



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

Public Assessment Report (PAR)

Gentamicin 80 mg/2 mL injection

Gentamycin Sulphate 80 mg/2 mL

A4-101813

Pharma-Line Healthcare G.D.W Limited Agbor

This report reflects the scientific assessment for the approval of gentamicin 80 mg/2 mL injection. The product was licenced in December 2025.

PART 1: ABSTRACT

Gentamicin injection containing gentamycin sulphate, manufactured at Shanxi Zhongbao Shuguang Pharmaceutical Co Limited, Jinzhong City, Shanxi Province, China, was granted marketing authorization by NAFDAC for the treatment of bacterial infections on 18 December 2025.

Gentamicin injection is indicated for the treatment of bacterial infections caused by susceptible Gram-negative organisms, including septicemia, respiratory tract infections, urinary tract infections, and intra-abdominal infections.

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 gentamicin 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 gentamicin 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 gentamicin has been presented in Part 5 of this report.

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

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

PART 2: ACCEPTED PRESENTATIONS

Product Name	Active Ingredients	Pharmaceutical Form/Description	Packaging	Pack size
Gentamicin injection	Gentamicin sulphate 80 mg/2 mL	Injection A clear/colourless solution in a glass ampoule	Glass ampoule available as 2 mL x 10 ampoules	2 mL x 10 ampoules

PART 3: SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

Refer to the NAFDAC Greenbook URL below for the SmPC

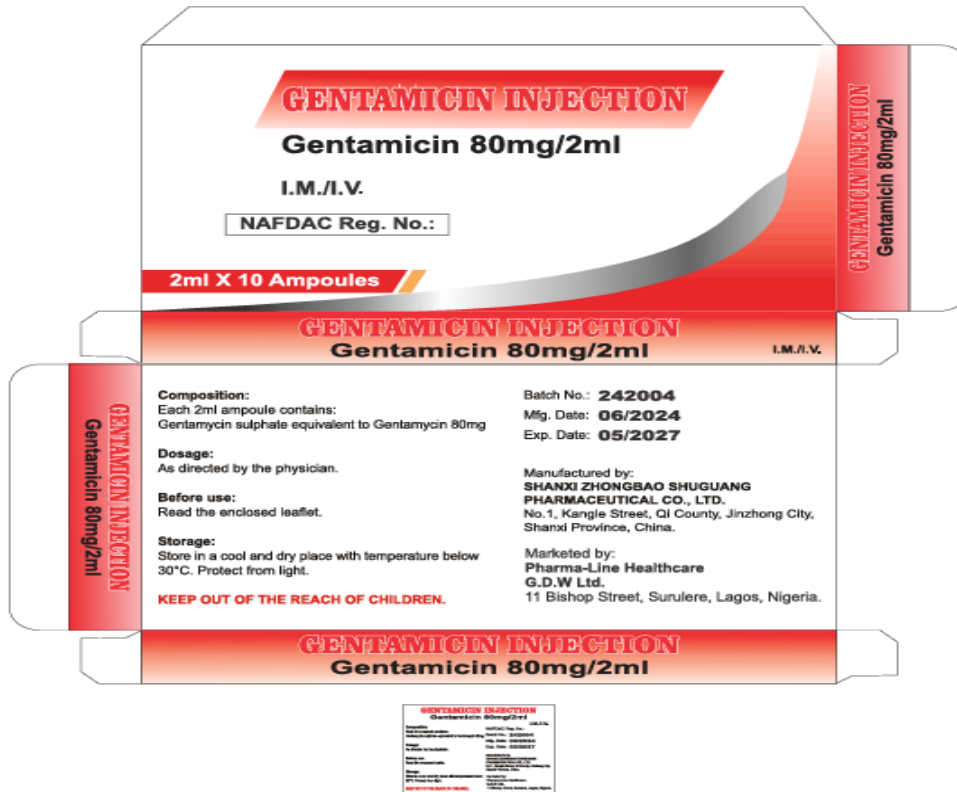
See: <https://greenbook.nafdac.gov.ng/>

PART 4: LABELLING

Primary label



Secondary label



PART 5: SCIENTIFIC DISCUSSION

5.1. About the Product

5.1.1 Name of the product

Gentamicin 80 mg/2 mL injection

5.1.2 Therapeutic indication

Gentamicin injection is indicated for the treatment of bacterial infections caused by susceptible gram-negative organisms, including septicemia, respiratory tract infections, urinary tract infections, and intra-abdominal infections.

5.1.3 Applicant

Pharma-Line Healthcare G.D.W Limited Agbor, No.11, Bishop Street, Off Agege Motor Road, Surulere, Lagos, Nigeria.

5.1.4 Pharmaceutical form

Injection

A clear/colourless solution in a glass ampoule.

5.1.5 Storage

Do not store above 30°C. Do not refrigerate or freeze. Store in the original package to protect from light.

5.1.6 Shelf life

36 months

5.1.7 Product presentation

Amber coloured glass ampoule available as 2 mL x 10 ampoules.

5.2 Drug Substance

5.2.1 Manufacturer

Gentamicin sulphate is manufactured by Yantai Justaware Pharmaceutical Co., Ltd, No 1, Yanfu Road, Zhifu District, Yantai City, Shandong Province P.R China.

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 gentamicin injection include anhydrous sodium sulfite, sodium bisulfite, disodium edetate and water for injection all being pharmacopoeial controlled. None of the excipients are derived from human or animal origin and TSE / BSE free certificates have been provided for the excipients.

5.4 Drug Product

5.4.1 Drug product manufacturer

Shanxi Zhongbao Shuguang Pharmaceutical Co. Limited, No 1, Kangle St., Qi County, Jinzhong City, Shanxi Province, P.R. Of China.

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, Gentalek 80mg injection, manufactured Lek Pharmaceuticals.

The manufacturing process used are steam sterilization and autoclaving.

5.4.3 Specification

The finished product specification is based on BP pharmacopoeial. The finished product specifications include identification by tlc and liquid chromatography, filling volume, pH, visible foreign matter, insoluble particles, bacterial endotoxin, sterile, 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. Do not refrigerate or freeze. Store in the original package to protect from light' have been accepted.

5.5 Conclusion

Based on the assessment of data submitted, the benefit–risk profile of gentamicin injection was acceptable for the following indication: ' for the treatment of bacterial infections caused by susceptible Gram-negative organisms, including septicaemia, respiratory tract infections, urinary tract infections, and intra-abdominal infections.', and is included in the list of approved medicinal products by NAFDAC.

PART 6: STEPS TAKEN FOR REGISTRATION

The applicant, Pharma-Line Healthcare G.D.W Limited, No. 11, Bishop Street, Off Agege Motor Road, Surulere, Lagos State, submitted application to the National Agency for Food and Drug Administration and Control (NAFDAC), for the registration of gentamicin.

The following are the steps for the registration of gentamicin

September 2024	Date of receipt of application
March 2025	Date of conclusion of assessment
April 2025	Date of inspection
18 December 2025	Date of issuance of Marketing Authorization

PART 7: STEPS TAKEN FOLLOWING REGISTRATION

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