I, the undersigned certify that all the information in this form and all accompanying documentation submitted to Eritrea for the registration of (fasdfa, Abacavir 120mg + Lamivudine 60mg, Dispersable Tab and AEROSOL FOAM ) manufactured at (Mylan Laboratories Limited , Semaetat and Mereb) is true and correct. I further certify that I have examined the following statements and I attest to their correctness:-

1. The current edition of the WHO Guidelines on good manufacturing Practices (GMP) for pharmaceuticals products or equivalent guideline is applied in full in all premises involved in the manufacture of this medicine.
2. The formulation per dosage form correlates with the master formula and with the batch manufacturing record.
3. The manufacturing procedure is exactly as specified in the master formula and batch manufacturing record.
4. Each batch of all starting materials is either tested or certified (in accompanying certificate of analysis for that batch) against the full specifications in the accompanying documentation and must comply fully with those specifications before it is released for manufacturing purposes.
5. All batches of the active pharmaceutical ingredient(s) are obtained from the source(s) specified in the accompanying documentation.
6. No batch of active pharmaceutical ingredient(s) will be used unless a copy of the batch certificate established by the manufacturer is available.
7. Each batch of the container/closure system is tested or certified against the full specifications in the accompanying documentation and complies fully with those specifications before released for the manufacturing purposes.
8. Each batch of the finished product is either tested, or certified (in an accompanying certificate of analysis for that batch), against the full specifications in the accompanying documentation and complies fully with release specifications before released for sale.
9. The person releasing the product is an authorized person as defined by the WHO Guidelines on good manufacturing Practices (GMP) for pharmaceuticals products
10. The procedures for control of the finished product have been validated. The assay method has been validated for accuracy, precision, specificity and linearity.
11. All the documentation referred to in this application is available for review during GMP inspection.
12. Clinical trials (where applicable) were conducted in accordance with ICH, WHO or equivalent guidelines for Good Clinical Practice,

I also agree that:

13. As a holder of marketing authorization/registration of the product I will adhere to Eritrean National Pharmacovigilance Policy requirements for handling adverse reactions.
14. As holder of registration I will adhere to Eritrean requirements for handling batch recalls of the products.

Name: Samson Teclezion Tesfamichael

Qualification:

Position:fasf

Date: 2022-04-13

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MFA
ERITREA
NATIONAL MEDICINES AND FOOD ADMINISTRATION

تلفون ٢٩١-١-١٢٥٥٢٥
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فاكس ٢٩١-١-١٢٢٨٩٩
ص.ب ٢١٢