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

Public Assessment Report (PAR)

Pentazocine injection 30 mg/mL

Pentazocine 30 mg/mL

A4 - 101705

Laveoney Integrated Limited

This report reflects the scientific assessment for the approval of Pentazocine injection. The product was licenced on 26 November 2025.

PART 1: ABSTRACT

Pentazocine injection, manufactured at Farbe Firma Private Limited, Atique Bakery, Ankleshwar-Gujarat, India, was granted marketing authorization by NAFDAC for the treatment of moderate to severe pain on 25 November 2025.

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

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

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

PART 2: ACCEPTED PRESENTATIONS

Product Name	Active Ingredients	Pharmaceutical Form/Description	Packaging	Pack size
Pentazocine injection	Pentazocine BP 30 mg/mL	A colourless or almost colourless solution packed in a Type I glass ampoule.	10 x 1mL, clear Fiolax, blue one point cut glass ampoule (USP Type I).	10 x 1mL

PART 3: SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

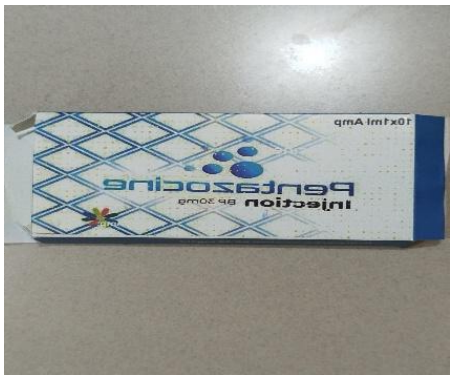
Refer to the NAFDAC Greenbook URL below for the SmPC

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 used for the relief of moderate to severe pain.

5.1.3 Manufacturer/applicant

Laveony Integrated Limited, 12, Thomas Laniyan Street, Anthony village Lagos State, Nigeria.

5.1.4 Pharmaceutical form

A colorless or almost colorless solution filled in 1mL, clear fiolax, blue one point cut glass ampoule (USP Type I).

5.1.5 Storage

Do not store above 30°C. Protect from Light. Always keep product in the carton provided.

5.1.6 Shelf life

36 months

5.1.7 Product presentation

Pentazocine injection is presented as in 10 x 1mL, filled in 1ml, clear fiolax, blue one point cut glass ampoule (USP Type I).

5.2 Drug Substance

5.2.1 Manufacturer

The active ingredient, pentazocine is manufactured by Sun Pharmaceutical Company Limited, Vill. Toansa, P.O Rail Majra, Distt. S.B.S Nagar (Nawanshahar) – 144533, Punjab, 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 pentazocine 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

M/s Farbe Firma Private Limited, Plot No: 1508, Near Atique Bakery, GIDC Estate, Ankleshwar-393002, 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, protect from light 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, Laveony Integrated Limited, 12, Thomas Laniyan Street, Anthony village Lagos State, Nigeria,submitted 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

November 2024	Date of receipt of application
June 2025	Date of conclusion of assessment
January 2025	Date of inspection
26 November 2026	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