Annex 4

PRODUCT SPECIFICATIONS

AND

TECHNICAL REQUIREMENTS

THIS DOCUMENT IS TO PROVIDE THE OFFERORS WITH THE PRODUCT(S) SPECIFICATIONS AND TECHNICAL REQUIREMENTS FOR THE PROCUREMENT OF COMMODITIES LISTED IN THE EOI:

**GHSC-PSM-TO2-2019-MALARIA\_PHARMACEUTICAL-EOI**

# Product Specifications

|  |
| --- |
| Artemether/Lumefantrine 20/120 mg Dispersible Tablet, 30 x 6x1 Blister Pack Tablets |
| Artemether/Lumefantrine 20/120 mg Dispersible Tablet, 30 x 6x2 Blister Pack Tablets |
| Artemether/Lumefantrine 20/120 mg Tablet, 30 x 6x1 Blister Pack Tablets |
| Artemether/Lumefantrine 20/120 mg Tablet, 30 x 6x2 Blister Pack Tablets |
| Artemether/Lumefantrine 20/120 mg Tablet, 30 x 6x3 Blister Pack Tablets |
| Artemether/Lumefantrine 20/120 mg Tablet, 30 x 6x4 Blister Pack Tablets |
| Artemether/Lumefantrine 80/480 mg Tablet, 1 x 6x1 Blister Pack Tablets |
| Artesunate/Amodiaquine 100/270 mg Tablet, 25 x 3 Blister Pack Tablets |
| Artesunate/Amodiaquine 100/270 mg Tablet, 25 x 6 Blister Pack Tablets |
| Artesunate/Amodiaquine 25/67.5 mg Tablet, 25 x 3 Blister Pack Tablets |
| Artesunate/Amodiaquine 50/135 mg Tablet, 25 x 3 Blister Pack Tablets |
| Artesunate/Mefloquine 100/200 mg Tablet, 3 Tablets |
| Artesunate/Mefloquine 100/200 mg Tablet, 6 Tablets |
| Dihydroartemisinin/Piperaquine 20/160 mg Tablet, 3 Blister Pack Tablets |
| Dihydroartemisinin/Piperaquine 20/160 mg Tablet, 3 Tablets |
| Dihydroartemisinin/Piperaquine 40/320 mg Tablet, 3 Tablets |
| Dihydroartemisinin/Piperaquine 40/320 mg Tablet, 9 Blister Pack Tablets |
| Amodiaquine 150 mg + Sulfadoxine/Pyrimethamine 500/25 mg Combo Pack Tablets, 25 x 1 SP + 3 AQ Co-Blister Tablets |
| Amodiaquine 150 mg + Sulfadoxine/Pyrimethamine 500/25 mg Dispersible Tablets, 25 x 1 SP + 3 AQ Co-Blister Tablets |
| Amodiaquine 150 mg + Sulfadoxine/Pyrimethamine 500/25 mg Dispersible Tablets, 50 x 1 SP + 3 AQ Co-Blister Tablets |
| Amodiaquine 150 mg Tablet, 1 x 6x1 Blister Pack Tablets |
| Amodiaquine 150 mg Tablet, 1 x 6x2 Blister Pack Tablets |
| Amodiaquine 153 mg + Sulfadoxine/Pyrimethamine 500/25 mg Combo Pack Tablets, 1 x 1 SP + 3 AQ Co-Blister Tablets |
| Amodiaquine 153 mg + Sulfadoxine/Pyrimethamine 500/25 mg Combo Pack Tablets, 50 x 1 SP + 3 AQ Co-Blister Tablets |
| Amodiaquine 153 mg + Sulfadoxine/Pyrimethamine 500/25 mg Dispersible Tablets, 1 x 1 SP + 3 AQ Co-Blister Tablets |
| Amodiaquine 153 mg + Sulfadoxine/Pyrimethamine 500/25 mg Dispersible Tablets, 50 x 1 SP + 3 AQ Co-Blister Tablets |
| Amodiaquine 75 mg + Sulfadoxine/Pyrimethamine 250/12.5 mg Combo Pack Tablets, 25 x 1 SP + 3 AQ Co-Blister Tablets |
| Amodiaquine 75 mg + Sulfadoxine/Pyrimethamine 250/12.5 mg Dispersible Tablets, 25 x 1 SP + 3 AQ Co-Blister Tablets |
| Amodiaquine 75 mg + Sulfadoxine/Pyrimethamine 250/12.5 mg Dispersible Tablets, 50 x 1 SP + 3 AQ Co-Blister Tablets |
| Amodiaquine 76.5 mg + Sulfadoxine/Pyrimethamine 250/12.5 mg Combo Pack Tablets, 1 x 1 SP + 3 AQ Co-Blister Tablets |
| Amodiaquine 76.5 mg + Sulfadoxine/Pyrimethamine 250/12.5 mg Combo Pack Tablets, 50 x 1 SP + 3 AQ Co-Blister Tablets |
| Amodiaquine 76.5 mg + Sulfadoxine/Pyrimethamine 250/12.5 mg Dispersible Tablets, 1 x 1 SP + 3 AQ Co-Blister Tablets |
| Amodiaquine 76.5 mg + Sulfadoxine/Pyrimethamine 250/12.5 mg Dispersible Tablets, 50 x 1 SP + 3 AQ Co-Blister Tablets |
| Atovaquone/Proguanil 100/250 mg Tablet, 12 Tablets |
| Chloroquine Phosphate 250 mg (150 mg base) Tablet, 10 Blister Pack Tablets |
| Chloroquine Phosphate 250 mg (150 mg base) Tablet, 10 x 10 Blister Pack Tablets |
| Chloroquine Phosphate 250 mg (150 mg base) Tablet, 100 Tablets |
| Chloroquine Phosphate 250 mg (150 mg base) Tablet, 1000 Tablets |
| Chloroquine Phosphate 50 mg/5 mL Syrup, 60 mL |
| Primaquine 15 mg Tablet, 100 Tablets |
| Primaquine 15 mg Tablet, 1000 Tablets |
| Primaquine 7.5 mg Tablet, 10 Blister Pack Tablets |
| Primaquine 7.5 mg Tablet, 10 x 10 Blister Pack Tablets |
| Primaquine 7.5 mg Tablet, 1000 Tablets |
| Quinine Sulfate 200 mg Tablet, 1000 Tablets |
| Quinine Sulfate 300 mg Film-Coated Tablet, 100 Blister Pack Tablets |
| Quinine Sulfate 300 mg Tablet, 10 x 10 Blister Pack Tablets |
| Quinine Sulfate 300 mg Tablet, 1000 Tablets |
| Artemether 20 mg/mL (1 mL) Ampoule, 1 Ampoule |
| Artemether 20 mg/mL (1 mL) Ampoule, 30 Ampoules |
| Artemether 20 mg/mL (1 mL) Ampoule, 6 Ampoules |
| Artemether 40 mg/mL (1 mL) Ampoule, 1 Ampoule |
| Artemether 40 mg/mL (1 mL) Ampoule, 30 Ampoules |
| Artemether 40 mg/mL (1 mL) Ampoule, 6 Ampoules |
| Artemether 80 mg/mL (1 mL) Ampoule, 1 Ampoule |
| Artemether 80 mg/mL (1 mL) Ampoule, 30 Ampoules |
| Artemether 80 mg/mL (1 mL) Ampoule, 6 Ampoules |
| Artesunate (w/ 1 Amp NaHCO3 5% + 1 Amp NaCl 0.9% + 2 x 10 mL Syringe) 60 mg Vial, 1 Set |
| Artesunate (w/ 1 Amp NaHCO3 5% + 1 Amp NaCl 0.9% + 2 x 5 mL Syringe) 60 mg Vial, 1 Set |
| Artesunate (w/ 1 Amp NaHCO3 5% + 1 Amp NaCl 0.9%) 120 mg Vial, 1 Set |
| Artesunate (w/ 1 Amp NaHCO3 5% + 1 Amp NaCl 0.9%) 30 mg Vial, 1 Set |
| Artesunate (w/ 1 Amp NaHCO3 5% + 1 Amp NaCl 0.9%) 60 mg Vial, 1 Set |
| Artesunate (w/ 1 Amp NaHCO3 5% + 1 Amp NaCl 0.9%) 60 mg Vial, 12 Sets |
| Artesunate (w/ 1 Amp NaHCO3 5% + 1 Amp NaCl 0.9%) 60 mg Vial, 4 Sets |
| Artesunate (w/ 1 Amp NaHCO3 5% + 1 Amp NaCl 0.9%) 60 mg Vial, 6 Sets |
| Artesunate 100 mg Suppository, 2 Suppositories |
| Artesunate 100 mg Suppository, 6 Suppositories |
| Artesunate 200 mg Suppository, 6 Suppositories |
| Artesunate 50 mg Suppository, 6 Suppositories |
| Quinine Dihydrochloride 200 mg/2 mL Ampoule, 100 Ampoules |
| Quinine Dihydrochloride 600 mg/2 mL Ampoule, 10 Ampoules |
| Quinine Dihydrochloride 600 mg/2 mL Ampoule, 100 Ampoules |
| Quinine-Resorcine Dihydrochloride 200 mg/2 mL Ampoule, 6 Ampoules |
| Quinine-Resorcine Dihydrochloride 400 mg/4 mL Ampoule, 6 Ampoules |
| Sulfadoxine/Pyrimethamine 500/25 mg Tablet, 10 x 3 Blister Pack Tablets |
| Sulfadoxine/Pyrimethamine 500/25 mg Tablet, 100 Tablets |
| Sulfadoxine/Pyrimethamine 500/25 mg Tablet, 1000 Tablets |
| Sulfadoxine/Pyrimethamine 500/25 mg Tablet, 150 Tablets |
| Sulfadoxine/Pyrimethamine 500/25 mg Tablet, 300 Tablets |
| Sulfadoxine/Pyrimethamine 500/25 mg Tablet, 50 x 3 Blister Pack Tablets |

# Conformity with Quality and Products Standards

For every product (and related manufacturing site) listed in your proposal, please supply the proper evidence of the following:

1. The product offered must be approved or authorized for use by a stringent regulatory authority (SRA[[1]](#footnote-2)); and/or
2. WHO pre-qualification is required.
3. Proof of registration of the offered pharmaceutical product(s) in (Country) (if applicable)

# Quality Assurance Provision

According to Annex 1 – PSM General Terms and Conditions

The vendor shall coordinate with GHSC-PSM’s Quality Assurance (QA) contractor, SGS, who will implement sampling, QA testing and acceptance within the terms and conditions outlined below.

For products containing artemisinin, suppliers will be asked to provide evidence of compliance with artemisinin sourcing requirements as outlined in annexes 10 and 12.

# Pre-Acceptance Sampling and Testing Requirements

Not applicable for this procurement

# Sampling Requirements

Unless otherwise specified in the Subcontract, each finished pharmaceutical product (FPP) batch delivered to GHSC-PSM shall be pre-shipment sampled by SGS and tested by a designated independent testing laboratory. The vendor shall advise SGS when the complete consignment is ready for sampling and supply SGS with the packing list and manufacturer’s Certificates of Analysis for each batch. SGS will submit the samples to the designated testing laboratory or may request the vendor to do this. The vendor is required to replace the sampled quantity by equal quantity of the same batch, so that the full quantity of FPPs ordered will be shipped.

In general, the consignment may not be shipped before independent test results show the products to be in compliance. In some cases, GHSC-PSM may determine that products may be shipped prior to receipt of the quality assurance testing results, in reliance on the vendor’s certification that the commodities procured under the subcontract are in compliance with the required technical specifications. In such case, GHSC-PSM will inform the vendor in writing. If after such written confirmation the consignment is shipped, the vendor accepts all responsibility for shipping costs and the costs of returning the goods if independent test results show non-compliance of goods and goods are deemed out of specification.

Per GMP requirements, vendors are required to retain reference samples of each batch delivered to GHSC-PSM in its finished primary packing for at least one year after the expiry date.

The Manufacturer’s chemical and physical test data shall be on record for each batch delivered to GHSC-PSM and shall be available to GHSC-PSM upon request for a length of time equal to five (5) years from the time of acceptance.

# Test Method

Unless otherwise specified in the Subcontract, each FPP batch delivered to GHSC-PSM shall comply with all product specifications and test procedures in effect at the time of subcontract award. Testing will be conducted per the FPP specifications and the test method(s) approved during the marketing authorization approval and/or WHO Prequalification. If the approved FPP and test method(s) is not a compendial method, the independent laboratory shall perform testing as per manufacturer’s validated in-house method. If method transfer was not yet performed by the independent laboratory, the manufacturer will be required to provide the in-house test method and the FPP. The manufacturer will also be requested to provide for method transfer and for each routine test the reference substances required for performing the laboratory tests.

# Compilation of Laboratory Testing Data

Not applicable for this procurement

# Lot Disposition

Not applicable for this procurement

# Frequency Monitoring

Unless otherwise specified in the Subcontract, each FPP batch delivered to GHSC-PSM shall be subject to sampling and testing requirements as specified above.

# Manufacturer Furnished Inspection Data

Not applicable for this procurement

# Post-Acceptance Inspection

Not applicable for this procurement

# Product Documentation

1. Evidence of compliance with standards indicated in Section II above
2. Recommended storage and transportation conditions acceptable for the climatic zone of the country of destination.

# Shelf life

All Goods with a shelf life, including all Pharmaceuticals, must be freshly manufactured, and thus have maximum possible shelf life. Goods with a maximum possible shelf life of less than 24 months shall have at least 85% of shelf life remaining when delivered. Goods with a maximum possible shelf life of more than 24 months shall have at least 24 months, or 85%, of shelf life remaining whichever is longer, when delivered. No Goods will be accepted which do not comply with these requirements unless Chemonics has agreed in writing to different requirements, in which case the Goods must strictly comply with those modified requirements.

# Shipping specifications

Please provide estimated weight, dimensions and number of pieces.

# Packaging and Packing

The pharmaceutical product to be supplied under this contract will be packed and protected to prevent damage or deterioration during transportation and storage. The box will be manufactured of a standard heavy-duty material appropriate for the destination countries where high heat and humidity is prevalent, that will withstand export handling and rough treatment, and ensure the safety, efficacy and quality of the product.

All products, including blisters and inserts, must be bilingual (French/English) or if specified, Portuguese. Other language requirements may be requested on a case by case basis.

# USAID Marking requirements

The vendor will be responsible for ensuring that all export shipping packages, whether shipped from the United States or from any other source country, carry the official PMI logo as specified below and “NOT FOR RETAIL SALE” on the tertiary packaging.

Emblems will be affixed by metal plate, decal, stencil, label, tag, or other means, depending upon the type of commodity or export shipping package and the nature of the surface to be marked. The emblem on each export-shipping package will be affixed in a manner which assures that the emblem will remain legible until the package reaches the consignee. The size of an emblem will vary depending upon the size of the commodity and the size of the package or export-shipping carton. The emblem will, in every case, be large enough to be clearly visible at a reasonable distance.

**PMI Logo:**

 

Emblems will be obtained by the Manufacturer(s) at its expense in the quantity and type required. The Manufacturer(s) will be required to affix PMI emblems in accordance with the marking requirements stated above.

# Innovation

1. Bar coding

Based on standards listed in Draft IDIQ.

1. EDI (Electronic Data Interchange)

Not applicable for this procurement

1. The following are acceptable SRAs as indicated under ADS 312 from the United States Agency for International Development (USAID) Global Health Bureau:

	* Australia’s Therapeutic Goods Administration (TGA)
	* European Medicines Agency (EMA)
	* Health Canada
	* Japanese Ministry of Health, Labor, and Welfare
	* Swiss Medic for the European Free Trade Area (EFTA)
	* United States Food and Drug Administration (FDA)
	* European Union member states admitted prior to 1996 (Austria, Belgium, Denmark, Finland, France,Germany, Greece, Ireland, Italy, Luxembourg, Netherlands, Portugal, Spain, Sweden, United Kingdom) [↑](#footnote-ref-2)