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

Public Assessment Report (PAR)

Pentazocine 30 mg/mL injection

Pentazocine 30 mg/mL

A4-101444

Nimo Pharmaceuticals Limited

This report reflects the scientific assessment for the approval of Pentazocine injection. The product was licenced in July, 2025.

PART 1: ABSTRACT

Pentazocine 30 mg/mL injection, manufactured at Farbe Firma Private Limited, Ankleshwar, Gujarat, India, was granted marketing authorization by NAFDAC for the relief of moderate to severe pain on 30 July 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 the drug product 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 the drug product 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 the drug product has been presented in Part 5 of this report.

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

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

PART 2: ACCEPTED PRESENTATIONS

Product Name	Active Ingredients	Pharmaceutical Form/Description	Packaging	Pack size
Pentazocine injection 30 mg/mL	Pentazocine 30mg/mL	Solution for injection A clear, colourless or almost colourless liquid	10 x 1mL glass ampoules containing transparent liquid are packed in a printed mono carton along with printed insert.	10 x 1mL

PART 3: SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

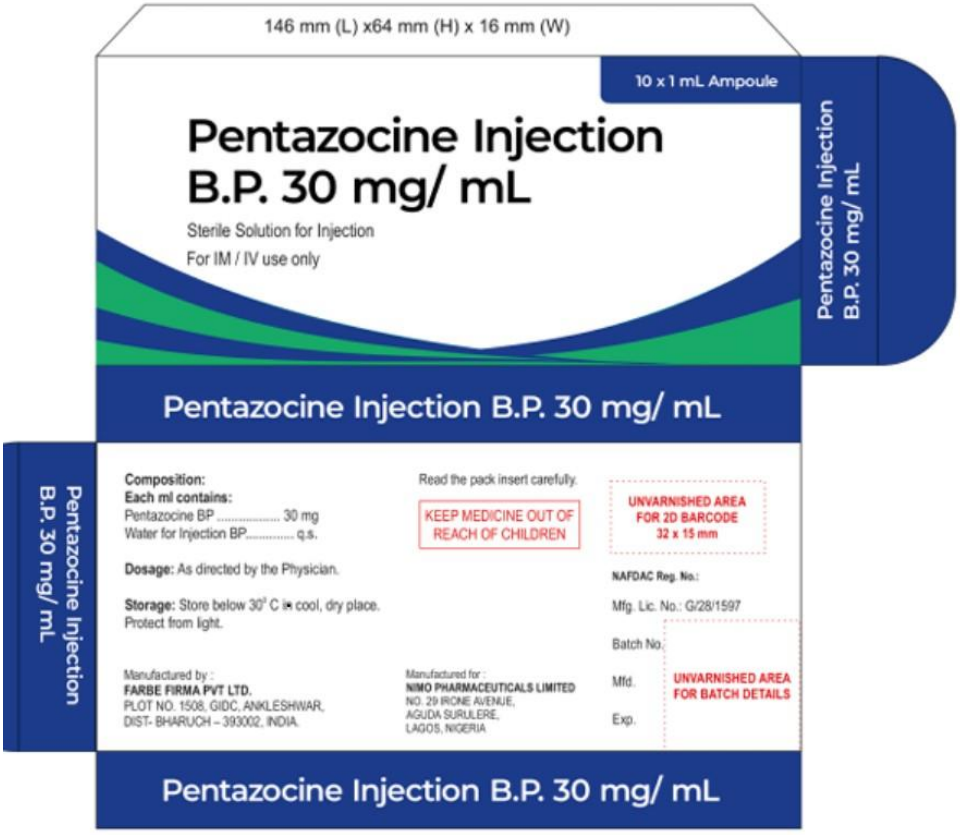
Refer to the NAFDAC Greenbook URL below for the SmPC

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

Pentazocine injection 30 mg/mL

5.1.2 Therapeutic indication

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

5.1.3 Applicant

Nimo Pharmaceuticals Limited, No. 29, Irone Avenue, Aguda, Surulere, Lagos State, Nigeria

5.1.4 Pharmaceutical form

Solution for injection

A clear, colourless or almost colourless liquid

5.1.5 Storage

Do not store above 30°C. Store in a dry place. Protect from light.

5.1.6 Shelf life

36 months

5.1.7 Product presentation

Pentazocine injection is a clear, colourless or almost colourless liquid in 1mL ampoule. It is available as 10 x 1mL ampoules, packed in a printed mono carton along with printed insert.

5.2 Drug Substance

5.2.1 Manufacture

The active pharmaceutical ingredient, pentazocine BP is manufactured by Sun Pharmaceutical Industries Limited,Vill. Toansa, P.O. Rail Majra Distt. S.B.S Nagar - 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 are sodium chloride, benzyl alcohol, lactic acid, and water for injection, all being pharmacopoeial controlled by acceptable specifications. None of the excipients are derived from human or animal origin.

5.4 Drug Product

5.4.1 Drug product manufacturer

The drug product is manufactured by Farbe Firma Private Limited, Plot No. 1508, G.I.D.C, near Antique Bakery, Ankleshwar - 393002, Gujarat, India.

5.4.2 Pharmaceutical development

The objective of the development was to manufacture a generic which is stable and bioequivalent to the reference product, Fortwin (Pentazocine lactate injection), manufactured by Ranbaxy Private Limited, India. The manufacturing method used was dry and steam sterilization and depyrogenation of vials. All the manufacturing processes were validated.

5.4.3 Specification

The finished product specification is based on British Pharmacopoeia monograph. The finished product specifications include identification by IR & TLC, average net volume, extractable volume, pH, bacterial endotoxin test, sterility, particulate matter, related substances 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 at a temperature not exceeding 30ºC in a dry place, protect from light and moisture have been accepted.

5.5 Conclusion

Based on the assessment of data submitted, the benefit–risk profile of Pentazocine injection 30 mg/mL was acceptable for the following indication: ‘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, Nimo Pharmaceuticals Limited, No. 29, Irone Avenue, Aguda, Surulere, Lagos State, Nigeria, submitted application to the National Agency for Food and Drug Administration and Control (NAFDAC), for the registration of Pentazocine injection 30 mg/ mL.

The following are the steps for the registration of Pentazocine injection

February 2025	Date of receipt of application
April 2025	Date of conclusion of assessment
July 2025	Date of inspection
30 July 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 30 mg/mL.