



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

Public Assessment Report (PAR)

Pentazocine injection 30 mg/mL

Pentazocine BP 30 mg/mL

A4-101577

Astranad Pharmaceuticals and Chemical Company Limited

This report reflects the scientific assessment for the approval of Astranad Pharmaceuticals and Chemical Company Limited Pentazocine injection. The product was licenced in September 2025.

PART 1: ABSTRACT

Pentazocine injection, manufactured at Alpha Laboratories Limited, Pigdamer, Indore, (MP)-India, was granted marketing authorization by NAFDAC for the relief 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 this pentazocine.

PART 2: ACCEPTED PRESENTATIONS

Product Name	Active Ingredients	Pharmaceutical Form/Description	Packaging	Pack size
Pentazocine injection 30 mg/mL	Pentazocine BP 30 mg/mL	A clear colorless solution filled in flint glass sealed ampoule with blue dot at constriction	10 x 1 mL USP Type I flint glass ampoule with a blue dot at constriction arranged in transparent tray and packed in a printed mono carton	10 x 1mL

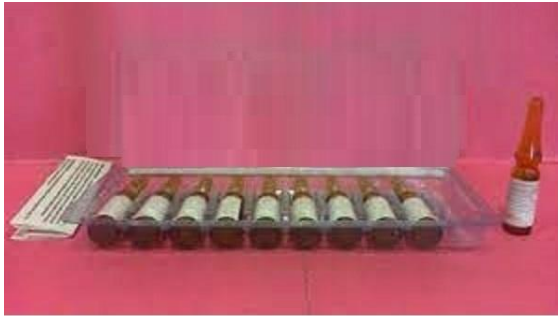
PART 3: SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

Refer to the NAFDAC Greenbook URL below for the SmPC

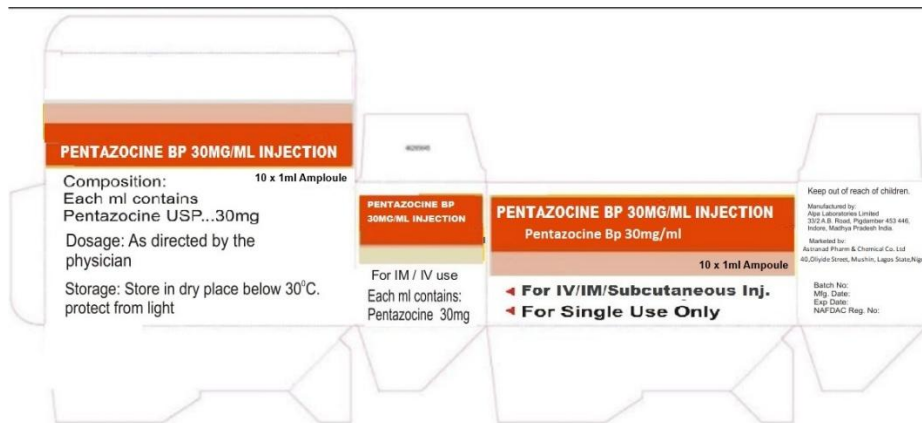
See: <https://greenbook.nafdac.gov.ng/>

PART 4: LABELLING

Primary label



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 Applicant

Astranad Pharmaceuticals and Chemical Company Limited, 40, Oliyide street, Mushin, Lagos.

5.1.4 Pharmaceutical form

A clear colorless solution filled in flint glass sealed ampoule with blue dot at constriction.

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 1 mL USP Type I flint glass ampoule with a blue dot at constriction arranged in transparent tray and packed in a printed mono.

5.2 Drug Substance

5.2.1 Manufacturer

The active ingredient, pentazocine is manufactured by Taj Pharma Active Pharmaceuticals Plot no. - 1019, Vill. - Sarigam, G.I.D.C., Road No. 10, Dist. - Valsad, State of Gujarat, 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, lactic acid and water for injection all being controlled by pharmacopoeial. None of the excipients are derived from human or animal origin.

5.4 Drug Product

5.4.1 Drug product manufacturer

Alpha Laboratories Limited. 33/2 A.B. Road, Pigdamer, Indore, (MP)-India.

5.4.2 Pharmaceutical development

The objective of the pharmaceutical development is to manufacture a generic product which is stable, deliver the intended performance, safe and bioequivalent in term of efficacy to the reference product, Fortwin (Pentazocine lactate injection IP), manufactured by Ranbaxy Private Limited, India.

The manufacturing method used was dry and steam sterilization. All the manufacturing processes were validated.

5.4.3 Specification

The finished product specification is based on BP monograph. The finished product specifications include identification by IR & TLC, average net volume, extractable volume, pH, bacterial endotoxin test, sterility, particulate matter, related substances, bacterial endotoxins test (BET) 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 in 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 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, Astranad Pharmaceuticals and Chemical Company Limited, 40, Oliyide Street, Mushin, Lagos, 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

October 2024	Date of receipt of application
September 2025	Date of conclusion of assessment
May 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.