

## DECLARATION OF SIMILARITY

To be used only for products that have SRA market authorisation but without SRA batch release.

- i. I \_\_\_\_\_ (Name of bidder, country) confirm that I have offered product (INN name and description) in UNICEF tender \_\_\_\_\_ (Ref Number.) or Purchase Order \_\_\_\_\_ (Ref Number).

ii. I declare that the product offered has registration in the SRA country as per below  
Description of product

Name of Marketing Authorization Holder:

MA reference number:

Name of MA issuing authority:

Website of MA issuing authority:

MA country:

Language of MA Pack/ Label/SmPC/PIL:

Name of manufacturer and address of manufacture site(s):

- iii. I further declare that the product is actively marketed in the SRA country mentioned above

YES NO

please list any other SRA country/ies where product is actively marketed:

- iv. I further declare that the product offered is the same in all aspects as that registered in the SRA country/ies listed above (name of SRA country/ies) with respect to the description of attributes in the table below: YES NO

Please state any differences in the space provided in the table below. If no differences, Indicate **NONE**

Description of attribute	SRA Registered Product	Product offered to UNICEF
<i>Example: Language of label</i>	<i>Example: French</i>	<i>Example: English</i>
Formulation (Qualitative and Quantitative composition)		
Manufacturing methods and process control		
FPP manufacture site/unit/blocks/lines		
Active Pharmaceutical ingredients (API) sources		
Sources of excipients		
Specifications of the Finished Pharmaceutical Product (FPP)		
Specifications of the Active Pharmaceutical Ingredients (API)		
Primary packaging type		
Secondary packaging type		
Primary pack size/volume		
Secondary pack size		
Language on label		
Language on SmPC/PIL		
QP released in SRA market		
Other (Specify)		

- v. I further declare that I \_\_\_\_\_ (name of bidder, country) have authorization from the MA holder in SRA country \_\_\_\_\_ (Name of MA holder, country) to offer in tender and supply this product outside the Jurisdiction of the SRA market where the product is registered with the stated claims of similarity and differences. YES NO

If yes, please attach evidence of the authorization signed by the MA holder.

- vi. In summary, I confirm that the product offered in tender \_\_\_\_\_ (Ref Number or PO \_\_\_\_\_ (ref number) has (select all that apply)  
Registration in SRA country but is manufactured, released & supplied from Non SRA market( mfg. site) using SRA approved packaging and labelling  
Registration in SRA country, but is manufactured, released & supplied from Non SRA market (mfg. site) in NON SRA approved packs

- vii. I confirm that the information provided is true and correct to the best of my knowledge.

Signed in: \_\_\_\_\_ (*place of signature*)

Date:

Signature:

Name of signatory:

Position/Job title:

*Should be Quality Assurance official or regulatory affairs official or equivalent such as Qualified Person acting as responsible for the Marketing Authorisation Holder.*