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**Declaration concerning API GMP compliance**

UNICEF Item description:

UNICEF ITB/RFP/RFQ number and/**OR:**

UNICEF Purchase Order Number:

I, *(Full Name)* ................................................. ……………………………………………………………………… declare that:

1. I am the authorised person with specific responsibility for GMP compliance of the Active Pharmaceutical Ingredient: ……………………………………………………………………………… manufactured at *(Name and physical address)* …………………………………………………………………………………………………..........…. and I am authorised to make this declaration.
2. The manufacture of the above named API at…………………………………………... is in accordance with WHO good manufacturing practices for active pharmaceutical ingredients (Annex 2, WHO Technical Report Series 957, 2010 or ICH Q7).
   1. This is based upon an on-site audit of the API manufacturer dated……………………. (within the last three years-Specify last Audit date-------------------------------)
   2. The audit report and all the other documentation relating to this declaration of GMP compliance of the API manufacturer will be made available to UNICEF for inspection upon request.
3. All batches of the above mentioned API manufactured by................................................................., and used in this FPP, have been fully tested in accordance with established specifications and released before further processing.
4. In case of serious API quality issues or regulatory non-compliance of the API manufacturer UNICEF will be immediately informed.

| Signature\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Name\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Job title\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Office Seal\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | Name and Address of FPP Manufacturing Site  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
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