



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

Public Assessment Report (PAR)

AMA Dextrose intravenous infusion 10.0% w/v

Dextrose monohydrate BP 10g

A11-100658

AMA Medical Manufacturing Limited

This report reflects the scientific assessment for the approval of Ama Dextrose intravenous infusion. The product was licenced in March 2025.
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PART 1: ABSTRACT

AMA Dextrose intravenous infusion, a sterile, non-pyrogenic intravenous fluid preparation containing 10g of anhydrous dextrose BP equivalent to dextrose monohydrate BP in every 100 mL of water for injection, manufactured at AMA Medical Manufacturing Limited, Kaduna State, Nigeria, was granted marketing authorization by NAFDAC for the replacement of body fluid, electrolytes and acid/base imbalance on 27 March 2025.

AMA Dextrose intravenous infusion is indicated for the replacement of body fluid, electrolytes and acid/base imbalance. 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 AMA Dextrose intravenous infusion 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 AMA Dextrose intravenous infusion 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 AMA Dextrose intravenous infusion has been presented in Part 5 of this report.

The detailed steps taken to approve AMA Dextrose intravenous infusion by NAFDAC have been presented in part 6 of this report.

No action or steps have been taken following the marketing authorization of AMA Dextrose intravenous infusion.

PART 2: ACCEPTED PRESENTATIONS

Product Name	Active Ingredients	Pharmaceutical Form/Description	Packaging	Pack size
AMA Dextrose intravenous infusion 10.0% w/v	Anhydrous dextrose BP equivalent to Dextrose monohydrate BP 10g.	An intravenous infusion containing a clear colourless solution.	Polypropylene pouch overwrapped in LDPE wrapper.	1000 mL

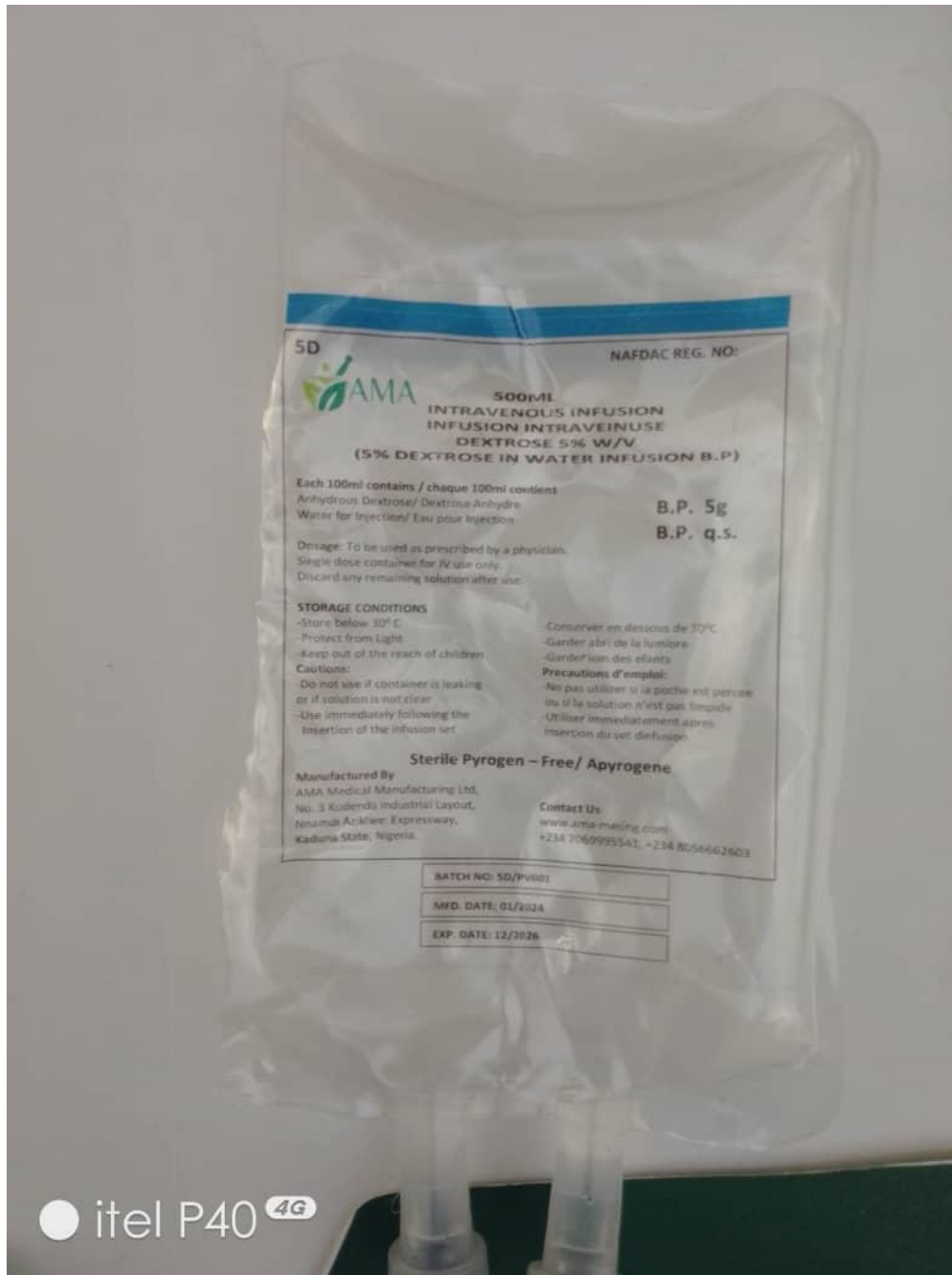
PART 3: SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

Refer to the NAFDAC Greenbook URL below for the SmPC

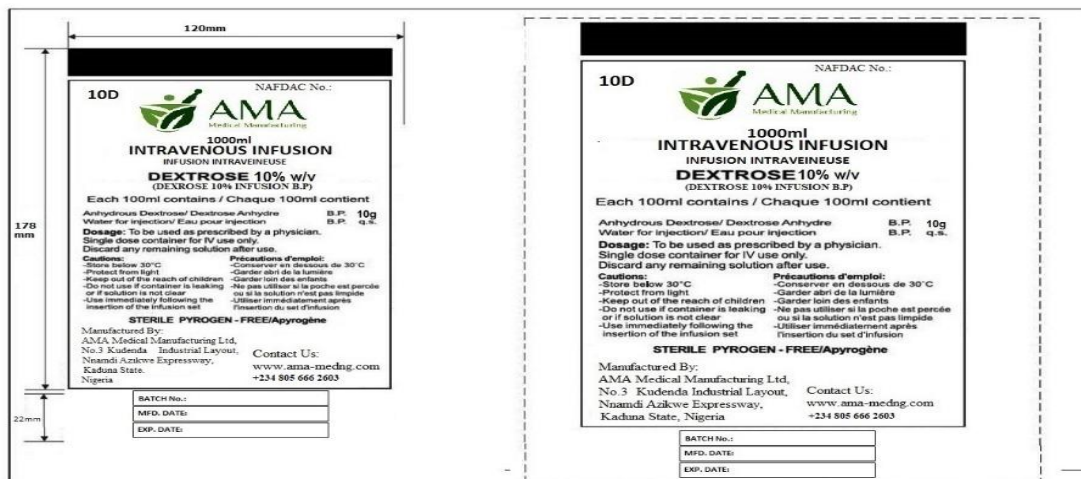
See: <https://greenbook.nafdac.gov.ng/>

PART 4: LABELLING

Primary label



Secondary label



PART 5: SCIENTIFIC DISCUSSION

5.1. About the Product

5.1.1 Name of the product

AMA Dextrose intravenous infusion 10.0% w/v

5.1.2 Therapeutic indication

AMA Dextrose intravenous infusion is used for the replacement of body fluid, electrolytes and acid/base imbalance.

5.1.3 Applicant

AMA Medical Manufacturing Limited. No.3 Kudenda Industrial Layout, Nnamdi Azikwe Express Way, Kaduna State, Nigeria.

5.1.4 Pharmaceutical form

An intravenous infusion containing a clear colourless solution.

5.1.5 Storage

Do not store above 30°C.

5.1.6 Shelf life

24 months

5.1.7 Product presentation

AMA Dextrose intravenous infusion is presented as 1000 ml in a polypropylene pouch overwrapped in LDPE wrapper containing a clear colourless solution.

5.2 Drug Substance

5.2.1 Manufacturer

Roquette Freres, 1, Rue De La Haute Loge 62136 Lestrem – France.

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 AMA Dextrose intravenous infusion include water for injection.

5.4 Drug Product

5.4.1 Drug product manufacturer

AMA Medical Manufacturing Limited. No.3 Kudenda Industrial Layout, Nnamdi Azikwe Express Way, Kaduna State, Nigeria.

5.4.2 Pharmaceutical development

The objective of the pharmaceutical development is to produce a safe, effective, stable, and high-quality product that consistently delivers the intended therapeutic effect as the reference product, Dana Dextrose 10% w/v, manufactured by Dana Pharmaceutical Limited.

The manufacturing method used superheated water spray system of sterilization done at 121°C (NMT ±2) for 15 ± 2 minutes at 1.5 – 2.0 bar and filtration method. All the manufacturing processes were validated.

5.4.3 Specification

The finished product specification is based on BP monograph. The finished product specifications include identification by IR & TLC, acidity/alkalinity pH test, inspection level code, critical reject limit, major reject limit, minor reject limit, bacterial endotoxin test, sterility, particulate matter, related substances, 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 24 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 AMA Dextrose intravenous infusion was acceptable for the following indication: 'for the replacement of body fluid, electrolytes and acid/base imbalance', and is included in the list of approved medicinal products by NAFDAC.

PART 6: STEPS TAKEN FOR REGISTRATION

The applicant, AMA Medical Manufacturing Limited. No.3 Kudenda Industrial Layout, Nnamdi Azikwe Express Way, Kaduna State, Nigeria, submitted application to the National Agency for Food and Drug Administration and Control (NAFDAC), for the registration of AMA Dextrose intravenous infusion.

The following are the steps for the registration of AMA Dextrose

February 2024	Date of receipt of application
February 2025	Date of conclusion of assessment
August 2024	Date of inspection
27 March 2025	Date of issuance of Marketing Authorization

PART 7: STEPS TAKEN FOLLOWING REGISTRATION

No action or steps have been taken following marketing authorization of AMA Dextrose intravenous infusion.