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

Public Assessment Report (PAR)

Bupivacaine hydrochloride injection 5 mg/mL
Bupivacaine hydrochloride USP

A4-101727

Venchura Pharmaceuticals Limited

This report reflects the scientific assessment for the approval of Venchura Pharmaceuticals Limited. The product was licenced on 26 November 2025.

PART 1: ABSTRACT

Bupivacaine hydrochloride injection, manufactured at Farbe Firma Private Limited, Ankleshwar, Bharuch, Gujarat, India, was granted marketing authorization by NAFDAC for intrathecal (subarachnoid) spinal anesthesia for surgery on 26 November 2025.

Bupivacaine hydrochloride injection is indicated for intrathecal (subarachnoid) spinal anesthesia for surgery.

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 Bupivacaine hydrochloride 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 Bupivacaine hydrochloride 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 Bupivacaine hydrochloride injection has been presented in Part 5 of this report.

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

No action or steps have been taken following the marketing authorization of Bupivacaine hydrochloride injection.

PART 2: ACCEPTED PRESENTATIONS

Product Name	Active Ingredients	Pharmaceutical Form/Description	Packaging	Pack size
Bupivacaine hydrochloride injection	Bupivacaine hydrochloride USP	Clear, colourless liquid filled in 5 mL glass ampoules	A clear colorless solution is filled and sealed in 5 mL yellow ring snap off ampoule. 5 such ampoules are packed in a carton along with leaflet.	5 mL x 5 ampoules

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

Bupivacaine hydrochloride injection 5mg/mL

5.1.2 Therapeutic indication

Bupivacaine hydrochloride injection is indicated for intrathecal (subarachnoid) spinal anaesthesia for surgery.

5.1.3 Manufacturer/applicant

Venchura Pharmaceuticals Limited, Emeka Okoye Emeka Okoye 5 Mercy Eneli Street, Surulere, Lagos.

5.1.4 Pharmaceutical form

Liquid injection

A clear, colourless, aqueous solution

5.1.5 Storage

Store below 30°C. Protect from light.

5.1.6 Shelf life

36 months

5.1.7 Product presentation

Bupivacaine hydrochloride injection is a clear, colourless liquid filled in 5 mL glass ampoules presented in 5 mL x 4 ampoules

5.2 Drug Substance

5.2.1 Manufacturer

Bupivacaine hydrochloride is manufactured by Dishman Pharmaceuticals and Chemicals Limited Survey no.47, Paiki Subplot No.1, Village: Lodariyal, Taluka: Sanand, District: Ahmedabad, PIN 382 220, India.

The API specifications are pharmacopeial 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 Bupivacaine hydrochloride injection include water for injection and dextrose (monohydrate) all being controlled by acceptable specifications all being pharmacopeial controlled. None of the excipients are derived from human or animal origin.

5.4 Drug Product

5.4.1 Drug product manufacturer

Farbe Firma Pvt. Limited, Plot No.1508, GIDC Estate, Ankleshwar-393 002, Dist-Bharuch, Gujarat, India.

5.4.2 Pharmaceutical development

The aim was to develop the product which would be similar in chemical characteristics and clinically bioequivalent to the innovator product, Bupitroy Heavy.

The manufacturing method used was sterilization, washing and depyrogenation of glass ampoules and aseptic filtration. All the manufacturing processes were validated.

5.4.3 Specification

The finished product specification is based on USP monograph. The finished product specifications include tests for description, identification, average net volume, extractable volume, pH, particulate matter, bacterial endotoxins test (BET), sterility, and assay. 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 36 months and Store below 30°C. Protect from light. have been accepted.

5.5 Conclusion

Based on the assessment of data on quality, safety and efficacy, the benefit–risk profile of Bupivacaine hydrochloride injection was acceptable for the following indication: 'It is indicated for intrathecal (subarachnoid) spinal anaesthesia for surgery' and is included in the list of approved medicinal products by NAFDAC.

PART 6: STEPS TAKEN FOR REGISTRATION

The applicant, Venchura Pharmaceuticals Limited, Emeka Okoye Emeka Okoye 5 Mercy Eneli Street, Surulere, Lagos submitted application to the National Agency for Food and Drug Administration and Control (NAFDAC), for the registration of Bupivacaine hydrochloride injection.

The following are the steps for the registration of Bupivacaine hydrochloride injection.

February 2024	Date of receipt of application
October 2025	Date of conclusion of assessment
September 2025	Date of inspection
25 November 2025	Date of issuance of Marketing Authorization

PART 7: STEPS TAKEN FOLLOWING REGISTRATION

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