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

Public Assessment Report (PAR)

Propofol 10 mg/mL injection

Propofol 10 mg/mL

A4-101748

Joviex Healthcare Limited

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

PART 1: ABSTRACT

Propofol injection manufactured at Kamla Lifesciences Limited, Palghar, Maharashtra, India, was granted marketing authorization by NAFDAC for the induction and maintenance of anaesthesia and for sedation in intensive care procedures on 26 November 2025.

Propofol injection is indicated for the induction and maintenance of anaesthesia and for sedation in intensive care procedures.

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

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

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

PART 2: ACCEPTED PRESENTATIONS

Product Name	Active Ingredients	Pharmaceutical Form/Description	Packaging	Pack size
Propofol 10 mg/mL injection	Propofol 10 mg/mL	Injection A milky white emulsion is filled in 20 mL flint tubular vial.	1x 20 mL flint tubular vial with 20 mm grey bromobutyl rubber plugs with 20 mm flip off aluminium seals.	1 x 20 mL

PART 3: SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

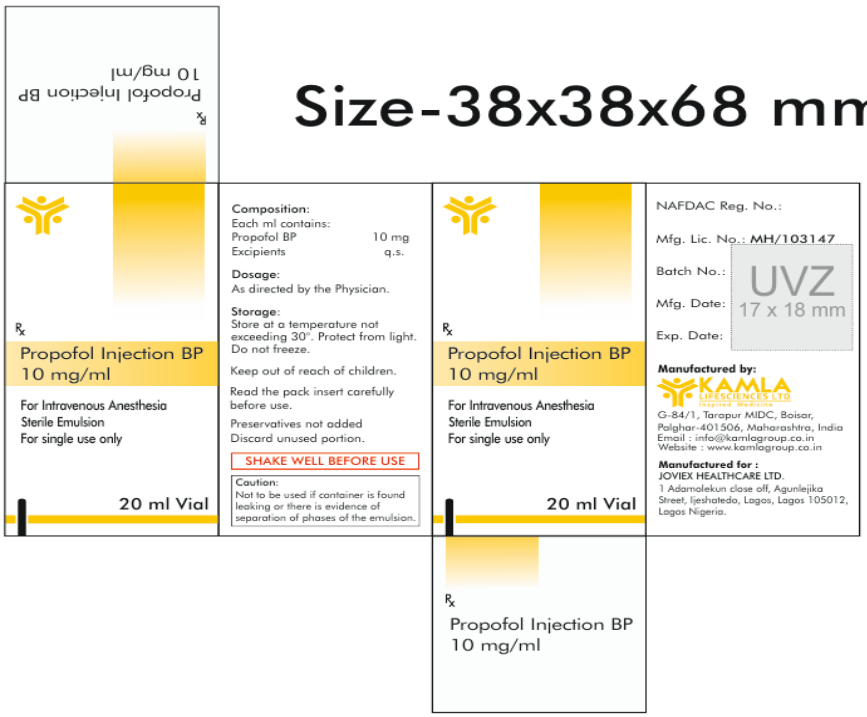
Refer to the NAFDAC Greenbook URL below for the SmPC

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

PART 4: LABELLING

Primary label

Secondary label



PART 5: SCIENTIFIC DISCUSSION

5.1. About the Product

5.1.1 Name of the product

Propofol 10 mg/mL injection

5.1.2 Therapeutic indication

Propofol injection is indicated for the induction and maintenance of anaesthesia and for sedation in intensive care procedures.

5.1.3 Applicant

Joviex Healthcare Limited, 1 Adamolekun close, off Agunlejika Street, Ijeshatedo, Lagos state.

5.1.4 Pharmaceutical form

A milky white emulsion filled in a 20 mL flint tubular vial.

5.1.5 Storage

Do not store above 30°C, protect from light.

5.1.6 Shelf life

18 months

5.1.7 Product presentation

Propofol injection is presented as a 20 mL flint tubular vial with 20 mm grey bromobutyl rubber plugs with 20 mm flip off aluminium seals containing a milky white emulsion, which is sealed and packed in a printed mono carton.

5.2 Drug Substance

5.2.1 Manufacturer

The active ingredient, propofol, is manufactured by Neuland Laboratories Limited, Unit-II, Plot No: 92, 93, 94, 257, 258, 259 Industrial Development Authority, Pashamylaram, Isnapur, Patancheru Mandal, Sangareddy District - 502 319 Telangana, 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 propofol injection include refined soya oil BP, egg lecithin 80% (Lipoid E 800) USP, glycerol BP, disodium edetate BP, sodium hydroxide BP, and water for injection BP, 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, G-84/1, Tarapur, Mumbai Indira Dandekar City, Boisar District – Palghar, Maharashtra 401506, India.

5.4.2 Pharmaceutical development

The objective of the pharmaceutical development is to manufacture a generic which is stable, delivers the intended performance, and is safe, in terms of efficacy to the reference product Diprivan currently licensed by Fresenius Kabi, United States of America.

The manufacturing method used was aseptic and involved steam sterilization, depyrogenation of vials, and 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 description, identification by infrared, pH, acidity and alkalinity, impurity, free fatty acid, lysolecithin, extractable volume, bacterial endotoxins, sterility, globule size 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 18 months and ‘Do not store above 30°C, protect from light’ have been accepted.

5.5 Conclusion

Based on the assessment of data submitted, the benefit–risk profile of propofol injection was acceptable for the following indication: 'for the induction and maintenance of anaesthesia and for sedation in intensive care procedures', and is included in the list of approved medicinal products by NAFDAC.

PART 6: STEPS TAKEN FOR REGISTRATION

The applicant, Joviex Healthcare Limited, 1 Adamolekun close, off Agunlejika Street, Ijeshatedo, Lagos state, submitted an application to the National Agency for Food and Drug Administration and Control (NAFDAC), for the registration of propofol injection.

The following are the steps for the registration of propofol injection

January 2025	Date of receipt of application
November 2025	Date of conclusion of assessment
June 2025	Date of inspection
26 November 2025	Date of issuance of Marketing Authorization

PART 7: STEPS TAKEN FOLLOWING REGISTRATION

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