



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

Public Assessment Report (PAR)

Berlin Pentazocine 30 mg/mL injection

Pentazocine BP 30 mg/mL

A4-101323

Berlin Pharmaceutical and Healthcare Limited

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

PART 1: ABSTRACT

Berlin pentazocine, manufactured at Alpa Laboratories Limited, Pigdamber, Indore, India, was granted marketing authorization by NAFDAC for the relief of moderate to severe pain on 27 May 2025.

Berlin 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 Berlin 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 Berlin 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 Berlin pentazocine has been presented in Part 5 of this report.

The detailed steps taken to approve Berlin pentazocine by NAFDAC have been presented in part 6 of this report.

No action or steps have been taken following the marketing authorization of Berlin pentazocine.

PART 2: ACCEPTED PRESENTATIONS

Product Name	Active Ingredients	Pharmaceutical Form/Description	Packaging	Pack size
Berlin pentazocine injection 30 mg/mL	Pentazocine BP 30 mg/mL	A colourless or almost colourless solution filled in flint glass sealed ampoule with blue dot at constriction.	1 mL flint glass ampoule with a blue dot at the constriction.	10 x 1 mL ampoule

PART 3: SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

Refer to the NAFDAC Greenbook URL below for the SmPC

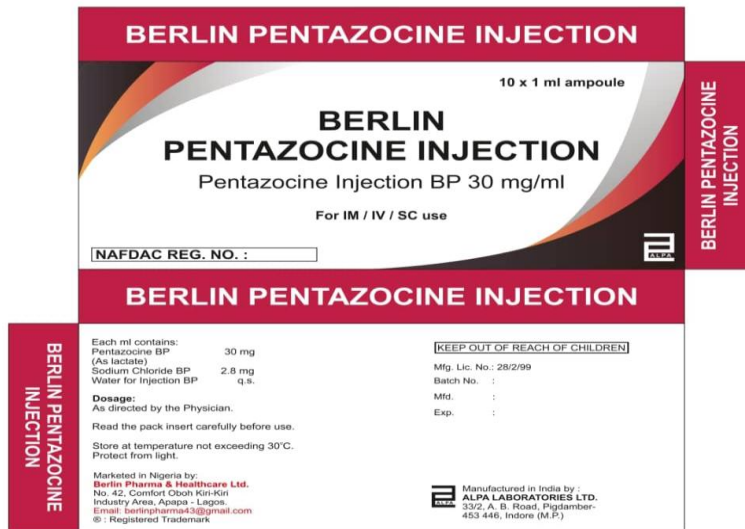
See: <https://greenbook.nafdac.gov.ng/>

PART 4: LABELLING

Primary label



Secondary label



147 mm (L) x 17 mm (W) x 65 mm (H)

PART 5: SCIENTIFIC DISCUSSION

5.1. About the Product

5.1.1 Name of the product

Berlin pentazocine injection 30 mg/mL

5.1.2 Therapeutic indication

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

5.1.3 Applicant

Berlin Pharmaceutical and Healthcare Limited. 42, Comfort Oboh, Kiri Kiri Industrial Area, Apapa-Lagos 101252, Nigeria.

5.1.4 Pharmaceutical form

An injection containing a colourless or almost colourless solution filled in flint glass sealed ampoule with blue dot at constriction.

5.1.5 Storage

Do not store above 30°C. Store in the original packaging. Protect from light.

5.1.6 Shelf life

36 Months

5.1.7 Product presentation

Berlin pentazocine injection is presented in 1 mL flint glass ampoule with a blue dot at the constriction containing a colourless or almost colourless solution.

5.2 Drug Substance

5.2.1 Manufacturer

The active 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 Berlin 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

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

5.4.2 Pharmaceutical development

The objective of the pharmaceutical development is to manufacture a generic 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, 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 'Do not store above 30°C, store in the original packaging, protect from light' have been accepted.

5.6 Conclusion

Based on the assessment of data submitted, the benefit–risk profile of Berlin pentazocine injection 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, Berlin Pharmaceutical and Healthcare Limited. 42, Comfort Oboh, Kiri Kiri Industrial Area, Apapa-Lagos 101252, Nigeria, submitted application to the National Agency for Food and Drug Administration and Control (NAFDAC), for the registration of Berlin pentazocine.

The following are the steps for the registration of Berlin pentazocine

October 2024	Date of receipt of application
March 2025	Date of conclusion of assessment
April 2025	Date of inspection
27 May 2025	Date of issuance of Marketing Authorization

PART 7: STEPS TAKEN FOLLOWING REGISTRATION

No action or steps have been taken following marketing authorization of Berlin pentazocine injection.