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

Public Assessment Report (PAR)

Clindamycin 150 mg/mL injection

Clindamycin 150 mg/mL

A4-101902

All Starbase Pharm Limited

This report reflects the scientific assessment for the approval of Clindamycin injection. The product was licenced in January 2026.

PART 1: ABSTRACT

Clindamycin injection containing clindamycin phosphate, manufactured at Kamla Lifesciences Limited, Boisar, Maharashtra, India, was granted marketing authorization by NAFDAC for the treatment of infections caused by susceptible anaerobic bacteria and certain gram-positive organisms~~, including infections of the respiratory tract, skin and soft tissues, bone and joints, and intra-abdominal or pelvic infections~~ on 27 January, 2026.

Clindamycin injection is indicated for the treatment of infections caused by susceptible anaerobic bacteria and certain gram-positive organisms, including infections of the respiratory tract, skin and soft tissues, bone and joints, and intra-abdominal or pelvic 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 Clindamycin injection 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 Clindamycin 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 Clindamycin injection has been presented in Part 5 of this report.

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

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

PART 2: ACCEPTED PRESENTATIONS

Product Name	Active Ingredients	Pharmaceutical Form/Description	Packaging	Pack size
Clindamycin injection	Clindamycin phosphate 150 mg/mL	Liquid injection A clear colourless liquid filled in 5 mL amber ampoule	A clear colourless liquid filled in 5 mL amber ampoule. Available as 5 x 5 mL	5 x 5 mL

PART 3: SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

Refer to the NAFDAC Greenbook URL below for the SmPC

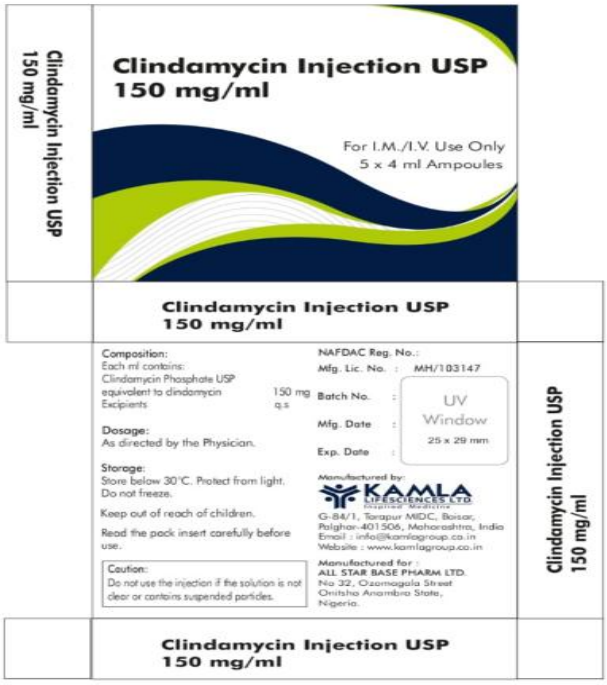
See: https://greenbook.nafdac.gov.ng/

PART 4: LABELLING

Primary label

Secondary label

Size-99 x 20 x 91 mm



PART 5: SCIENTIFIC DISCUSSION

5.1. About the Product

5.1.1 Name of the product

Clindamycin 150 mg/mL injection

5.1.2 Therapeutic indication

Clindamycin injection is indicated for the treatment of serious infections caused by susceptible anaerobic bacteria and certain gram-positive organisms, including infections of the respiratory tract, skin and soft tissues, bone and joints, and intra-abdominal or pelvic infections.

5.1.3 Applicant

All Star Base Pharm Limited, No 32, Ozomagala Street Onitsha, Anambra State, Nigeria

5.1.4 Pharmaceutical form

Liquid injection

A clear colourless liquid is filled in 5 mL amber ampoule

5.1.5 Storage

Do not store above 30°C. Protect from light.

5.1.6 Shelf life

24 months

5.1.7 Product presentation

A clear colourless liquid is filled in 5 mL amber Ampoule, such 5 ampoules. Available as 5 x 5mL ampoules.

5.2 Drug Substance

5.2.1 Manufacturer

Clindamycin phosphate is manufactured by Zhejiang Hisoar Chuannan Pharmaceutical Co Ltd, No. 23, Donghai 5th Avenue, Zhejiang Chemical Materials Base Linhai Zone, Linhai City, Zhejiang Province, China

The API specifications are pharmacopoeial and in-house 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 clindamycin injection include benzyl alcohol, disodium edetate, sodium hydroxide, water for injection all being pharmacopoeial controlled. None of the excipients are derived from human or animal origin.

5.4 Drug Product

5.4.1 Drug product manufacturer

Kamla Lifesciences Limited, Plot No. G-84/1, Tarapur M.I.D.C, Boisar-401 506, Tal. & Dist. Palghar, Maharashtra, 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, Dalacin C injection, manufactured by Pfizer, Belgium.

The manufacturing method used was dry sterilization and filtration.

5.4.3 Specification

The finished product specification is based on USP pharmacopoeial. The finished product specifications include identification by HPLC, pH, sterility, particulate matter, uniformity of volume, bacterial endotoxins, 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 ‘Do not store above 30°C. Protect from light’ have been accepted.

5.6 Conclusion

Based on the assessment of data submitted, the benefit–risk profile of clindamycin injection was acceptable for the following indication: ' for the treatment of serious infections caused by susceptible anaerobic bacteria and certain gram-positive organisms, including infections of the respiratory tract, skin and soft tissues, bone and joints, and intra-abdominal or pelvic infections.', and is included in the list of approved medicinal products by NAFDAC.

PART 6: STEPS TAKEN FOR REGISTRATION

The applicant, All Star Base Pharm Limited, No. 32, Ozomagala Street Onitsha Anambra State Nigeria, submitted application to the National Agency for Food and Drug Administration and Control (NAFDAC), for the registration of clindamycin injection.

The following are the steps for the registration of Clindamycin injection

March 2025	Date of receipt of application
January 2026	Date of conclusion of assessment
December 2025	Date of inspection
27 January, 2026	Date of issuance of Marketing Authorization

PART 7: STEPS TAKEN FOLLOWING REGISTRATION

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