EVERY KNEE SHALL BOW
EVERY TONGUE SHALL CONFESS
(Phil. 2 : 10 - 11)

STANDARDIZATION OF HERBAL MEDICINAL PRODUCTS

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HerbFEST 2013, ABUJA **8 - 10 OCTOBER 2013**

INTRODUCTION

DEFINITION OF STANDARDIZATION OF HERBAL PRODUCT

- The **European Medicines Agency's** definition says:

  Standardization of herbal product is **the process of** herbal drug preparation to a defined content of constituents or group of substances, with known therapeutic activity, which can be used to standardize a biological effect or a chemical marker compound

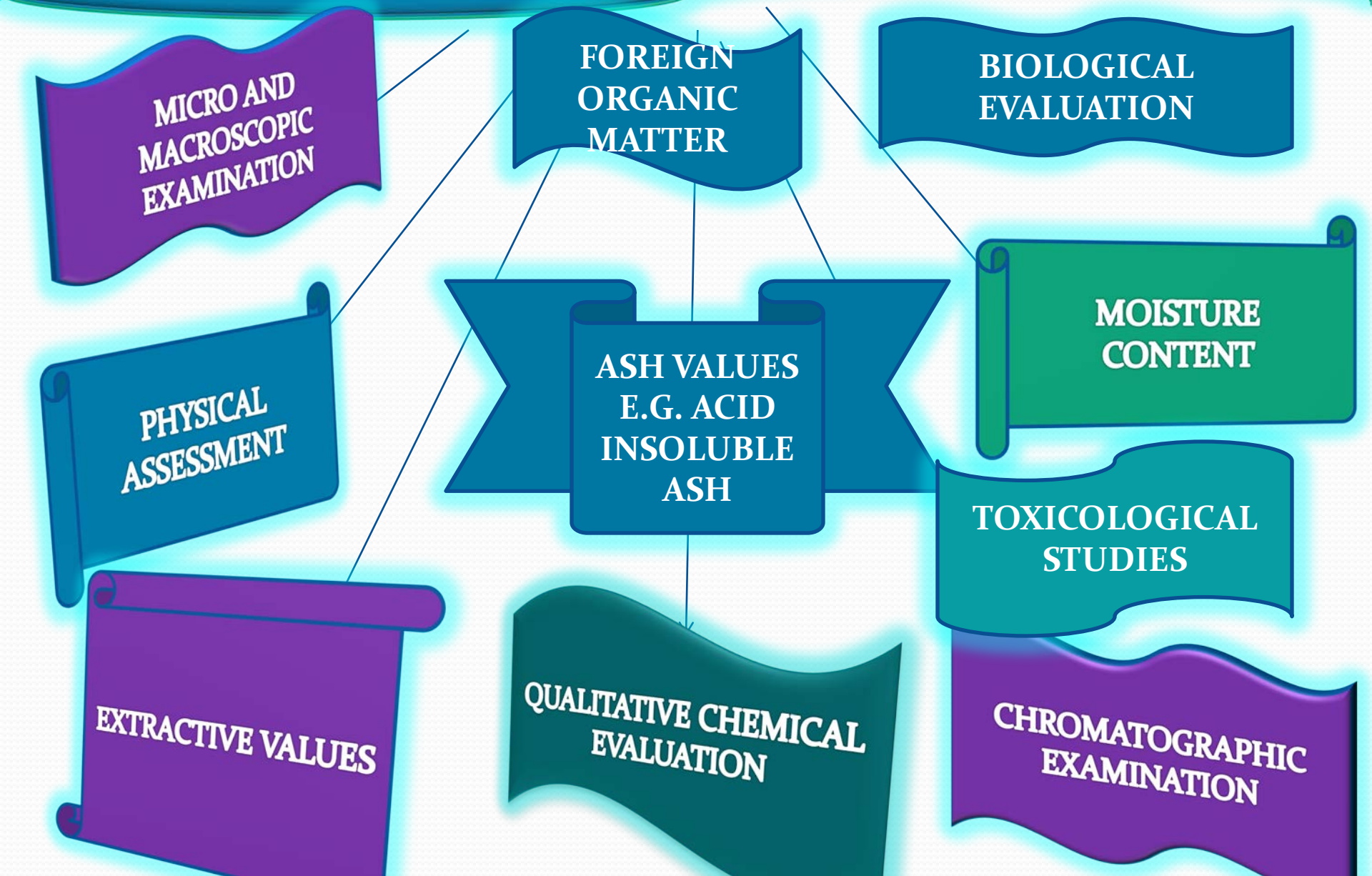
MY OWN DEFINITION IS:

Standardization **of medicinal plant or herbal product is a process of establishing a group of data representing the inherent or in-burn identities, family & ancestral qualities, peculiar appearances, unique and unshared features, private and specific characteristics, definite and constant qualitative as well as quantitative values all of which are referred to as the official standards for the plant or herbal product**

WHY STANDARDIZATION

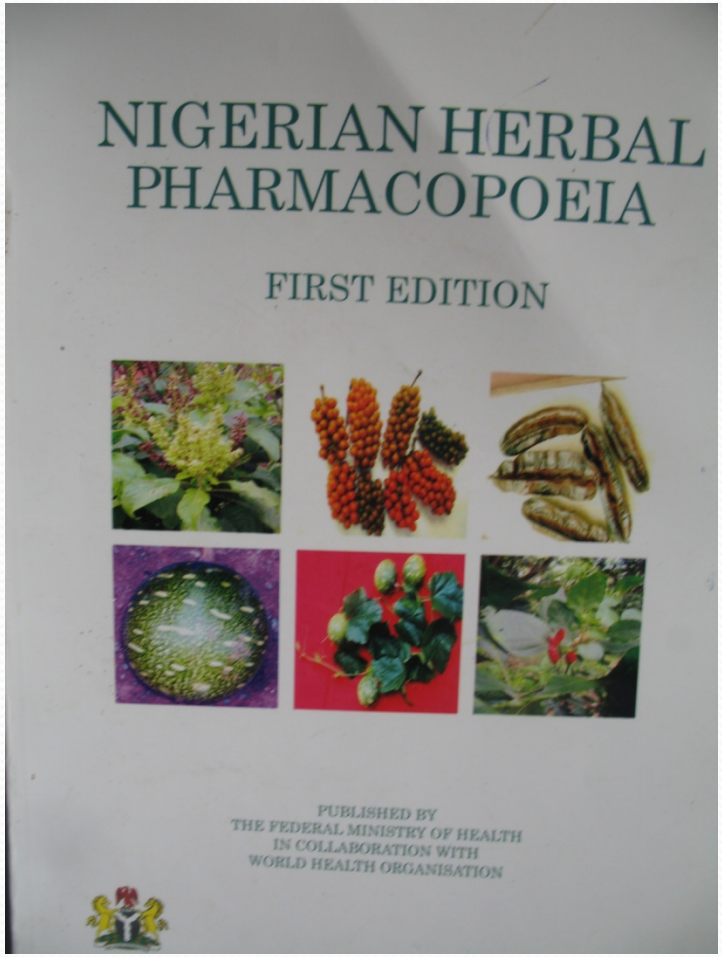
- ENSURES SAFETY
- MAINTAINS EFFICACY
- PROVIDES EVALUATION TOOLS
- PROVIDES QUALITY CONTROL TOOLS
- IMPROVES CONSUMER ACCEPTABILITY
- FACILITATES REPEATABILITY & REPRODUCIBILITY
- FOR TRACKING CRUDE DRUG ADULTERATION

SOME STANDARDS FOR MEDICINAL PLANT MONOGRAPHS (WHO 1996)

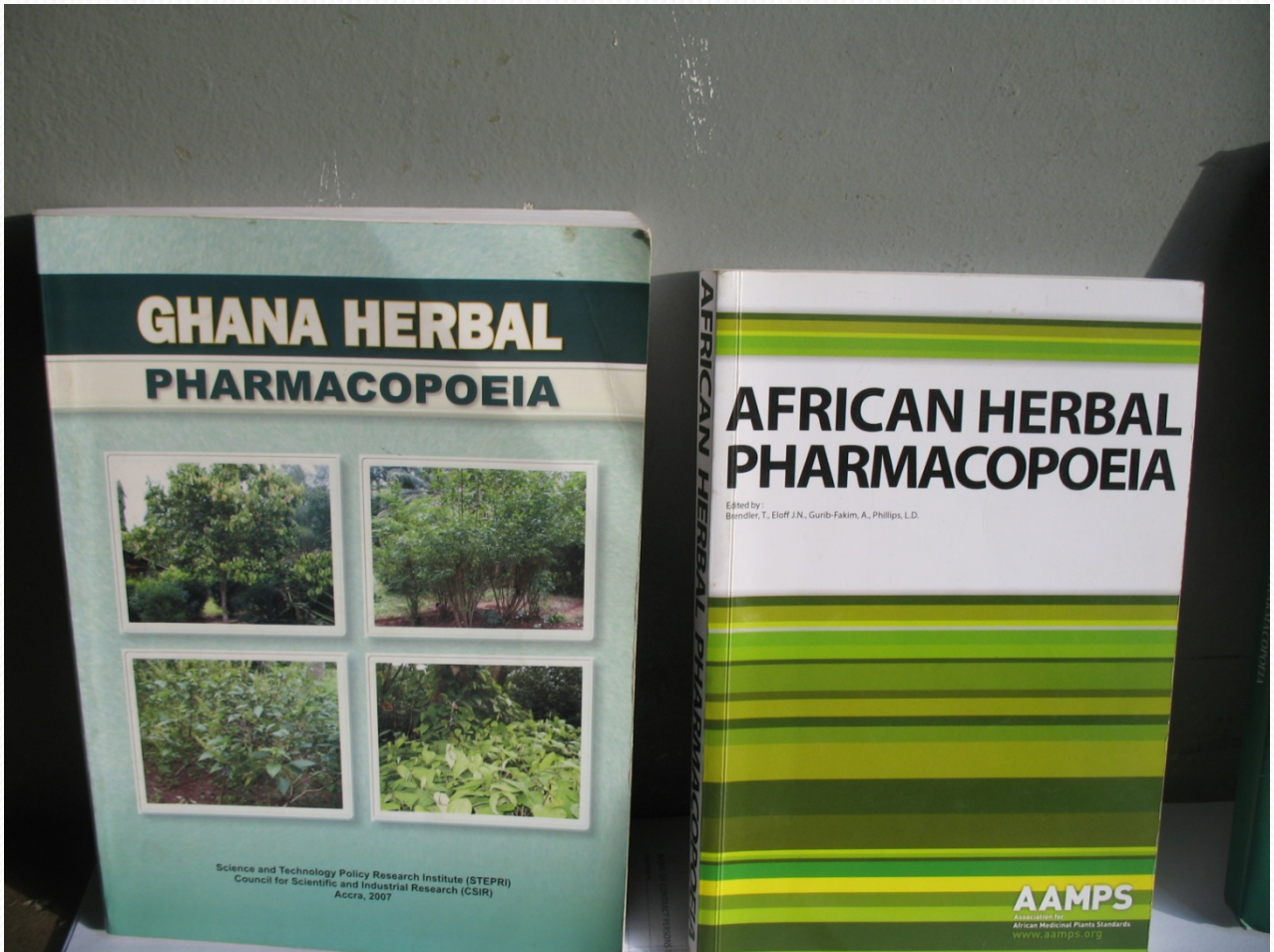


- **STANDARDS ARE BROUGHT ABOUT BY THE PROCESS OF STANDARDIZATION**
- **AN ASSEMBLY OF SEVERAL STANDARDS MAKE UP A MEDICINAL PLANT MONOGRAPH**
- **AND SEVERAL MEDICINAL PLANT MONOGRAPHS CONSTITUTE A NATIONAL, SUB-REGIONAL OR REGIONAL HERBAL PHARMACOPOEIA**

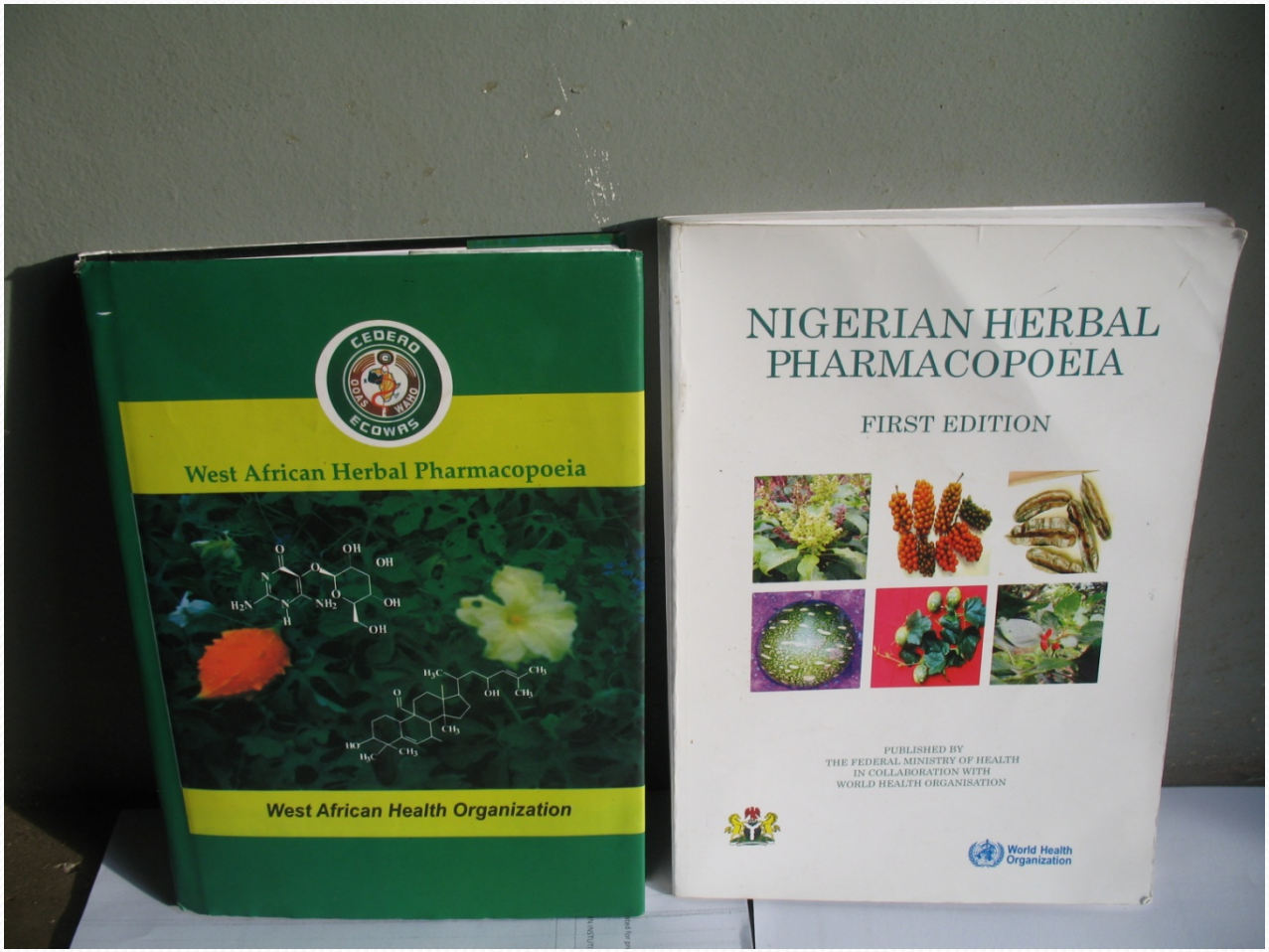
THE NIGERIAN HERBAL PHARMACOPOEIA (NHP, 2008) ……41 plant monographs



GHANA HERBAL PHARMACOPOEIA (GHP,1993 & 2007) AND AFRICAN HERBAL PHARMACOPOEIA (AfriHP,2007)



WEST AFRICAN HERBAL PHARMACOPOEIA (WAHP, 2013)…….54 plant monographs



WE MUST SERIOUSLY START TALKING OF FINISHED PRODUCT MONOGRAPHS IN NIGERIA

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THE VILLAGE CHEMIST PRODUCTS AS MODEL

VILLAGE CHEMIST FORMULATION & PACKAGING ROOM

FINISHED HERBAL MEDICINAL PRODUCTS MUST ALSO BE STANDARDIZED FOR THEIR MONOGRAPHS

MAMA DECOCTION MODERN BOILER AND STORAGE TANK

MAMA DECOCTION MODERN EXTRA TANKS AND BOTTLING MACHINE

TIPS FOR STANDARDIZATION OF FINISHED HERBAL MEDICINAL PRODUCTS 1

- Explore standards of each of the plant components e.g. physical, botanical, chemical & biological, etc
- Optimize & Maintain best preparation method
- Describe & Use color, taste & smell @ each level of the production line
- Describe micro-chemical test s & colour formation
- Describe chemical index for quality control and for NAFDAC validation
- Describe biological index for quality control and for NAFDAC validation
- Find & Maintain the most active plant formulation ratios

FURTHER TIPS FOR STANDARDIZATION OF FINISHED HERBAL MEDICINAL PRODUCTS 2

- Documentation and use of the fingerprint spectra of the finished product e.g. TLC, HPLC, UV/VIS for quality control and for NAFDAC validation
- Description & provision of *minimum, maximum* and *toxic* dose levels

- All of these standards will form the monograph for the herbal medicinal product
- One or more standards can stand for quality control and evaluation tool for finished products

EXAMPLES FROM THE VILLAGE CHEMIST

(1). SENNA ALATA LEAF (2). DATURA METEL

- *Alata Tea bag (laxative)*
- Bontrager -color reaction for anthraquinon content
- Biologic Senna-Equivalent as bioactivity index in rats
- % total Sennoside content calculated as Sennoside A by colorimetry
- TLC & Microscopic fingerprints

- *Daturine Tablet(antiplasmo)*
- Alkaloidal colour reaction as spot-test detection
- % total alkaloids calculated as hyoscyamine by HPLC
- % total alkaloids calculated as hyoscyamine by colorimetry
- TLC & **Microscopic** fingerprints

EXAMPLES FROM THE VILLAGE CHEMIST

(3)MAMA ANTIMALARIAL PAEDIATRIC SYRUP

EXAMPLES FROM THE VILLAGE CHEMIST

(3). MAMA SYRUP STANDARDS FOR EVALUATION & QUALITY CONTROL

- **Using TLC Fingerprints**

MAMA Syrup: R_f = 0.32, 0.59, 0.65, 0.74, 0.79, **0.90**

Plant A: R_f = 0.38, 0.60, 0.68, 0.75, 0.82, **0.91**

Plant B: R_f = 0.47, 0.56, 0.63, 0.72, 0.81, **0.91**

Reference Compound =R_f **0.91**

- **Using HPLC Fingerprints**

MAMA Syrup: R_t =1.18(14.9%), 1.30 (6.75%), 1.40(18.5%), 1.70(5.6%), 1.79(14.6%), 2.23 (15.9%), 2.58(5.1%), 3.19(14.6%), 3.68(4%) = 9pks

Plant A: R_t = 1.16

Plant B: R_t = 1.17(23%), 1.53(15.1%),1.78(39.2%), 2.18(17.8%), 2.95(2.1%), 3.56(2.8%) = 6pks

Reference compound R_t =1.17

EXAMPLES FROM THE VILLAGE CHEMIST

(4) MAMA ANTIMALARIAL DECOCTION

EXAMPLES FROM THE VILLAGE CHEMIST

EFFECTS OF PLANT FORMULATION RATIO ON ANTIMALARIAL ACTIONS OF MAMA DECOCTION

- MAMA (1:1:1:1 chemo-suppressive & curative)**
- MAMA-3 (2:2:2:1 chemo-suppressive & curative)
- MAMA-1 (1:2:2:2 curative & prophylactic)
- MAMA-2 (2:1:2:2 curative ALONE)(least useful)
- MAMA-4 (1:1:2:2 prophylactic ALONE)

PLAYING WITH RATIOS AMONG FOUR DIFFERENT PLANTS, FOUR CLASSES OF ANTIMALARIALS & FIVE PRODUCTS WERE FORMULATED & DEVELOPED

EFFORCEMENT OF STANDARDIZATION ETHICS

"SOME KEY REQUIREMENTS "

- NAFDAC staff & herbal producers should be trained regularly on current herbal standardization tools
- NAFDAC should classify registration requirements into: Pharmacognostical Standards (PSD), Safety (SSD), Quality (QSD) Chemical (CSD) & Biol.(BSD
- NAFDAC should adapt & be trained on various ECOWAS tools for herbal regulation & must be in constant training dialogue with herbal producers
- NAFDAC to regularly communicate the ethics of herbal standardization to herbal producers

MARCHING FORWARD: A RECOMMENDATION FOR NAFDAC AND THE HERBAL PRODUCERS

IN THE NEAR FUTURE, EVERY APPLICATION FOR HERBAL PRODUCT REGISTRATION TO NAFDAC MUST BE ACCOMPANIED BY ITS MONOGRAPH AS A FINISHED PRODUCT, CONSISTING OF THEIR PECULIAR CHARACTERISTICS AS OFFICIAL STANDARDS UPON WHICH QUALITY CONTROL ON SAFETY, EFFICACY, QUALITY AND ACCEPTABILITY OF THE FINISHED PRODUCT WOULD DEPEND.....this is my story

THANK GOD FOR YOUR ATTENTION

AM RIDING ON THE CROSS OF JESUS CHRIST
FOR THE LORD IS MY REFUGE
(Psa 46 : 1 - 4)