**ANNEX V: Letter of Access to CEP**

<Applicant>

<Address>

<Address>

<Post code> <Town>

<Country

<Date>

Rwanda Food and Drugs Authority

P.O. Box 1948 Kigali

Rwanda

Dear Sir/Madam,

**Subject:** **Authorization to access Certificate of Suitability (CEP)**

Reference is made to the above subject matter.

Consent is hereby granted to Rwanda FDA to make reference to this company's Certificate(s) of Suitability (CEPs) [*number(s)*] for [*API(s) name(s)*] in the evaluation of applications relating to the registration of [*medicine name(s)*] submitted to Rwanda FDA by (*applicant’s name*).

This consent does/does not\*\* include authorization to supply information or extracts from or the whole of the data to:

(Name of company or individual)

The API is manufactured by:

(*Names and addresses of all manufacturing sites and manufacturing steps carried out at site*)

A formal agreement exists between the applicant of the medicine and the manufacturer of the API, which ensures that information will be communicated between them. Except as permitted by the Rwanda FDA guidelines relating to changes to medicines, such changes will not be made to the API to be used in manufacture of the medicine destined to be distributed in Rwanda before written approval is granted by the Rwanda FDA.

In addition, we commit that we will inform Rwanda FDA in the event that the CEP is withdrawn.

I understand that the consequences of failure to obtain approval for changes where approval is necessary may include de-registration and recall of batches of medicines.

Any questions arising from Rwanda FDA evaluation of this CEP should be forwarded to:

(*Name and address*)

Yours faithfully

{Signature of Company Representative}

{Name}

{Position in Company}

{Date}