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

Public Assessment Report (PAR)

Pentazocine injection 30 mg/ Ml

Pentazocine 30 mg/mL

A4-101713

Mighty Favour Pharmaceutical 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, Ankleshwar, Bharuch, India was granted marketing authorization by NAFDAC for the relief of moderate to severe pain on 26 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 injection.

PART 2: ACCEPTED PRESENTATIONS

Product Name	Active Ingredients	Pharmaceutical Form/Description	Packaging	Pack size
Pentazocine injection	Pentazocine BP 30 mg/mL	Solution for injection A clear colorless and odorless liquid filled in a glass ampoule of 1 mL.	Solution for injection packed in 1 mL, clear, fiolax, blue one point cut glass ampoule.	10 x 1 mL ampoule

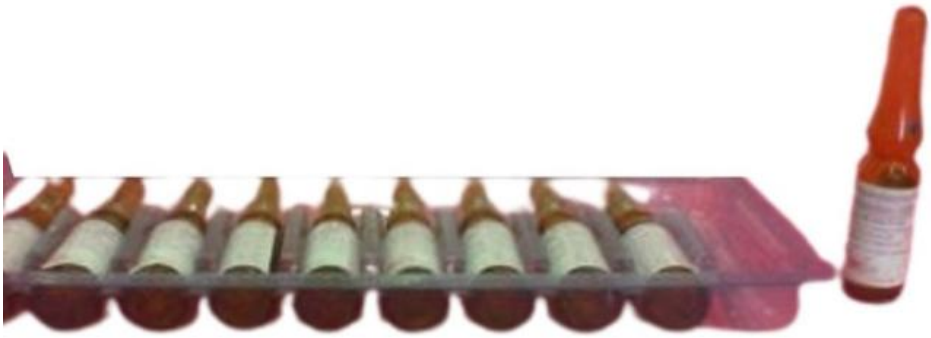
PART 3: SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

Refer to the NAFDAC Greenbook URL below for the SmPC

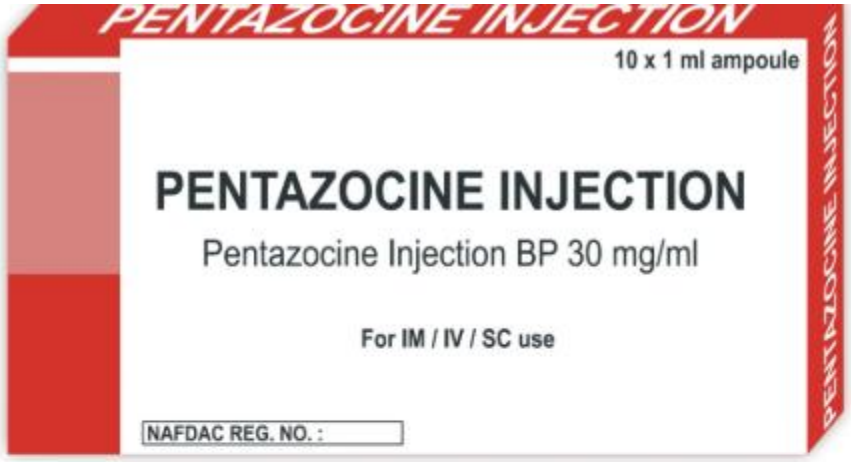
See: https://greenbook.nafdac.gov.ng/

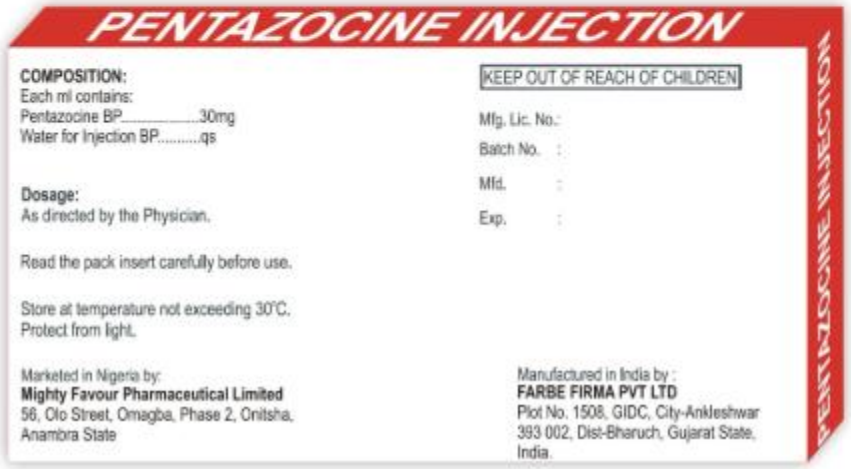
PART 4: LABELLING

Primary label



Secondary label





PART 5: SCIENTIFIC DISCUSSION

5.1. About the Product

5.1.1 Name of the product

Pentazocine injection 30 mg/mL

5.1.2 Therapeutic indication

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

5.1.3 Applicant

Mighty favour pharmaceutical limited, No. 56, Olo Street Omagba, Phase I, Onitsha, Anambra State, Nigeria.

5.1.4 Pharmaceutical form

Solution for injection

A clear colorless or almost colorless and odorless solution filled in a 1 mL glass ampoule.

5.1.5 Storage

Do not store above 30°C

5.1.6 Shelf life

36 months

5.1.7 Product presentation

A colorless or almost clear colorless and odorless solution filled in a 1 mL glass ampoule.

5.2 Drug Substance

5.2.1 Manufacturer

Pentazocine is manufactured by Sun Pharmaceuticals Industries Limited, Vill. Toansa, P.O. Rail Majra, Distt. 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 pentazocine BP, sodium chloride BP, lactic acid BP water for injection 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, Plot number 1508, GIDC Estate, Ankleshwar- 393002, India

5.4.2 Pharmaceutical development

The aim of the pharmaceutical development was to develop a quality, stable parenteral dosage form of pentazocine injection equivalent as the comparator product Talwin injection. The manufacturing method used was filtration, aseptic filling and depyrogenation of ampoules.

5.4.3 Specification

The finished product specification is based on British Pharmacopoeia. The finished product specifications include identification (by IR, TLC), pH, related substances, bacterial endotoxins, extractable volume, particulate contamination, sterility, assay by UV. 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 30°C/75%RH have been accepted.

5.5 Conclusion

Based on the assessment of data submitted, the benefit–risk profile of Pentazocine injection was acceptable 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 Mighty Favour Pharmaceutical Limited, No. 56, Olo Street Omagba, Phase I, Onitsha, Anambra 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 injection

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