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

Public Assessment Report (PAR)

Harvad Ketamine 50 mg/mL injection

Ketamine 50 mg/mL

A4-101507

Harvad Pharmaceutica Co Ltd

This report reflects the scientific assessment for the approval of Harvad Ketamine injection**.** The product was licenced in August 2025.

PART 1: ABSTRACT

Harvad Ketamine injection containing Ketamine 50 mg/mL, manufactured at Alpa Laboratories Limited, Indore (MP), India, was granted marketing authorization by NAFDAC as an anesthetic agent for diagnostic and surgical procedures on 27 August 2025.

Harvad Ketamine 50 mg/mL injection is indicated for as an aesthetic agent for diagnostic and surgical procedures in adults and children.

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 Harvard Ketamine 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 Harvard Ketamine 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 Harvad Ketamine has been presented in part 5 of this report.

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

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

PART 2: ACCEPTED PRESENTATIONS

Product Name	Active Ingredients	Pharmaceutical Form/Description	Packaging	Pack size
Harvad Ketamine	Ketamine 50 mg/mL	Solution for injection Clear and colourless solution	10 mL tubular glass vials with 20 mm rubber stoppers and 20 mm sky blue flip of seals	1 x 10 mL vial

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

Harvad Ketamine 50 mg/mL injection

5.1.2 Therapeutic indication

Harvad Ketamine 50 mg/mL injection is indicated for as an aesthetic agent for diagnostic and surgical procedures in adults and children.

5.1.3 Manufacturer/applicant

Harvad Pharmaceutical Company Ltd, 20, Jayeola Abidoye Street, Thomas Estate, Lekki, Lagos

5.1.4 Pharmaceutical form

Solution for injection

Clear and colourless solution

5.1.5 Storage

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

5.1.6 Shelf life

36 months

5.1.7 Product presentation

Harvad Ketamine is presented in 10 mL tubular glass vials with 20 mm rubber stoppers and 20 mm sky blue flip of seals. Available in 1 x 10 mL vial

5.2 Drug Substance

5.2.1 Manufacturer

Ketamine hydrochloride is manufactured by Supriya Lifescience Ltd, A-5/2, Lote Parshuram Industrial Area, M.I.D.C, Taluka – Khed, District – Ratnagiri, Maharashtra – 415 722, 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 Harvad Ketamine include Benzethonium chloride, a preservative agent and Sodium hydroxide as alkalizing agent all of pharmacopoeial grade.

5.4 Drug Product

5.4.1 Drug product manufacturer

Alpa Laboratories Limited, 33/2 A.B Road, Pig Amber, Indore (MP)-India.

5.4.2 Pharmaceutical development

The excipients Harvad Ketamine injection was manufactured using sterile filtration method. The excipients used were optimized and compactible with the active ingredients.

5.4.3 Specification

The finished product specification is based on pharmacopoeial. The finished product specifications include description, identification by UV, assay, pH, extractable volume, particulate matter, sterility bacteria endotoxin test and related substances. 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. Protect from light' have been accepted.

5.6 Conclusion

Based on the assessment of data on quality, bioequivalence, safety and efficacy, the benefit–risk profile of Harvad Ketamine was acceptable for the following indication: 'as an aesthetic agent for diagnostic and surgical procedures in adults and children', and is included in the list of approved medicinal products by NAFDAC.

PART 6: STEPS TAKEN FOR REGISTRATION

The applicant, Harvad Pharmaceutical Company Ltd, 20, Jayeola Abidoye Street, Thomas Estate, Lekki, Lagos, submitted application to the National Agency for Food and Drug Administration and Control (NAFDAC), for the registration of Harvad Ketamine.

The following are the steps for the registration of Harvad Ketamine

September 2024	Date of receipt of application
May 2025	Date of conclusion of assessment
April 2025	Date of inspection
27 August 2025	Date of issuance of Marketing Authorization

PART 7: STEPS TAKEN FOLLOWING REGISTRATION

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