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

Public Assessment Report (PAR)

Pentazocine 30 mg/mL injection

Pentazocine BP 30 mg/mL

A4-101798

Healthtrust Pharmacy and Stores

This report reflects the scientific assessment for the approval of pentazocine injection. The product was licenced in December 2025.

PART 1: ABSTRACT

Pentazocine injection manufactured at Farbe Firma Private Limited, Ankleshwar, Gujarat, India, was granted marketing authorization by NAFDAC for the relief of severe pain and as a pre-operative medication on 18 December 2025.

Pentazocine injection is indicated for the relief of severe pain and as a pre-operative medication.

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

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

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

PART 2: ACCEPTED PRESENTATIONS

Product Name	Active Ingredients	Pharmaceutical Form/Description	Packaging	Pack size
Pentazocine 30 mg/mL injection	Pentazocine 30 mg/mL	Injection A colourless solution filled in 1 mL amber glass ampoule	colourless solution filled in 1 mL amber glass ampoule	10 x 1mL

PART 3: SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

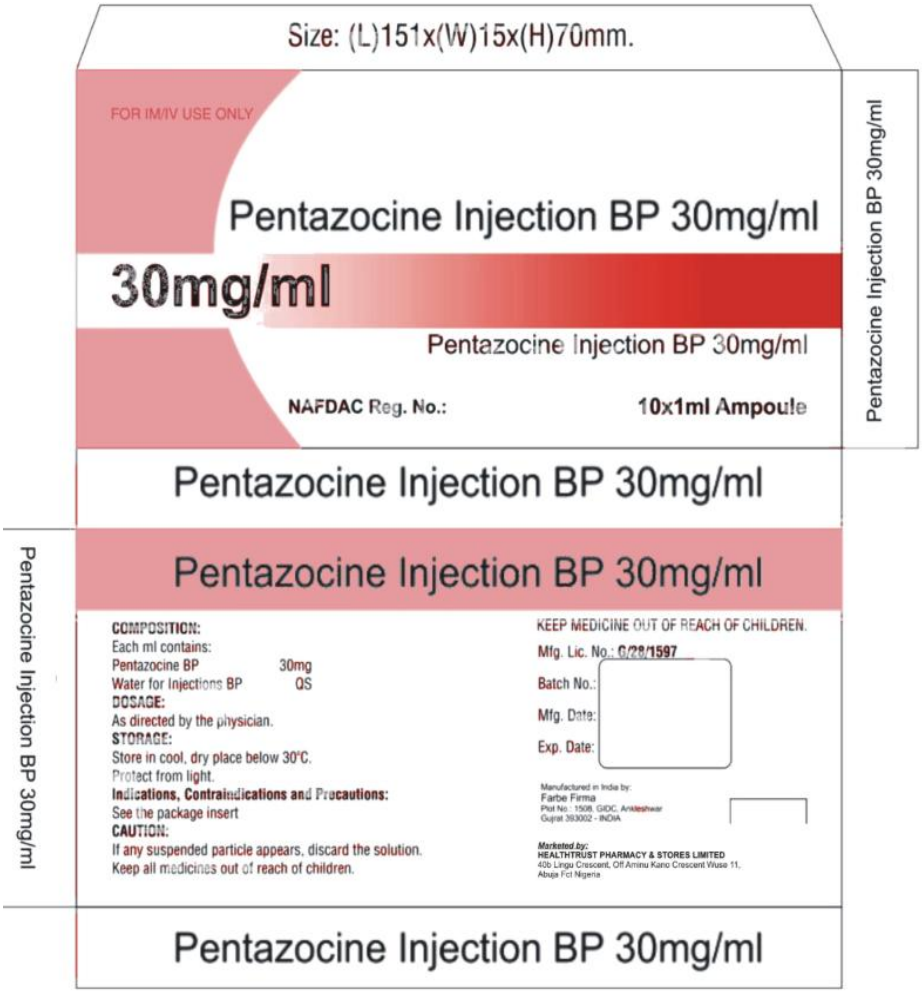
Refer to the NAFDAC Greenbook URL below for the SmPC

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

Pentazocine 30 mg/mL injection

5.1.2 Therapeutic indication

Pentazocine injection is indicated for the relief of moderate to severe pain.

5.1.3 Applicant

Healthtrust Pharmacy and Stores, No. 4 Akapo Street, off Adeniji Adele Road, Lagos Island, Lagos, Nigeria.

5.1.4 Pharmaceutical form

A colourless or almost colourless solution packed in a 1 mL glass ampoule.

5.1.5 Storage

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

5.1.6 Shelf life

36 months

5.1.7 Product presentation

Pentazocine injection is presented as 10 x 1mL glass ampoules containing a colourless or almost colourless solution, placed in a transparent tray, and packed in a printed mono carton.

5.2 Drug Substance

5.2.1 Manufacturer

The active ingredient, pentazocine, is manufactured by Sun Pharmaceutical Industries Limited, Village Toansa, P.O. Rail Majra, District S.B.S. Nagar (Nawanshahar) - 144 533 Punjab, 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 pentazocine injection include sodium chloride BP, lactic acid 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

Farbe Firma Private Limited, Plot No. 1508, Gujarat Industrial Development Corporation, Ankleshwar, Gujarat - 393 002, 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 Talwin injection, currently licensed by Hospira, Incorporated, United States of America.

The manufacturing method used was dry and steam sterilization, and depyrogenation of anpoules. All the manufacturing processes were validated.

5.4.3 Specification

The finished product specification is based on BP monograph. The finished product specifications include description, identification by infrared and thin layer chromatography, pH, related substances, bacterial endotoxins, extractable volume, particulate contamination, 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 ‘Do not store above 30°C, protect from light’ have been accepted.

5.5 Conclusion

Based on the assessment of data submitted, the benefit–risk profile of pentazocine injection was acceptable for the following indication: 'for the relief of severe pain and as a pre-operative medication', and is included in the list of approved medicinal products by NAFDAC.

PART 6: STEPS TAKEN FOR REGISTRATION

The applicant, Healthtrust Pharmacy and Stores, No. 4 Akapo Street, off Adeniji Adele Road, Lagos Island, Lagos, Nigeria, submitted an application to the National Agency for Food and Drug Administration and Control (NAFDAC), for the registration of pentazocine injection.

The following are the steps for the registration of pentazocine injection

October 2024	Date of receipt of application
November 2025	Date of conclusion of assessment
December 2025	Date of inspection
18 December 2025	Date of issuance of Marketing Authorization

PART 7: STEPS TAKEN FOLLOWING REGISTRATION

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