



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

Public Assessment Report (PAR)

Heparin 5000 IU/mL injection

Heparin sodium 5000 IU/mL

A4-101881

Chez Resources Pharmaceutical Limited

This report reflects the scientific assessment for the approval of heparin injection. The product was licenced in January 2026.

PART 1: ABSTRACT

Heparin injection manufactured at Bharat Parenteral Limited, Savli, Gujarat, India, was granted marketing authorization by NAFDAC for the prevention and treatment of thromboembolism and for extracorporeal anticoagulation on 27 January 2026.

Heparin is indicated for the prevention and treatment of thromboembolism and for extracorporeal anticoagulation.

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 heparin 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 heparin 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 heparin injection has been presented in Part 5 of this report.

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

No action or steps have been taken following the marketing authorization of heparin.

PART 2: ACCEPTED PRESENTATIONS

Product Name	Active Ingredient	Pharmaceutical Form/Description	Packaging	Pack size
Heparin 5000 IU/mL injection	Heparin sodium BP 5000 IU/mL	Injection A clear and colourless solution filled in an intactly sealed 5 mL amber glass vial USP Type-I.	10 x 5 mL amber glass vials containing clear and colourless solution packed in mono carton.	10 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

Heparin 5000 IU/mL injection.

5.1.2 Therapeutic indication

Heparin is indicated for the prevention and treatment of thromboembolism and for extracorporeal anticoagulation.

5.1.3 Applicant

Chez Resources Pharmaceutical Limited, No. 7, Calabar Street, Anambra.

5.1.4 Pharmaceutical form

A clear and colourless solution filled in an intactly sealed 5 mL amber glass vial.

5.1.5 Storage

Do not store above 30°C, protect from light.

5.1.6 Shelf life

24 months

5.1.7 Product presentation

Heparin injection is presented as 10 x 5 mL vials containing a clear and colourless solution packed in one mono carton along with a package insert.

5.2 Drug Substance

5.2.1 Manufacturer

The active ingredient, heparin sodium, is manufactured by Yino Pharma Limited, 2 Cuiping Erxiang, Yubei District, Chongqing, 401120, China.

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 heparin injection include sodium chloride BP, benzyl alcohol BP and water for injections BP, all being pharmacopoeial controlled.

None of the excipients are derived from human or animal origin.

5.4 Drug Product

5.4.1 Drug product manufacturer

Bharat Parenteral Limited, Survey No. 144 - A, Jarod Samlaya Road, Village Haripura, Tal. Savli, District Vadodara – 391520, Gujarat, India.

5.4.2 Pharmaceutical development

The objective of the pharmaceutical development is to manufacture a generic which is stable, delivers the intended performance, and is safe, in terms of efficacy to the reference product Heparin sodium injection manufactured by Pfizer Limited.

The manufacturing method used was aseptic and involved steam sterilization, sterile filtration, aseptic filling, sealing, and packaging. All the manufacturing processes were validated.

5.4.3 Specification

The finished product specification is based on BP monograph and in-house specifications. The finished product specifications include identification test, assay, pH, limit of detection, bacterial endotoxin and related substances, sterility, extractable volume, and test for subvisible particle count. 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, protect from light’ have been accepted.

5. Conclusion

Based on the assessment of data, the benefit–risk profile of heparin injection was acceptable for the following indication: ‘for the prevention and treatment of thromboembolism and for extracorporeal anticoagulation’ and is included in the list of approved medicinal products by NAFDAC.

PART 6: STEPS TAKEN FOR REGISTRATION

The applicant, Chez Resources Pharmaceutical Limited, No. 7, Calabar Street, Anambra, submitted an application to the National Agency for Food and Drug Administration and Control (NAFDAC), for the registration of heparin injection.

The following are the steps for the registration of heparin injection

November 2024	Date of receipt of application
October 2025	Date of conclusion of assessment
August 2025	Date of inspection
27 January 2026	Date of issuance of Marketing Authorization

PART 7: STEPS TAKEN FOLLOWING REGISTRATION

No action or steps have been taken following marketing authorization of heparin injection.