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

Public Assessment Report (PAR)

Pentazocine injection 30 mg/mL

Pentazocine 30 mg/mL

A4-101560

IG Akuma Divine Pharmaceuticals Limited

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

PART 1: ABSTRACT

Pentazocine injection manufactured at Shukra Pharmaceuticals Limited, 795, Rakanpur-Santej Road, Rakanpur-3 827 21 Taluka: Kalol, Gandhinagar, Gujarat, India, was granted marketing authorization by NAFDAC for the treatment of moderate to severe pain on 24 September 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 BP injection 30 mg/mL	Pentazocine 30 mg/mL	A colurless or almost colourless solution packed in a Type I glass ampoule.	10 x 1mL Type I glass ampoule with printed label, packed in Rondo tray and enclosed in a printed carton	10 x 1mL

PART 3: SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

Refer to the NAFDAC Greenbook URL below for the SmPC

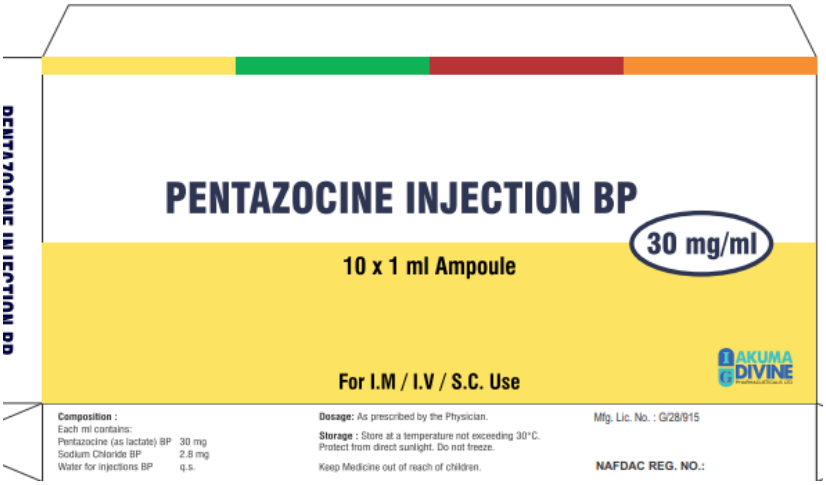
See: https://greenbook.nafdac.gov.ng/

PART 4: LABELLING

Primary label

<p

Secondary label



PART 5: SCIENTIFIC DISCUSSION

5.1. About the Product

5.1.1 Name of the product

Pentazocine injection BP 30 mg/mL

5.1.2 Therapeutic indication

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

5.1.3 Manufacturer/applicant

Pentazocine is manufactured at Shukra Pharmaceuticals Limited, 795, Rakanpur-Santej Road, Rakanpur-3 827 21 Taluka, Kalol, Gandhinagar, Gujarat, India. The local applicant is Divine Pharmaceuticals Limited, No. 10 Umuchu Street, Fegge, Onitsha Anambra State, 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. Protect from light

5.1.6 Shelf life

36 months

5.1.7 Product presentation

Pentazocine injection is presented as in 10 x 1mL Type I glass ampoule with printed label, packed in Rondo tray and enclosed in a printed carton.

5.2 Drug Substance

5.2.1 Manufacturer

The active ingredient, pentazocine is manufactured by Ind-Swift Laboratories Limited, SCO 850, NAC, Shivalik Enclave,NAC Manimajra, Chandigarh – 160101, 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

Shukra Pharmaceuticals Limited, 795, Rakanpur-Santej Road, Rakanpur-3 827 21 Taluka, Kalol, Gandhinagar, 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 IP 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, washing and depyrogenation of glass ampoules 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 on quality, bioequivalence, safety and efficacy, 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, IG Akuma Divine Pharmaceuticals Limited No 10 Umuchu Street, Fegge, 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

October 2024	Date of receipt of application
April 2025	Date of conclusion of assessment
August 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 Pentazocine injection.