stable at these conditions, with no apparent negative trend. Based on the data submitted, the proposed shelf life of 24 months and 'Do not store above 30°C and protect from light' have been accepted.

5.5 Conclusion

Based on the assessment of data submitted ~~on quality, safety and efficacy~~, the benefit–risk profile of iron sucrose injection was acceptable for the following indication: 'for the treatment of iron deficiency anemia ', and is included in the list of approved medicinal products by NAFDAC.

PART 6: STEPS TAKEN FOR REGISTRATION

The applicant, Joviex Healthcare Limited, 1 Adamolekun close off, Agunlejika Street Ijeshatedo, Lagos Nigeria, submitted application to the National Agency for Food and Drug Administration and Control (NAFDAC), for the registration of iron sucrose injection.

The following are the steps for the registration of iron sucrose injection

November 2024	Date of receipt of application
June 2025	Date of conclusion of assessment
April 2024	Date of inspection
24 February 2026	Date of issuance of Marketing Authorization

PART 7: STEPS TAKEN FOLLOWING REGISTRATION

No action or steps have been taken following marketing authorization of Iron sucrose injection