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

Public Assessment Report (PAR)

Hafell injection 30 mg/mL

Pentazocine 30 mg/mL

A4-101538

Mennel Pharmaceuticals Limited

This report reflects the scientific assessment for the approval Hafell Pentazocine injection The product was licenced on 24 September 2025.

PART 1: ABSTRACT

Hafell injection, containing pentazocine 30 mg/mL, manufactured at Bharat Parenteral Limited, Haripura, Tal. Savli, Vadodara Gujarat, India was granted marketing authorization by NAFDAC for the relief of moderate to severe pain on 24 September 2025.

Hafell is indicated for the relief of moderate to severe pain.

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 Hafell 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 Hafell 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 Hafell has been presented in Part 5 of this report.

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

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

PART 2: ACCEPTED PRESENTATIONS

Product Name	Active Ingredients	Pharmaceutical Form/Description	Packaging	Pack size
Hafell injection	Pentazocine 30 mg/mL	A clear colourless solution filled in hermetically sealed clear glass ampoule with red ring on neck.	1 mL clear glass ampoule with red ring on neck. Such 10-ampoule packed in a carton with pack insert	10 x 1mL

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

Hafell injection

5.1.2 Therapeutic indication

Hafell injection is used for the relief of moderate to severe pain.

5.1.3 Manufacturer/applicant

Mennel Pharmaceuticals Limited, 9 Umuabi close Emene, Enugu Nigeria.

5.1.4 Pharmaceutical form

A colorless or almost colorless solution packed in a type 1 glass ampoule.

5.1.5 Storage

Store below 30°C, in a dry place. Protect from light & freezing.

5.1.6 Shelf life

24 months

5.1.7 Product presentation

Hafell injection is presented in 10 x 1mL clear glass ampoule with red ring on neck, packed in a tray and enclosed in a printed carton

5.2 Drug Substance

5.2.1 Manufacturer

The active ingredient, pentazocine is manufactured by is manufactured by Sun Pharmaceutical Industries Limited Vill. Toansa, P.O. Rail Majra, Dist. Nawanshahar - 144 533, Punjab India.

The API specifications are pharmacopeia 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 Hafell injection include sodium chloride, lactic acid and water for injection all being controlled by pharmacopeial. None of the excipients are derived from human or animal origin.

5.4 Drug Product

5.4.1 Drug product manufacturer

Bharat Parenteral Limited, Plot No- 144 & 146, Jarod-Samilyala Road, Vill. Haripura, Ta. Savli, Dist-Baroda, Gujarat, India.

5.4.2 Pharmaceutical development

The objective of the pharmaceutical development was to develop a stable, safe, and effective generic formulation of pentazocine lactate injection 30 mg/mL, comparable in quality, safety, and efficacy to the reference listed product, Fortwin, manufactured by Ranbaxy Laboratories Limited, India.

The manufacturing method used was dry and steam sterilization, and aseptic filtration. All the manufacturing processes were validated.

5.4.3 Specification

The finished product specification is based on BP monograph. The finished product specifications include tests for description, identification by IR and TLC, average net volume, extractable volume, pH, particulate matter (visible and sub-visible), bacterial endotoxins test (BET), sterility, related substances, and assay (content of pentazocine lactate). 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, in a dry place. Protect from light & freezing have been accepted.

5.5 Conclusion

Based on the assessment of data submitted, the benefit–risk profile of Pentazocine was acceptable for the following indication: ‘for the relief of moderate to severe pain ', and is included in the list of approved medicinal products by NAFDAC.

PART 6: STEPS TAKEN FOR REGISTRATION

The applicant, Mennel Pharmaceuticals Limited, 9 Umuabi close Emene Enugu Nigeria submitted application to the National Agency for Food and Drug Administration and Control (NAFDAC), for the registration of Hafell.

The following are the steps for the registration of Hafell

June 2024	Date of receipt of application
September 2025	Date of conclusion of assessment
June 2025	Date of inspection
24 September 2025	Date of issuance of Marketing Authorization

PART 7: STEPS TAKEN FOLLOWING REGISTRATION

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