



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

Public Assessment Report (PAR)

Fdpenta 30 mg/ mL injection

Pentazocine 30 mg/ mL

A4-101389

F-Dumsom Nigeria Limited.

This report reflects the scientific assessment for the approval of Fdpenta injection. The product was licenced in June 2025.

PART 1: ABSTRACT

Fdpenta containing pentazocine is manufactured at Sakar Healthcare Limited, Sarkhej-Bavla Highway, Changodar-382 213, Ahmedabad, Gujarat State, India, was granted marketing authorization by NAFDAC for the relief of moderate to severe pain on 25 June 2025.

Fdpenta 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 Fdpenta 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 Fdpenta injection 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 Fdpenta injection has been presented in Part 5 of this report.

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

No action or steps have been taken following the marketing authorization of Fdpenta injection.

PART 2: ACCEPTED PRESENTATIONS

Product Name	Active Ingredients	Pharmaceutical Form/Description	Packaging	Pack size
Fdpenta injection	Pentazocine 30 mg/ mL	Liquid injection A colourless or almost colourless solution	1 mL clear glass ampoule. containing a colourless or almost colourless solution	10 x 1 mL 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



PART 5: SCIENTIFIC DISCUSSION

5.1. About the Product

5.1.1 Name of the product

Fdpenta injection 30 mg/ mL

5.1.2 Therapeutic indication

Fdpenta injection 30 mg /mL is used for the relief of moderate to severe pain.

5.1.3 Manufacturer/applicant

Manufactured by Stallion Laboratories Private Limited, at Sakar Healthcare Limited, Block No. 10-13, Sarkhej-Bavla Highway, Changodar-382 213, Ahmedabad, Gujarat State, India. The local agent is F-Dumson Nigeria Limited, 10 Nwobodoze Street, Ajao Estate, Lagos, Nigeria.

5.1.4 Pharmaceutical form

Solution

A colourless or almost colourless solution. Available as 10 x 1 mL ampoules

5.1.5 Storage

Store at a temperature not exceeding 30°C in a dry place. Protect from excess heat and moisture.

5.1.6 Shelf life

24 months

5.1.7 Product presentation

Fdpenta injection is a colourless or almost colourless solution in 1mL ampoules. Available as 10 x 1mL ampoules, placed in transparent tray and packed in a printed mono carton.

5.2 Drug Substance

5.2.1 Manufacturer

The active pharmaceutical ingredient (API) pentazocine BP is manufactured by Ind-Swift Laboratories Limited Sco 850, Shivalik Enclave, Nac Manimajra Chandigarh – 160 101 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 Fdpenta 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

Stallion Laboratories Private Limited at Sakar Healthcare Limited, Block No. 10-13, Sarkhej-Bavla Highway, Changodar-382 213, Ahmedabad, Gujarat State, 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 24 months and Store at a temperature not exceeding 30°C in a dry place. Protect from excess heat and moisture. Have been accepted.

5.6 Conclusion

Based on the assessment of data submitted, the benefit–risk profile of Fdpenta injection 30 mg/ mL 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, F-Dumsom Nigeria Limited, 10 Nwobodoze Street, Ajao Estate, submitted application to the National Agency for Food and Drug Administration and Control (NAFDAC), for the registration of Fdpenta.

The following are the steps for the registration of Fdpenta injection

November 2023	Date of receipt of application
December 2023	Date of conclusion of assessment
April 2025	Date of inspection
25 June 2025	Date of issuance of Marketing Authorization

PART 7: STEPS TAKEN FOLLOWING REGISTRATION

No action or steps have been taken following marketing authorization of Fdpenta 30mg /mL injection .