



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

Public Assessment Report (PAR)

Afi Pentazocine injection 30 mg/mL

Pentazocine 30 mg/mL

A4 - 101558

Afi Healthcare Limited

This report reflects the scientific assessment for the approval of AFI Pentazocine. The product was licenced on 24 September 2025.

PART 1: ABSTRACT

Afi Pentazocine injection, manufactured at Merit Organics Limited, Gujarat, India was granted marketing authorization by NAFDAC for the relief of moderate to severe pain on 24 September, 2025.

Afi 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 Afi 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 Afi 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 Afi Pentazocine has been presented in part 5 of this report.

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

No action or steps have been taken following the marketing authorization of Afi Pentazocine.

PART 2: ACCEPTED PRESENTATIONS

Product Name	Active Ingredients	Pharmaceutical Form/Description	Packaging	Pack size
Afi Pentazocine injection 30 mg/mL	Pentazocine 30 mg/mL	A colourless or almost colourless solution packed in glass ampoule.	10 x 1mL glass ampoules containing transparent liquid are placed 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

Carton Size:
L-150mm x W-15mm x H-70mm

10 x 1 ml Ampoules

AFI Pentazocin
Pentazocine Injection BP 30 mg/ml
For IM / IV Use

NAFDAC REG. NO. :

AFI Pentazocin

<p>Composition: Each ml contains: Pentazocine Lactate BP 30 mg Eq. to Pentazocine BP 30 mg Water for injection BP q.s.</p> <p>Dosage: As directed by the physician.</p> <p>Storage: Store below 30°C, protect from light.</p> <p>Keep all medicine out of reach of children. Should be used for severe acute pain only for a period not exceeding 5 days</p>	<p>Mfg. Lic. No. : G/25/1267</p> <p>Batch No. : Mfg. Date : Exp. Date :</p> <p>Manufactured in India by: Merit Organics Ltd. 2104/2/A, G.I.D.C., Sarigam, Bhiwad - 396 155, Gujarat, India E-mail : merit@meritorganics.com</p> <p>Marketed by: AFI HEALTHCARE LIMITED 34 Ilorin Street, Fegge Onitsha Anambra State Onitsha 430003, Anambra Nigeria.</p>
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AFI Pentazocin

PART 5: SCIENTIFIC DISCUSSION

5.1. About the Product

5.1.1 Name of the product

Afi Pentazocine injection 30 mg/mL

5.1.2 Therapeutic indication

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

5.1.3 Manufacturer/applicant

Afi Health Care Limited, No 34 Ilorin Street Fegge Onitsha, Anambra State

5.1.4 Pharmaceutical form

A colourless or almost colourless solution packed in glass ampoule.

5.1.5 Storage

Store below 30°C in a dry place. Protect from light

5.1.6 Shelf life

36 months

5.1.7 Product presentation

Afi Pentazocine injection is presented in 10 x 1 mL colour ampoules are placed in transparent tray and packed in a printed mono carton along with leaflet.

5.2 Drug Substance

5.2.1 Manufacturer

The active ingredient, pentazocine is manufactured by Aquatic Formulations India Limited 1209, 1210, 1211, Cabin B, 12th Floor, Universal Majestic, P.L. Lokhande Marg, Chembur Mumbai Mumbai City MH 400043 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 Afi 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

Merit Organics Limited, Plot No 2104/2/A, G.I.D.C, Sarigam , Bhilad, Valsad-396155 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 35m and Store below 30°C in a dry place. 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 Afi 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, Afi Health Care Limited, No. 34 Ilorin Street Fegge Onitsha, submitted application to the National Agency for Food and Drug Administration and Control (NAFDAC), for the registration of Afi Pentazocine injection.

The following are the steps for the registration of Afi Pentazocine injection

September 2024	Date of receipt of application
April 2025	Date of conclusion of assessment
September 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 Afi Pentazocine injection.