



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

Public Assessment Report (PAR)

AMA I.V Dextrose 5% w/v in normal saline 0.9% w/v infusion

Dextrose anhydrous 5.0% w/v and sodium chloride 0.9% w/v

A11-100654

AMA Medical Manufacturing Limited

This report reflects the scientific assessment for the approval of AMA I.V Dextrose 5% w/v in normal saline 0.9% w/v. The product was licenced in October 2024.

PART 1: ABSTRACT

AMA I.V Dextrose 5% w/v in normal saline 0.9% w/v containing dextrose anhydrous and sodium chloride, manufactured at AMA Medical Manufacturing Limited, Kudenda, Kaduna, Nigeria, was granted marketing authorization by NAFDAC for the management and treatment of electrolyte and acid/base imbalance on 05 October 2024

AMA I.V Dextrose 5% w/v in normal saline 0.9% w/v is indicated for management and treatment of electrolyte 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 I.V Dextrose 5% w/v in normal saline 0.9% w/v 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 I.V Dextrose 5% w/v in normal saline 0.9% w/v 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 I.V Dextrose 5% w/v in normal saline 0.9% w/v has been presented in Part 5 of this report.

The detailed steps taken to approve AMA I.V Dextrose 5% w/v in normal saline 0.9% w/v by NAFDAC have been presented in part 6 of this report.

No action or steps have been taken following the marketing authorization of AMA I.V Dextrose 5% w/v in normal saline 0.9% w/v.

PART 2: ACCEPTED PRESENTATIONS

Product Name	Active Ingredients	Pharmaceutical Form/Description	Packaging	Pack size
AMA I.V Dextrose 5% w/v in normal saline 0.9% w/v infusion	Dextrose anhydrous 5.0% w/v and sodium chloride 0.9% w/v	Colourless odourless non-viscous non-volatile intravenous solution in a polypropylene pouch	Flexible polypropylene pouch overwrapped in LDPE wrapper	40 x 250 mL, 20 x 500 mL, 10 x 1000 mL

PART 3: SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

Refer to the NAFDAC Greenbook URL below for the SmPC

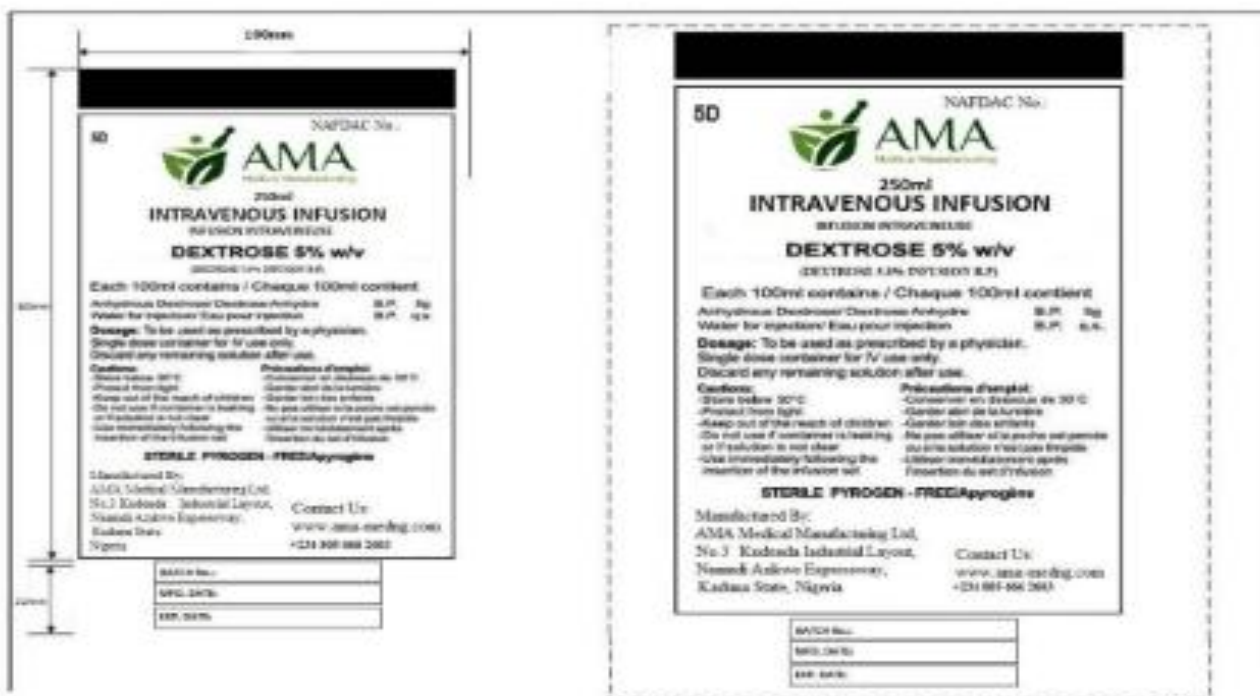
See: <https://greenbook.nafdac.gov.ng/>

PART 4: LABELLING

Primary label



Secondary label



PART 5: SCIENTIFIC DISCUSSION

5.1. About the Product

5.1.1 Name of the product

AMA I.V Dextrose 5% w/v in normal saline 0.9% w/v infusion.

5.1.2 Therapeutic indication

AMA I.V Dextrose 5% w/v in normal saline 0.9% w/v is used in the management and treatment of electrolyte and acid/base imbalance

5.1.3 Applicant

AMA Medical Manufacturing Limited, No.3 Kaduna Industrial Layout, Nnamdi Azikiwe Expressway, Kudenda, Kaduna, Nigeria.

5.1.4 Pharmaceutical form

Colourless odourless non-viscous non-volatile intravenous solution in a polypropylene pouch

5.1.5 Storage

Store below 30°C, protect from light, do not refrigerate.

5.1.6 Shelf life

36 months

5.1.7 Product presentation

AMA I.V Dextrose 5% w/v in normal saline 0.9% w/v is a colourless, odourless, non-viscous, non-volatile intravenous solution filled in a flexible polypropylene pouch overwrapped in LDPE wrapper

5.2 Drug Substance

5.2.1 Manufacturer

Dextrose anhydrous is manufactured by Roquette Freres, 1, rue de la haute Loge, Lestrem – France; and sodium chloride manufactured by K+S Minerals and Agriculture GmbH, Werk Borth, Karlstraße, Rheinberg, Germany.

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 I.V Dextrose 5% w/v in normal saline 0.9% w/v include water for injection.

5.4 Drug Product

5.4.1 Drug product manufacturer

AMA Medical Manufacturing Limited, No.3 Kaduna Industrial Layout, Nnamdi Azikwe Expressway, Kudenda, Kaduna, Nigeria

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 in the British Pharmacopoeia.

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 pharmacopoeial. The finished product specifications include identification, Ph, assay, particulate count, bacterial endotoxin and sterility test. 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 'Store below 30°C, protect from light, do not refrigerate' have been accepted.

5.5 Conclusion

Based on the assessment of data submitted, the benefit–risk profile of AMA I.V Dextrose 5% w/v in normal saline 0.9% w/v was acceptable for the following indication: 'for the management and treatment of electrolyte 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 Kaduna Industrial Layout, Nnamdi Azikwe Expressway, Kudenda, Kaduna, Nigeria, submitted application to the National Agency for Food and Drug Administration and Control (NAFDAC), for the registration of AMA I.V Dextrose 5% w/v in normal saline 0.9% w/v.

The following are the steps for the registration of AMA I.V Dextrose 5% w/v in normal saline 0.9% w/v.

July 2023	Date of receipt of application
August 2024	Date of conclusion of assessment
August 2024	Date of inspection
5 October 2024	Date of issuance of Marketing Authorization

PART 7: STEPS TAKEN FOLLOWING REGISTRATION

No action or steps have been taken following marketing authorization of AMA I.V Dextrose 5% w/v in normal saline 0.9% w/v infusion