



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

Public Assessment Report (PAR)

Isoflurane liquid inhalation 99.9%

Isoflurane 99.9%

A4-101718

Smart Way Pharma Limited

This report reflects the scientific assessment for the approval of Isoflurane liquid inhalation. The product was licenced in November 2025

PART 1: ABSTRACT

Isoflurane liquid inhalation containing isoflurane, manufactured at Acidima International Trading, October city, Egypt, was granted marketing authorization by NAFDAC for the induction and maintenance of general anesthesia on 26 November 2025

Isoflurane liquid inhalation is indicated for the induction and maintenance of general anesthesia.

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 isoflurane liquid inhalation 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 isoflurane liquid inhalation 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 isoflurane liquid inhalation has been presented in Part 5 of this report.

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

No action or steps have been taken following the marketing authorization of isoflurane liquid inhalation.

PART 2: ACCEPTED PRESENTATIONS

Product Name	Active Ingredients	Pharmaceutical Form/Description	Packaging	Pack size
Isoflurane liquid inhalation	Isoflurane 99.9%	Clear colourless volatile non-flammable liquid in amber glass bottle	250 mL USP Type III amber glass bottle with purple polypropylene cap	1 x 250 mL

PART 3: SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

Refer to the NAFDAC Greenbook URL below for the SmPC

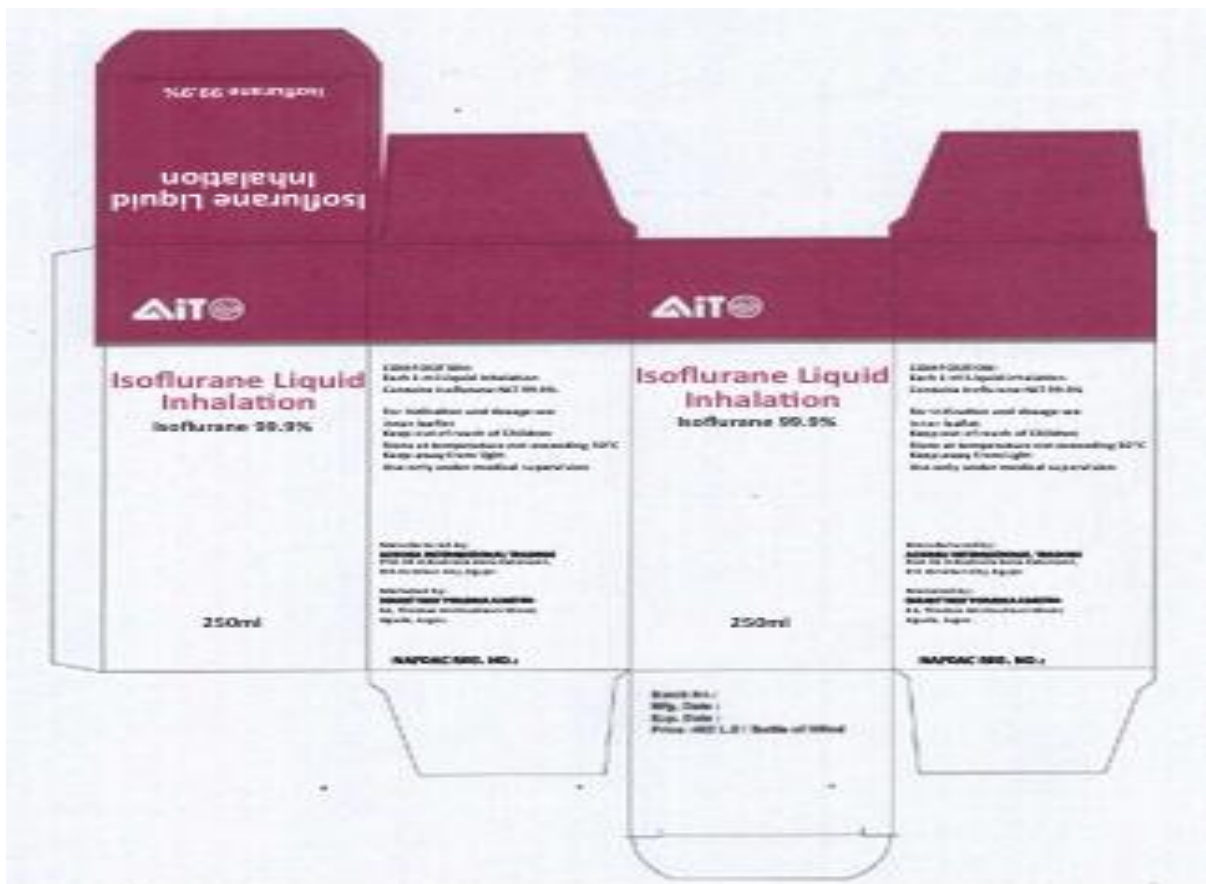
See: <https://greenbook.nafdac.gov.ng/>

PART 4: LABELLING

Primary label



Secondary label



PART 5: SCIENTIFIC DISCUSSION

5.1. About the Product

5.1.1 Name of the product

Isoflurane liquid inhalation 99% v/v

5.1.2 Therapeutic indication

Isoflurane liquid inhalation is indicated for the induction and maintenance of general anaesthesia.

5.1.3 Applicant

Smart Way Pharma Limited, No 61, Thomas Animashaun Street, Aguda, Surulere, Lagos State, Nigeria.

5.1.4 Pharmaceutical form

A clear colourless volatile non-flammable liquid in amber glass bottle.

5.1.5 Storage

Do not store above 30°C.

5.1.6 Shelf life

36 months

5.1.7 Product presentation

Isoflurane liquid inhalation is a clear colourless volatile non-flammable liquid filled in a USP Type III amber glass bottle with purple polypropylene cap.

5.2 Drug Substance

5.2.1 Manufacturer

Isoflurane is manufactured by Piramal Pharma Limited, Sy. Nos. 7 – 70, 70/1 & 70/2, Digwal (V), Kohir (M). Sangareddy (D), Telangana State, 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

There are no other ingredients used in the formulation of isoflurane liquid inhalation.

5.4 Drug Product

5.4.1 Drug product manufacturer

Acidima International Trading, Plot No 41 Industrial Zone Extension, 6th October City, Egypt.

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, Forane injection manufactured by Baxter International Inc., USA.

The product is manufactured by an aseptic filtration and filling process following the sterilization/ depyrogenation of the processing equipment and accessories, filters and packaging materials. All the manufacturing processes were validated.

5.4.3 Specification

The finished product specification is based on in-house. The finished product specifications include description, identification, fill volume, related substances, particulate matter, water, related substances (fluorides, chlorides), assay if isoflurane, limit of non-volatile residue and microbiology analysis. 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' have been accepted.

5.6 Conclusion

Based on the assessment of data submitted, the benefit–risk profile of Isoflurane liquid inhalation was acceptable for the following indication: 'for the induction and maintenance of general anaesthesia', and is included in the list of approved medicinal products by NAFDAC.

PART 6: STEPS TAKEN FOR REGISTRATION

The applicant, Smart Way Pharma Limited, no. 61, Thomas Animashaun Street, Aguda, Surulere, Lagos State, Nigeria, submitted application to the National Agency for Food and Drug Administration and Control (NAFDAC), for the registration of Isoflurane liquid inhalation.

The following are the steps for the registration of isoflurane liquid inhalation

August 2024	Date of receipt of application
September 2025	Date of conclusion of assessment
August 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 isoflurane liquid inhalation