

**List Of Malaria Pharmaceutical Products
classified according to the Global Fund Quality Assurance Policy**

Edition: Version 108 - 27th November 2020

The list is an overview of pharmaceutical products subject to the Global Fund Quality Assurance Policy that are listed in National and/or WHO standard treatment guidelines and classified according to the various options (A, B, and ERP reviewed) defined in the Global Fund Quality Assurance Policy (July 2009, amended in December 2010). The list is developed as a tool to assist Principal Recipients (PR) of Global Fund grants to identify the status of finished pharmaceutical products according to the Global Fund Quality Assurance Policy.

The pharmaceutical products are classified based on the following information

A classified product - Listed on WHO prequalification list;

B classified product - Stringent NDRA Registration letter/Marketing Authorization;

ERP reviewed product- **Permitted for time-limited procurement** based on advice by the Expert Review Panel (ERP);

Please note that the list is not an exhaustive list. A PR can procure product(s) not listed in the current list as long as PR demonstrates that the product is compliant with the Global Fund Quality Assurance Policy.

The Global Fund list includes the following information:

- **"Important Notes" for helpful information;**
 - **A, B, and ERP reviewed products;**
 - **Period validity of the ERP reviewed products;**
 - **"+" means combination product, both fixed-dose combination (co-formulated) and co-packaged product (i.e. co-blister)**
 - **[A+B]+C means A and B are in fixed-dose formulation and C is co-packaged**
- YELLOW signifies a new entry; PINK signifies modification of an existing entry.**

For more information, please look at:

<https://www.theglobalfund.org/en/sourcing-management/quality-assurance/>.

Expert Review Panel (ERP): Expert Review Panel is an independent technical body composed of external technical experts, hosted by WHO Department of Essential Medicines and Pharmaceutical Policies, to review the potential risks/benefits associated with the use of FPPs that are not yet WHO-prequalified or SRA-authorized and to advise the Global Fund in its decision on whether to allow grant funds to be used to procure FPP. ERP reviewed products can be procured for a limited time (maximum 12 months). However, under certain circumstances, it is possible to extend the recommendation period. Contracts to supplier/manufacturer for an ERP reviewed products should not be longer than the validity period of the recommendation of that product. For detail information on ERP process and Quality Assurance information, please look at <https://www.theglobalfund.org/en/sourcing-management/quality-assurance/>.

Procurement of ERP Reviewed Products: Principal Recipients (PRs) must inform the concerned Fund Portfolio Manager (FPM) at the Global Fund in writing by filling the “Notification Form” (available on website) if they intend to procure ERP-reviewed product(s). The Global Fund Secretariat will review the notification request and upon issuing a “ no objection” letter to the PR for the requested selection, procurement can only proceed.

Important Notes

This List may be used by Principal Recipients of Global Fund grants when considering options with respect to procurement of pharmaceutical products pharmaceutical products subject to the Global Fund Quality Assurance Policy. The list aims at providing countries with information that will assist them in their procurement options. Please note that the list is not designed to be a basis for countries to select medicines to be included in their National Treatment Guidelines or to replace any applicable and legally required procurement processes. The Global Fund requires its grant recipients to comply with applicable procurement laws and provides the list only for the **identification of products/manufacturers that comply with the Global Fund’s quality assurance policy**. It is important to note that there is no strict requirement to procure according to the list, as long as the Principal Recipients can ensure that the product selected is compliant with the Quality Assurance policy criteria. Furthermore, the Principal Recipient should not rely solely on the information provided in the list but should obtain evidence of products compliance with the Quality Assurance policy. For the above reasons, **we strongly encourage users to ensure they are using the most recent version on our website when conducting procurement.**

The Lists will be updated regularly based on evidence received by the Global Fund. Interested parties are invited to supply information and evidence of products meeting the policy criteria on an ongoing basis. For the above reasons, **we strongly encourage users to ensure they are using the most recent version on our website when conducting procurement.**

According to the Global Fund QA policy, if there are two or more A or B classified manufacturers available for any given product AND the product is available from these manufacturers (available-means that the manufacturer can supply the selected product within 90 days after receiving the Purchase Order), then such product must be procured from A or B classified product manufacturers. The PR must notify by writing to the Global Fund Secretariat (Fund Portfolio Manager) and receive the "No Objection" letter from GF secretariat before procuring any products complying with option " ERP Reviewed".

For ease of reference, each "product" has been identified in this list with a unique "Product reference number" (Column A). Please see examples below.

Several different dosage forms may be grouped under the same Product Reference Number and therefore will be considered the same type of products when identifying the number of available manufacturers for the application of this policy. These products share the same dosing protocol, target the same population, and there are no fundamental differences among them. For example, within solid forms, some capsules will have same reference number as tablets while within liquids, oral solution and suspension are grouped together. Similarly, the entero coated tablet or dispersible tablet will not share the same reference number as non entero coated or dispersible tablets.

| Product Ref. No | International proprietary name | Non- | Strength | Dosage form | Supplier/Manufacturer * | Global Fund QA Standard | WHO Pre-qualified/SRA | Manufacturing site* | Country | Material | Pack |
|-----------------|--------------------------------|------|----------|-------------|-------------------------|-------------------------|-----------------------|---------------------|-----------|-------------|------|
| 16 | XYZ | | 50mg | Tablet | "Pharma Company A" | A - B | Yes | "Pharmaville" | Country A | HDPE bottle | 60 |
| 17 | | | 100mg | Tablet | "Pharma Company B" | A - B | Yes | "Pharmaville" | Country B | HDPE bottle | 60 |

The example above shows 2 different variants of the same medicine. Because the strength is different, it is considered 2 different products (there are two different reference numbers 16 and 17). If the strength had been the same but the dosage form had been different (i.e. tablet and liquid) it would also have been considered two different "products".

| Product Ref. No | International proprietary name | Non- | Strength | Dosage form | Supplier/Manufacturer* | Global Fund QA Standard | WHO Pre-qualified/SRA | Manufacturing site* | Country | Packaging | |
|-----------------|--------------------------------|------|----------|-------------|------------------------|-------------------------|-----------------------|---------------------|-----------|----------------------|--------|
| | | | | | | | | | | Material | Pack |
| 25 | ABC | | 150mg | Tablet | "Pharma Company A" | A - B | Yes | "Pharmaville" | Country A | Blister, HDPE bottle | 10, 60 |
| | | | | Capsules | "Pharma Company B" | A - B | Yes | "Pharmaville" | Country B | HDPE Bottle, Blister | 60, 10 |

In this second example both products have same reference number (25) because both manufacturers are supplying the same strength and the dosage forms are considered similar as per explanation above.

* See below

Disclaimer:

The Global Fund does not endorse or warrant the fitness of any product on the List for a particular purpose, including in regard of its safety and/or efficacy in the treatment of HIV/AIDS, tuberculosis or malaria. In addition, the Global Fund assumes no responsibility for any misstatement or omission from the list and directs Principal Recipients of Global Fund grants to conduct their own independent confirmation that the information on a given product on the list is accurate before relying on it to make a purchase order for that product, and to ensure that any purchase is in compliance with all the requirements of the Global Fund's quality assurance policy. The Global Fund does not warrant or represent that the products listed have obtained regulatory approval for use of treatment of any disease in any particular country of the world, or that their use is otherwise in accordance with the national laws and regulations of any country, including, but not limited to, intellectual property laws. The Global Fund disclaims any and all liability and responsibility for any injury, death, damage or loss of any kind whatsoever that may arise as a result of, or in connection with the procurement, distribution and use of any product included in the list.

*** As from the version 89, please note that we consider under**

**Supplier / Manufacturer :
Marketing authorization/ product authorization or license holder**

**Manufacturing Site:
The Site responsible for the release of the FPP.**

List of A or B products:

If there are two or more ‘A’ or ‘B’ products available, then the product **must be procured from one of the A or B products.**

Note: if the product intended for selection is not listed in this list , please refer to the List of ERP (Expert Review Panel) Reviewed Products which are permitted for time limited procurement:

| Ref.No | International Non-proprietary name | Strength/ Dose | Dosage form | Supplier/ Manufacturer(s) | Global Fund QA Standard | WHO Prequalification/ SRA | Manufacturing site | Country | Material | Pack |
|--------|------------------------------------|----------------|----------------------|-------------------------------|-------------------------|---------------------------|--------------------|---------|------------|--|
| 1 | Artesunate | 30 mg | Powder for injection | Guilin Pharmaceutical Co. Ltd | A | Yes | Guilin, Guangxi, | China | Glass Vial | Vial; 1 vial of artesunate powder is co-packed with 1 ampoule of sodium bicarbonate injection (0.5mL:25mg) and 1 ampoule of sodium chloride injection (2.5mL:22.5mg) |
| 2 | Artesunate | 60 mg | Powder for injection | Guilin Pharmaceutical Co. Ltd | A | Yes | Guilin, Guangxi, | China | Glass Vial | Vial [1 vial of artesunate powder is co-packed with 1 ampoule of sodium bicarbonate injection (1ml:50mg) and 1 ampoule of sodium chloride injection (5ml:45mg)] |

| Ref.No | International Non-proprietary name | Strength/ Dose | Dosage form | Supplier/ Manufacturer(s) | Global Fund QA Standard | WHO Prequalification/ SRA | Manufacturing site | Country | Material | Pack |
|--------|------------------------------------|----------------|------------------------|-------------------------------|-------------------------|---------------------------|---|------------------------|--|--|
| | Artesunate | 60 mg | Powder for injection | Ipca Laboratories Ltd | A | MA135 | Ipca Laboratories Ltd, Sejavta, Ratlam, Madhya Pradesh, 457 002 | India | Glass Vial | Powder, solvent and diluent for solution for injection 60mg + 5%w/v + 0.9%w/v-1ml of sodium bicarbonate 5% w/v, ampoule: 5ml of sodium chloride 0.9% w/v |
| 3 | Artesunate | 120 mg | Powder for injection | Guilin Pharmaceutical Co. Ltd | A | Yes | Guilin, Guangxi, | China | Glass Vial | Vial; 1 vial of artesunate powder is co-packed with 1 ampoule of sodium bicarbonate injection (2mL:100mg) and 1 ampoule of sodium chloride injection (10mL:90mg) |
| | Arthemether | 80mg/ml | Solution for injection | Sanofi | A | MA087 | Haupt Pharma Livron SAS, 1 rue Comte de Sinard, Livron sur Drôme, 26250 | France | Glass Vial | Ampoule, 1mlx6 |
| 4 | Artemether + Lumefantrine (FDC) | 20 mg+120 mg | Tablet | Novartis Pharma | A - B | Yes | Beijing; Suffern Philadelphia Istanbul | China USA Turkey | Blister | 6, 12, 18, 24 |
| | Artemether + Lumefantrine (FDC) | 20 mg+120 mg | Tablet | Ajanta Pharma | A | Yes | Paithan, Aurangabad | India | PVC/PVd C/Alu blister | 2*8, 3*8, 6*30, 12*30, 18*30, 24*30 |
| | Artemether + Lumefantrine (FDC) | 20 mg+120 mg | Tablet | Cipla Ltd. | A | MA064 | Patalganga; Himachal Pradesh, Goa Kurkumbh, Indore; Quality Chemical Industries Ltd, Kampala, | India Uganda | PVC-PCTFEE/ Alu Blister Alu-Alu Blister | 6, 12, 18, 24 |
| | Artemether + Lumefantrine (FDC) | 20 mg + 120 mg | Tablet | IPCA Laboratories Ltd | A | Yes | Dadra and Nagar Haveli, | India | Alu/PVC/PVDC Blister | 6, 12, 18, 24 |

| Ref.No | International Non-proprietary name | Strength/ Dose | Dosage form | Supplier/ Manufacturer(s) | Global Fund QA Standard | WHO Prequalification/ SRA | Manufacturing site | Country | Material | Pack |
|--------|------------------------------------|----------------|---------------------|---------------------------|-------------------------|---------------------------|---|------------------------|--|---|
| | Artemether + Lumefantrine (FDC) | 20 mg + 120 mg | Tablet | Strides Arcolab Limited | A | Yes | Bangalore | India | PVC/PE/PVDC/Alu blister | 4 x 6's |
| | Artemether + Lumefantrine (FDC) | 20 mg + 120 mg | Tablet | Macleods | A | Yes | Kachigam Daman Oxalis lab, Baddi Solan Dist | India | Al/PVC/PE/PVDC Al/PVC/Alu blister | blister 3 x 8; 1 x 6, 2 x 6, 3 x 6, 4 x 6 |
| | Artemether + Lumefantrine (FDC) | 20 mg + 120 mg | Tablet | Mylan Labs | A | MA099 | Sinnar, Nashik, Maharashtra, | India | Blister Alu/Alu (desiccant embedded); Alu/Alu; Alu/PVC/Alu blister; Alu/PVC/PE/PVdC | 6x1, 6x2, 6x3, 6x4; 18x1; 24x1; 18x10;24x10;18x30; 24x30 |
| 5 | Artemether + Lumefantrine (FDC) | 20 mg + 120 mg | Dispersible tablets | Novartis Pharma | A | Yes | Rockford, Illinois Conshohocken, Pennsylvania Suffern Istambul Beijing | USA Turkey China | PVC/Alu blister or PVC/PCTFE/Alu blister | 6*30; 12*30; 18*30 |
| | Artemether + Lumefantrine (FDC) | 20 mg + 120 mg | Dispersible tablets | Ajanta Pharma | A | Yes | Paithan, Aurangabad, Maharashtra | India | PVC/PVdC/Alu blister | 6, 12 |
| | Artemether + Lumefantrine (FDC) | 20 mg + 120 mg | Dispersible tablets | Strides Shasun Limited | A | MA110 | Oral Solid Dosage Forms Division, KRS Gardens, 36/7, Suragajakkanahalli, Indlawadi Cross, Anekal Taluk, Bangalore, Karnataka, 562 106 | India | Alu/PVC/PVdC | 6x1, 12x1 |
| | Artemether + Lumefantrine | 20mg+120mg | Dispersible Tablet | IPCA Laboratories Ltd | A | MA136 | Ipca Laboratories Ltd - Plot No : 255/1, Village Athal, Dadra and Nagar Haveli (U.T), Silvassa - 396 230, India | India | Alu-Alu blister and PVC/ACLAR/PVC-Alu blister | 1 x 6's 1 x 12's 30 x 1 x 6's 30 x 1 x 12's 30 x 6's 30 x 12's |

| Ref.No | International Non-proprietary name | Strength/ Dose | Dosage form | Supplier/ Manufacturer(s) | Global Fund QA Standard | WHO Prequalification/ SRA | Manufacturing site | Country | Material | Pack |
|--------|------------------------------------|----------------|--------------------|------------------------------|-------------------------|---------------------------|---|---------|---------------------------|--------------------------------|
| | Artemether + Lumefantrine | 20mg+120mg | Dispersible Tablet | Cipla Limited | A | MA115 | Cipla Ltd, Unit IV, Plot No 9, 10 & 15 Indore Special Economic Zone, Phase II, Pithampur, Dhar District, Madhya Pradesh, 454 775, India | India | Alu/PVC/Aclar/PVC blister | 6x1;12x1;18x1;6x30;12x30;18x30 |
| | Artemether + Lumefantrine | 20mg+120mg | Dispersible Tablet | Macleods Pharmaceuticals Ltd | A | MA137 | Oxalis Labs, Vill. Theda, P.O.lodhimajra, Baddi, Distt. Solan | India | Bilster, Alu-PVC/PE/PVdC | 6x17 |
| 6 | Artemether + Lumefantrine (FDC) | 40 mg + 240 mg | Tablet | Mylan Labs | A | Yes | Sinnar, Nashik, Maharashtra, | India | Alu/Alu blister | 1x12 |
| | Artemether + Lumefantrine (FDC) | 40 mg + 240 mg | Tablet | Ajanta Pharma | A | MA128 | B4/5/6 MIDC Industrial Area, Aurangabad, Paithan District, Maharashtra | India | Alu/PVC-PVdC, Blister | 6x1 |
| | Artemether + Lumefantrine | 40mg+240mg | Tablet | Cipla Limited | A | MA120 | Vill. Malpur, Baddi, Distt. Solan (H.P.) 173205 | India | Alu/PVC/Aclar/PVC blister | 6x1 |
| | Artemether + Lumefantrine | 40mg +240mg | Tablet FDC | Macleods Pharmaceuticals Ltd | A | MA143 | Oxalis Labs Village Theda, P.O Lodhimajra, Baddi, Distt. Solan, Himachal Pradesh, 174101 | India | Alu/PVC/PE/PVDC Blister | 10x10 |
| | Artemether + Lumefantrine (FDC) | 60 mg + 360 mg | Tablet | Ajanta Pharma | A | MA129 | B4/5/6 MIDC Industrial Area, Aurangabad, Paithan District, Maharashtra | India | Alu/PVC-PVdC, Blister | 6x1 |
| | Artemether + Lumefantrine | 60mg+360mg | Tablet | Cipla Limited | A | MA121 | Vill. Malpur, Baddi, Distt. Solan (H.P.) 173205 | India | Alu/PVC/Aclar/PVC blister | 6x1 |
| 7 | Artemether + Lumefantrine (FDC) | 80 mg + 480 mg | Tablet | Ajanta Pharma | A | MA130 | B4/5/6 MIDC Industrial Area, Aurangabad, Paithan District, Maharashtra | India | Alu/PVC-PVdC, Blister | 6x1 |

| Ref.No | International Non-proprietary name | Strength/ Dose | Dosage form | Supplier/ Manufacturer(s) | Global Fund QA Standard | WHO Prequalification/ SRA | Manufacturing site | Country | Material | Pack |
|--------|---|---|---------------------|-----------------------------------|-------------------------|---------------------------|---|-------------|--|--------------------------|
| | Artemether + Lumefantrine (FDC) | 80 mg + 480 mg | Tablet | Novartis Pharma | A | Yes | Ramapo, Rockland County Philadelphia, Pennsylvania Rockford, Illinois Istambul | USA; Turkey | PVC/PE/PVDC/Alu blister | 1x6 |
| | Artemether + Lumefantrine | 80mg+480mg | Tablet | Cipla Limited | A | MA122 | Vill. Malpur, Baddi, Distt. Solan (H.P.) 173205 | India | Alu/PVC/Aclar/PVC blister | 6x1 |
| | Artemether + Lumefantrine | 80mg+480mg | Tablet, film coated | Macleods Pharmaceuticals Ltd | A | MA142 | Oxalis Labs, Vill. Theda, P.O.lodhimajra, Baddi, Distt. Solan | India | Blister Alu/PVC/PE/PVdC | 15x10 |
| | Artemether + Lumefantrine | 80mg+480mg | Tablet FDC | Strides Pharma Global PTE Limited | A | MA138 | Strides Pharma Science Limited, Oral Solid Dosage Forms Division, KRS Gardens, 36/7, Suragajakkanahalli, Indlawadi Cross, Anekal Taluk, Bangalore, Karnataka, 562 106 | India | PVC/PE/PVDC blister | 6x1 |
| | Artesunate | 100mg | Suppository | Cipla Limited | A | MA124 | Cipla Limited, D7, MIDC Industrial area Kurkumbh Dist Pune 413802 INDIA | India | Alu/Alu Blister | 2' |
| | Artesunate | 100 mg | Suppository | Strides Shasun Ltd - India | A | MA123 | Strides Shasun ltd- 36/7, Suragajakkanahalli Indlavadi Cross, Anekal Taluk Bangalore | India | Alu/Alu (Alu foil/OPA/Alu/PVC) blister | 2' |
| 8 | Artesunate + Amodiaquine (Co-Blistered) | 50 mg + 150 mg | Tablet | Guilin Pharmaceutical Co. Ltd | A | Yes | Guilin, Guangxi, | China | PVC/ALU blisters; | 3x(4+4), 3+3, 6+6, 12+12 |
| 9 | Artesunate + Amodiaquine (Co-Blistered) | 50 mg + 153 mg (200mg as Hydrochloride) | Tablet | Cipla Ltd. | A | Yes | Goa; Patalanga | India | PVC/PVDC/Alu blister | 3+3, 6+6, 12+12 |
| | Artesunate + Amodiaquine (Co-Blistered) | 50 mg + 153 mg (200mg as Hydrochloride) | Tablet | IPCA Laboratories Ltd | A | Yes | Dadra and Nagar Haveli | India | PVdC/PVC/Alu blister | 12+12, 6+6, 3+3 |

| Ref.No | International Non-proprietary name | Strength/ Dose | Dosage form | Supplier/ Manufacturer(s) | Global Fund QA Standard | WHO Prequalification/ SRA | Manufacturing site | Country | Material | Pack |
|--------|---|-----------------|-------------|---|-------------------------|---------------------------|--|---------|--|--------------------------------|
| | Artesunate + Amodiaquine (Co-Blistered) | 50 mg + 153 mg | Tablet | Strides Arcolab Limited | A | Yes | Bangalore | India | PVdC/PVC/Alu blister | 10x(12+12), 10x(6+6), 10x(3+3) |
| 10 | Artesunate + Pyronaridine | 60mg+180mg | Tablet | Shin Poong Pharmaceutical Co., Ltd, S.Korea | A-B | EMA Art 58 H-W-2319 | Shin Poong Pharmaceutical Co., Ltd,Gyeonggi-do | S.Korea | Aluminium/PVC/Aluminium-PA foil blisters | 90(9'sx10) |
| 11 | Artesunate + Pyronaridine | 20mg+60mg | granules | Shin Poong Pharmaceutical Co., Ltd, S.Korea | A-B | EMA Art 58 H-W-2319-3 | Shin Poong Pharmaceutical Co., Ltd,Gyeonggi-do | S.Korea | Sachet | 90 |
| 12 | Amodiaquine+Artesunate (FDC) | 67.5 mg + 25 mg | Tablet | Sanofi Aventis | A | Yes | Maphar Lab,Casablanca | Morocco | Al/Alu Blister | 3*1, 3*25 |
| | Amodiaquin(as Hydrochloride)+Artesunate (FDC) | 67.5 mg + 25 mg | Tablet | IPCA Laboratories Ltd | A | Yes | Dadra and Nagar Haveli | India | Al/Alu Blister | 10x1x3; 25x3 |
| | Amodiaquin(as Hydrochloride)+Artesunate (FDC) | 67.5 mg + 25 mg | Tablet | Guilin Pharmaceutical Co. Ltd | MA083 | Yes | Guilin, Guangxi, China | China | Alu/PA/Alu/PVC blister | 3 |
| | Amodiaquin(as Hydrochloride)+Artesunate (FDC) | 67.5 mg + 25 mg | Tablet | Ajanta Pharma | A | Yes | Paithan, Aurangabad, Maharashtra | India | Al/Alu Blister | 1x3 |
| | Amodiaquin(as Hydrochloride)+Artesunate (FDC) | 67.5 mg + 25 mg | Tablet | Cipla Ltd. | A | Yes | Patalganga | India | Blister | 1X3 |
| | Amodiaquin(as Hydrochloride)+Artesunate (FDC) | 67.5 mg + 25 mg | Tablet | Micro Labs Ltd | A | MA132 | Plot No. S-155 to S-159 & N1, Phase III & Phase IV, Verna Industrial Estate, Verna, Goa, 403 722 | India | Blister,Alu/Alu; Blister, Alu-PVC/Aclar | 3x1, 3x10, 3x25 |
| | Amodiaquin(as Hydrochloride)+Artesunate (FDC) | 67.5 mg + 25 mg | Tablet | Macleods Pharmaceuticals Ltd | A | MA125 | Unit 2, Plot No 25-27, Survey No 366, Premier Industrial Estate, Kachigam, Daman, 396 210 | India | Blister;Alu/Alu | 10x10 |
| | Amodiaquin(as Hydrochloride)+Artesunate (FDC) | 135 mg + 50 mg | Tablet | Micro Labs Ltd | A | MA133 | Plot No. S-155 to S-159 & N1, Phase III & Phase IV, Verna Industrial Estate, Verna, Goa, 403 722 | India | Blister,Alu/Alu; Blister, Alu-PVC/Aclar | 3x1, 3x10, 3x25 |
| 13 | Amodiaquine+Artesunate (FDC) | 135 mg + 50 mg | Tablet | Sanofi Aventis | A | Yes | Maphar Lab,Casablanca | Morocco | Al/Alu Blister | 3*1, 3*25 |

| Ref.No | International Non-proprietary name | Strength/ Dose | Dosage form | Supplier/ Manufacturer(s) | Global Fund QA Standard | WHO Prequalification/ SRA | Manufacturing site | Country | Material | Pack |
|--------|---|----------------|-------------|-------------------------------|-------------------------|---------------------------|---|-----------------|---|--|
| | Amodiaquin(as Hydrochloride)+Artesunate (FDC) | 135 mg + 50 mg | Tablet | IPCA Laboratories Ltd | A | Yes | Dadra and Nagar Haveli, | India | Al/Alu Blister | 10x1x3; 25x3 |
| | Amodiaquin(as Hydrochloride)+Artesunate (FDC) | 135 mg + 50 mg | Tablet | Guilin Pharmaceutical Co. Ltd | MA084 | Yes | Guilin, Guangxi, China | China | Alu/PA/Alu/PVC blister | 3 |
| | Amodiaquin(as Hydrochloride)+Artesunate (FDC) | 135 mg + 50 mg | Tablet | Ajanta Pharma | A | Yes | Paithan, Aurangabad, Maharashtra | India | Al/Alu Blister | 1x3 |
| | Amodiaquin(as Hydrochloride)+Artesunate (FDC) | 135 mg + 50 mg | Tablet | Cipla Ltd. | A | Yes | Patalganga | India | Blister | 1X3 |
| | Amodiaquin(as Hydrochloride)+Artesunate (FDC) | 135 mg + 50 mg | Tablet | Macleods Pharmaceuticals Ltd | A | MA126 | Unit 2, Plot No 25-27, Survey No 366, Premier Industrial Estate, Kachigam, Daman, 396 210 | India | Blister;Alu/Alu | 10x10 |
| 14 | Amodiaquine+Artesunate (FDC) | 270 mg +100 mg | Tablet | Sanofi Aventis | A | Yes | Maphar Lab,Casablanca, Morocco; Rottendorf Pharma, Ennigerloh, Germany; Batch released by: I41Sanofi-Aventis Maroc, Casablanca, Morocco | Morocco Germany | Al/Alu Blister | 3*1, 3*25,6*1, 6*25 |
| | Amodiaquin(as Hydrochloride)+Artesunate (FDC) | 270 mg +100 mg | Tablet | IPCA Laboratories Ltd | A | Yes | Dadra and Nagar Haveli, | India | Al/Alu Blister | 10x1x3; 10x1x6; 25x3; 25x6 |
| | Amodiaquin(as Hydrochloride)+Artesunate (FDC) | 270 mg +100 mg | Tablet | Guilin Pharmaceutical Co. Ltd | MA085 | Yes | Guilin, Guangxi, China | China | Alu/PA/Alu/PVC blister | 3, 6 |
| | Amodiaquin(as Hydrochloride)+Artesunate (FDC) | 270 mg +100 mg | Tablet | Ajanta Pharma | A | Yes | Paithan, Aurangabad, Maharashtra | India | Al/Alu Blister | 1x3, 1x6 |
| | Amodiaquin(as Hydrochloride)+Artesunate (FDC) | 270 mg +100 mg | Tablet | Cipla Ltd. | A | Yes | Patalganga | India | Blister | 1X3, 1X6 |
| | Amodiaquin(as Hydrochloride)+Artesunate (FDC) | 270 mg +100 mg | Tablet | Micro Labs Ltd | A | MA133 | Plot No. S-155 to S-159 & N1, Phase III & Phase IV, Verna Industrial Estate, Verna, Goa, 403 722 | India | Blister,Alu/Alu; Blister, Alu-PVC/Aclar | 3x1, 3x10, 3x25, 6x1, 6x10, 6x25; 3x1, 3x10, 3x25, 6x1, 6x10, 6x25 |

| Ref.No | International Non-proprietary name | Strength/ Dose | Dosage form | Supplier/ Manufacturer(s) | Global Fund QA Standard | WHO Prequalification/ SRA | Manufacturing site | Country | Material | Pack |
|--------|---|-------------------------------------|--------------------------|------------------------------|-------------------------|---------------------------|---|-------------|------------------------------|-------------------------------------|
| | Amodiaquin(as Hydrochloride)+Artesunate (FDC) | 270 mg +100 mg | Tablet | Macleods Pharmaceuticals Ltd | A | MA127 | Unit 2, Plot No 25-27, Survey No 366, Premier Industrial Estate, Kachigam, Daman, 396 210 | India | Blister;Alu/Alu | 10x10, 3x1, 3x6, 3x25, 6x25 |
| | Amodiaquin (as Hydrochloride) +(Sulfadoxine+Pyrimethamine) | 150mg+ (500mg/25mg) | Co-Blistered tablet | Guilin Pharmaceuticals | A | MA098 | Guilin Pharmaceuticals Co. Ltd, No. 43 Quilidian road, Guilin | China | Blister | 50x(3+1) 25x(3+1) |
| | Amodiaquine (as Hydrochloride) + Sulfadoxine/ Pyrimethamine | 76.5mg+ 250mg/ 12.5mg | Co-blistered Disp tablet | Guilin Pharmaceuticals | A | MA116 | Guilin Pharmaceuticals Co. Ltd, No. 43 Quilidian road, Guilin | China | Alu/PVC Blister | 50x (3+1) |
| | Amodiaquine (as Hydrochloride) + Sulfadoxine/ Pyrimethamine | 153mg +500mg/ 25mg | Co-blistered Disp tablet | Guilin Pharmaceuticals | A | MA117 | Guilin Pharmaceuticals Co. Ltd, No. 43 Quilidian road, Guilin | China | Alu/PVC Blister | 50x (3+1) |
| 15 | Artesunate + Mefloquine (Co-Blistered) | 200 mg + 250 mg | Tablet | Mepha | B | Yes | Dornacherstrasse, Aesch | Switzerland | Co-blister | 3+6 |
| 16 | Artesunate+ Mefloquin (as Hydrochloride) (FDC) | 25mg+50mg | Tablet | Cipla Ltd. | A | Yes | Patalganga | India | Alu/Alu strip | 1x3, 2x3 |
| 17 | Artesunate+ Mefloquin (as Hydrochloride) (FDC) | 100mg+200mg | Tablet | Cipla Ltd. | A | Yes | Patalganga | India | Alu/Alu strip | 1x3, 2x3 |
| | Artesunate + (Sulfadoxine+Pyrimethamine) | 50mg+ (500mg+25mg) | Tablet Co-blister | Guilin Pharmaceuticals | A | MA066 | Guilin Pharmaceutical Co Ltd, No 43 Qilidian Road, Guilin, Guangxi, 541 004 | China | Alu/PVC Co-Blister | 1x(3+1), 1x(6+2) |
| | Artesunate + (Sulfadoxine+Pyrimethamine) | 100 mg+ (500mg+25mg) | Tablet Co-blister | Guilin Pharmaceuticals | A | MA068 | Guilin Pharmaceutical Co Ltd, No 43 Qilidian Road, Guilin, Guangxi, 541 004 | China | Alu/PVC Co-Blister | (3+6) x1, (2+3) x1 |
| 21 | Chloroquine (as Phosphate) | 250mg as phosphate (155mg as base) | Tablet | Alliance Pharmaceuticals, UK | B | Yes | AndersonBrecon (UK) Limited, | UK | HDPE Bottle; Blister | 100; 20 |
| | Chloroquine (as Phosphate) | 250mg as phosphate (155 mg as base) | Sugar coated Tablet | Remedica | B | Yes | Limassol | Cyprus | PP/PE/ Bottle Al/PVC Blister | 500, 1000 10*10 tabs; (100*10 tabs) |
| 22 | Mefloquine | 250mg | Tablet | Acino | B | Yes | Liesberg | Switzerland | Blister | 8 |

| Ref.No | International Non-proprietary name | Strength/ Dose | Dosage form | Supplier/ Manufacturer(s) | Global Fund QA Standard | WHO Prequalification/ SRA | Manufacturing site | Country | Material | Pack |
|-----------|---|--|---------------------|---------------------------|-------------------------|---------------------------|---|-------------|--|---------------------------------|
| | Mefloquine | 250mg | Tablet | Roche, UK | B | Yes | Roche Welwyn Garden City | UK | Blister | 8 |
| | Mefloquine | 250mg | Tablet | LTT Pharma Lexon UK | B | Yes | Hoffmann-LA Roche | Swiss | Blister | 8 |
| | Mefloquine | 250mg | Tablet | Mepha Pharma AG, Basel | B | Yes | Acino Pharma AG, Aesch | Switzerland | Blister | 4, 6, 8 |
| 23 | Piperaquine tetraphosphate (as the tetrahydrate; PQP) + Dihydroartemisinin (DHA). | 160mg+20mg | Film coated Tablet | Alfasigma S.p.A | A-B | MA093 | Pomezia | Italy | PVC/PVd C/Alu blister | 3 |
| | Dihydroartemisinin/Piperaquine phosphate | 20mg +160mg | Disp tablet FDC | Guilin | A | MA141 | Oral Solid Dosage Workshop II No. 43, Qilidian Road, Guilin 541004, Guangxi | China | Blister, PA/Alu-PVC/Alu | 3x1 |
| | Dihydroartemisinin/Piperaquine phosphate | 40mg +320mg | Disp tablet FDC | Guilin | A | MA139 | Oral Solid Dosage Workshop II No. 43, Qilidian Road, Guilin 541004, Guangxi | China | Blister, PA/Alu-PVC/Alu | 3x1 |
| | Dihydroartemisinin/Piperaquine phosphate | 80mg + 640mg | Tablet FDC | Guilin | A | MA140 | Oral Solid Dosage Workshop II No. 43, Qilidian Road, Guilin 541004, Guangxi | China | Blister, PA/Alu-PVC/Alu | 6x1 |
| | Dihydroartemisinin/Piperaquine phosphate | 40mg +320mg | Tablet FDC | Guilin | A | MA131 | Oral Solid Dosage Workshop II No. 43, Qilidian Road, Guilin 541004, Guangxi | China | Blister, PA/Alu-PVC/Alu | 9x1 |
| | Dihydroartemisinin/Piperaquine phosphate | 60mg/480mg | Tablet, Film-coated | Guilin | A | MA151 | Oral Solid Dosage Workshop II No. 43, Qilidian Road, Guilin 541004, Guangxi | China | Blister, PA/Alu-PVC/Alu | 6x25 |
| | Dihydroartemisinin/Piperaquine phosphate | 30mg +240mg | Disp tablet FDC | Guilin | A | MA157 | Oral Solid Dosage Workshop II No. 43, Qilidian Road, Guilin 541004, Guangxi | China | Polyamide(PA)/Aluminium/ Polyvinyl Chloride(PVC)/Aluminium blister | 3x25 |
| 24 | Piperaquine tetraphosphate (as the tetrahydrate; PQP) + Dihydroartemisinin (DHA). | 320mg+ 40mg | Film coated Tablet | Alfasigma S.p.A | A-B | MA094 | Pomezia | Italy | PVC/PVd C/Alu blister | 3, 6 ,9, 12 |
| 25 | Primaquine | 7.5mg (as base) (equivalent to 13.2mg Primaquine Phosphate) | Film coated Tablet | Remedica | B | Yes | Limassol | Cyprus | PP/PE/ Bottle Al/PVC Blister | 100; 1000 10*10 tab, 10*100 tab |

| Ref.No | International Non-proprietary name | Strength/ Dose | Dosage form | Supplier/ Manufacturer(s) | Global Fund QA Standard | WHO Prequalification/ SRA | Manufacturing site | Country | Material | Pack |
|--------|------------------------------------|---|---|----------------------------------|-------------------------|---------------------------|--|---------|--------------------------------|--------------------------------------|
| 26 | Primaquine | 15mg (as base) (equivalent to 26.3mg Primaquine Phosphate) | Tablet | Sanofi / Valeant Pharmaceuticals | B | Yes | Laval, Quebec | Canada | HDPE bottle | 100 |
| 30 | Proguanil | 100mg | Tablet | Alliance Pharma (Ireland) Ltd | B | Yes | ANDERSONBRECON (UK) LIMITED WYE VALLEY BUSINESS PARK BRECON ROAD, HAY-ON-WYE, HEREFORD HEREFORDSHIRE, HR3 5PG | UK | HDPE Bottle; Blister | 100; 98 |
| 27 | Quinine Di Hydrochloride | 300 mg/ml (600 mg/2 ml or 30 %) | Injectable solution- Route of administration- IV | Renaudin Laboratoire | B | Yes | Zone Artisanale Errobi | France | Ampoule | 10, 100 |
| 28 | Quinine Sulphate | 300 mg | Film coated Tablet | Remedica | B | Yes | Limassol | Cyprus | P/P Container / Al/PVC Blister | 100, 1000 10*10 tabs; 10*100 tabs |

| Ref.No | International Non-proprietary name | Strength/ Dose | Dosage form | Supplier/ Manufacturer(s) | Global Fund QA Standard | WHO Prequalification/ SRA | Manufacturing site | Country | Material | Pack |
|-----------|------------------------------------|--------------------------------|--------------------|---------------------------|-------------------------|---------------------------|--|---------|-----------------------------|---|
| | Quinine Sulphate | 300 mg (248mg of quinine base) | Film coated Tablet | Co-Pharma, UK | B | Yes | Strides Arcolab | India | Al/PVC blister packs | 2x14tabs, (box of 28 tabs) |
| | Sulfadoxine+Pyrimethamine | 500mg+25mg | Tablet FDC | Guilin Pharmaceuticals | A | MA113 | Guilin Pharmaceuticals Co. Ltd, No. 43 Quilidian road, | China | HDPE bottle; Blister | 100's,1000's 3', 3x50, 3x100 |
| 29 | Sulfadoxine + Pyrimethamine | 500mg + 25mg | Tablet | Remedica | B | Yes | Limassol | Cyprus | Al/PVC blister PE container | 1*3 tabs and , 10* 3tabs 100's and 1000's |

End of A or B products list

**List Of Malaria Pharmaceutical Products
classified according to the Global Fund Quality Assurance Policy**

Edition: Version 108 - 27th November 2020

List of ERP (Expert Review Panel) Reviewed Products which are permitted for time limited procurement:

If there is no or only one A or B product available (supply of the product cannot be done within 90 days after the receipt of the Purchase Order by the manufacturer) , grant funds may be used to procure a ERP reviewed product eligible for procurement for limited time (12 months) period. The PR must send the “notification form” (available at https://www.theglobalfund.org/media/5863/psm_notification_form_en.doc) to the Global Fund and upon receiving the “ No Objection” letter form the Global Fund, the procurement can proceed. Please note that the QC test of the selected ERP product will be performed by the Global Fund.

| Ref.No | International Non-proprietary name | Strength/ Dose | Dosage form | Supplier/ Manufacturer(s) | Global Fund QA Standard | Period Validity for ERP Review | Manufacturing site | Country | Material | Pack |
|--------|---|---------------------|--------------------|---------------------------|-------------------------|--------------------------------|---|---------|---|----------|
| | Pyrimethamine/Sulfadoxine + Amodiaquine (hydrochloride) | 12.5mg/250mg + 75mg | Dispersible tablet | S KANT HEALTHCARE LIMITED | ERP reviewed | 19-08-21 | PLOT NO. 1802-1805, G.I.D.C. PHASE III, VAPI 396 195. GUJARAT, INDIA | INDIA | Alu-PVC/PVd C co-blister | 25', 50' |
| | Pyrimethamine/Sulfadoxine + Amodiaquine (hydrochloride) | 25mg/500mg + 150mg | Dispersible tablet | S KANT HEALTHCARE LIMITED | ERP reviewed | 19-08-21 | PLOT NO. 1802-1805, G.I.D.C. PHASE III, VAPI 396 195. GUJARAT, INDIA | INDIA | Alu-PVC/PVd C co-blister | 25', 50' |
| | Sulfadoxine + Pyrimethamine | 250mg+12.5mg | Dispersible tablet | Macleods | ERP reviewed | 12-10-21 | Unit -II, Plot No.- 25-27, Survey No: 366, Premier Industrial Estate, Kachigam, Daman (U.T.), 396210 | INDIA | aluminium foil with clear PVC /PVdC blister | 10x1 |
| | Artemether + Lumefantrine | 20mg+120mg | Dispersible tablet | Guilin | ERP reviewed | 16-01-21 | Oral Solid Dosage Workshop I Guilin Pharmaceutical Co., Ltd No. 43, Qilidian Road, Guilin 541004, Guangxi | China | Alu-PVC/PVd C blister | 6' |
| | Artemether + Lumefantrine | 40mg +240mg | Dispersible tablet | Guilin | ERP reviewed | 16-01-21 | Oral Solid Dosage Workshop I Guilin Pharmaceutical Co., Ltd No. 43, Qilidian Road, Guilin 541004, Guangxi | China | Alu-PVC/PVd C blister | 6' |

| | | | | | | | | | | |
|--|---------------------------|-------------|----------------------|----------|--------------|----------|--|-------|-----------------------|--|
| | Artemether + Lumefantrine | 60mg +360mg | Dispersible tablet | Guilin | ERP reviewed | 16-01-21 | Oral Solid Dosage Workshop I Guilin Pharmaceutical Co., Ltd No. 43, Qilidian Road, Guilin 541004, Guangxi | China | Alu-PVC/PVd C blister | 6' |
| | Artesunate | 60mg | powder for Injection | Macleods | ERP reviewed | 20-03-21 | Phase I, Unit II Plot No. 25 – 27, Survey No. 366, Premier Industrial Estate, Kachigam, Daman – 396210 & Immacule Lifesciences Pvt Limited Village Thanthawal, Ropar Road, Nalagarh, Dist.-. Solan Himachal Pradesh - 174101 | India | Glas Vial 10 mL | 1 vial of artesunate powder is co-packed with Sodium Bicarbonate 50mg/ml injection (solvent) & 5mL Sodium Chloride 9mg/ml injection (diluent). |

End of ERP Reviewed products list