



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

Public Assessment Report (PAR)

Glack Pentazocine 30 mg/ mL injection

Pentazocine 30 mg/ mL

A4-101421

Glack Pharma Limited

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

PART 1: ABSTRACT

Pentazocine injection, manufactured at Alpa Laboratories Limited, Pigdamber, Indore (M.P.), India, was granted marketing authorization by NAFDAC for the relief of moderate to severe pain on 30 July 2025.

Pentazocine is indicated for 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 30 mg/ mL	Solution for injection A clear colourless or almost colourless solution filled in 1mL USP Type I flint glass sealed ampoules with blue dot at constriction.	Clear colorless or almost colored solution in a 1 mL USP Type I flint glass ampoule with a blue dot at the constriction. They are packed in 10 x 1 mL ampoules and such 10 ampoules packed in a PVC tray in a printed mono carton along with pack insert.	10 x 1mL ampoules

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

<p>For IV/IM use 1mlX10 Ampoules</p> <p style="text-align: center;">PENTAZOCINE INJECTION Pentazocine Lactate BP 30mg/ml</p> <p style="text-align: center;">NAFDAC Reg. No.:</p>		<p>PENTAZOCINE INJECTION Pentazocine Lactate BP 30mg/ml</p>
<p>PENTAZOCINE INJECTION Pentazocine Lactate BP 30mg/ml</p>		
<p>PENTAZOCINE INJECTION</p>	<p>Composition: Each ml contains: Pentazocine Lactate BP eq. to Pentazocine..... 30 mg Water for injections BP..... q.s.</p> <p>Dosage: As directed by the physician. Store below 30°C in a dry place Protect from light. Do not freeze. Keep medicine out of reach of children.</p>	<p>Batch No.: GL204 Mfg. Date : 07/2024 Exp. Date: 06/2027</p> <p>Manufactured by: Alpa Laboratories Ltd 33/2, A.B. Road, Pigdambar-453 446, Indore (M.P), India.</p> <p>Marketed by: GLACK PHARMA LTD. NO. 22, STELLA OSHOLAKE STREET, AJAO ESTATE, ISOLO, LAGOS STATE, NIGERIA.</p>

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 used for the relief of moderate to severe pain.

5.1.3 Applicant

Glack Pharm Limited, No. 22, Stella Osholake Street, off International Airport Road, Ajao Estate, Isolo, Lagos State, Nigeria.

5.1.4 Pharmaceutical form

Solution for injection

A clear colourless or almost colourless solution filled in 1mL Type 1 USP flint glass sealed ampoules with blue dot at constriction.

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 solution in 1mL flint glass sealed ampoule with blue dot at constriction. It is available as 10 x 1mL ampoules, placed in a PVC tray and packed in a printed mono carton along with printed insert.

5.2 Drug Substance

5.2.1 Manufacturer

The active pharmaceutical ingredient, pentazocine BP is manufactured by Taj Pharma Active Pharmaceuticals. Plot.No.-1019, Vill. -Sarigam, G.I.D.C Road No. 10, Dist-Valsad, State of Gujarat.

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 the Pentazocine injection are sodium chloride, benzyl alcohol, lactic acid, and water for injection (WFI), 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 Pentazocine injection is manufactured by Alpa Laboratories Limited, 33/2, A.B. Road Pigdamber - 453446, Indore (M.P.), 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 the storage conditions of do not store above 30°C, store in a dry place and protect from light have been accepted.

5.6 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, Glack Pharm Limited, No. 22, Stella Osholake Street, off International Airport Road, Ajao Estate, Isolo, Lagos State, Nigeria submitted application to the National Agency for Food and Drug Administration and Control (NAFDAC), for the registration of Pentazocine injection BP 30 mg/mL.

The following are the steps for the registration of Pentazocine injection 30 mg/mL.

September 2024	Date of receipt of application
March 2025	Date of conclusion of assessment
April 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 30 mg/mL injection.