

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

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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:

<http://www.theglobalfund.org/en/about/procurement/list/>

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.

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".

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.

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
	Amikacin (as sulfate)	500 mg/2ml	Injection for IM/IV use	Pharmatex, Italy	B	Yes	Fisio Pharma Palomonte	Italy	Glass Vial	10 x 2ml
	Amikacin	500 mg/2ml	Injection, for IM/IV use	Medochemie	B	Yes	Limassol	Cyprus	Glass vial, ampoules	Pack of 10, 100
	Amikacin	500 mg/2ml	Injection, for IM/IV use	Vianex	B	Yes	Vianex S.A. - Plant A', Attiki, Greece	Greece	Glass Vial	1x2ml
	Amikacin (as sulfate)	500 mg/2ml	Injection	Pharmathen Hellas S.A.	B	Yes	Pharmathen S.A, Pallini Attiki, Greece; DEMO S.A. Krioneri Attiki, Greece	Greece	Glass ampoule 2ml	1, 5 or 10 ampoules per carton
	Amikacin (as sulfate)	500 mg/2ml	Solution for Injection	Qilu Pharmaceutical Co.,Ltd,	A	TB319	Qilu Pharmaceutical Co., Ltd., No. 317, Xinluo Road, High-tech Zone, Jinan, Shandong, 250101	China	Glass ampoule 2ml	10 x1
2	Amoxicillin + Clavulanic acid	250mg : 62.5mg/ 5ml	Powder for oral susp	Glaxo SmithKline Ltd.	B	Yes	Middlesex	UK	Bottle	100ml
	Amoxicillin + Clavulanic acid	250mg + 62.5mg/ 5ml	Powder for oral susp	Brown & Burk UK	B	Yes	Micro Labs, Veersandhra, Anekal, Bangalore	India	HDPE bottle	100ml
	Amoxicillin + Clavulanic acid	250mg + 62.5mg/ 5ml	Powder for oral susp	Medreich UK	B	Yes	Medreich Ltd Virgonagar Bangalore	India	Glass bottle	100ml with measure cup
3	Amoxicillin + Clavulanic acid	125mg + 31.25mg/ 5ml	Powder for oral susp	Glaxo SmithKline Ltd.	B	Yes	Middlesex	UK	Bottle	100ml
	Amoxicillin + Clavulanic acid	125mg + 31.25mg/ 5ml	Powder for oral susp	Brown & Burk UK	B	Yes	Micro Labs, Veersandhra, Anekal, Bangalore	India	HDPE bottle	100ml
	Amoxicillin + Clavulanic acid	125mg + 31.25mg/ 5ml	Powder for oral susp	Medochemie, Limassol (Cyprus)	B	No	Medochemie, Limassol	Cyprus	HDPE bottle	100ml
4	Amoxicillin + Clavulanic acid	250mg+125mg	Tablet	Brown & Burk UK	B	Yes	Micro Labs, Veersandhra, Anekal, Bangalore	India	Blister	8, 10, 14, 16, 21
	Amoxicillin + Clavulanic acid	250mg+125mg	Tablet	Remedica	B	Yes	Limassol	Cyprus	Alu/ Alu Blister	10 (2x10 tablets in carton box)
5	Amoxicillin + Clavulanic acid	500mg + 125mg	Film coated Tablet	Remedica	B	Yes	Limassol	Cyprus	Alu/ Alu Blister	10 (2x10 tablets in carton box)

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
	Amoxicillin + Clavulanic acid	500mg+125mg	Tablet	Brown & Burk UK	B	Yes	Micro Labs, Veersandhra, Anekal, Bangalore	India	Blister	8, 10, 14, 16, 21, 50 & 100's
	Amoxicillin + Clavulanic acid	500mg+125mg	Tablet	Medochemie	B	Yes	Limassol	Cyprus	Al/PVC Blister	16, 20, 100
	Amoxicillin + Clavulanic acid	500mg+125mg	Tablet	Reig Jofre	B	Yes	Toledo	Spain	Blister Bottle	6, 12(2*6), 24(4*6) 500
	Amoxicillin + Clavulanic acid	500mg+125mg	Tablet	Glaxo SmithKline Ltd.	B	Yes	Middlesex, Worthing	UK	Blister	14
6	Amoxicillin + Clavulanic acid	875mg + 125mg	Tablet	Medochemie	B	Yes	Limassol	Cyprus	Al/PVC Blister	14
	Amoxicillin + Clavulanic acid	875mg + 125mg	Tablet	Reig Jofre	B	Yes	Toledo	Spain	Blister Bottle	6, 12(2*6), 24(4*6) 500
	Amoxicillin + Clavulanic acid	875mg + 125mg	Tablet	Glaxo SmithKline Ltd.	B	Yes	Middlesex	UK	Blister	14
	Amoxicillin + Clavulanic acid	875mg+125mg	Tablet	Brown & Burk UK	B	Yes	Micro Labs, Veersandhra, Anekal, Bangalore	India	Blister	2x7, 3x7, 5x5, 10x10
	Amoxicillin + Clavulanic acid	875mg+125mg	Tablet	Medreich UK	B	Yes	Medreich Ltd Virgonagar, Bangalore	India	PVC/Alu blister	2x8(16)
	Bedaquiline Fumarate *	20mg	Tablet	Janssen Cilag, Belgium	B	NDA 204384	Recipharm Pharmaservices private Ltd	India	HDPE Bottle	60
7	Bedaquiline Fumarate *	100mg	Tablet	Janssen Cilag, Belgium	B	NDA 204384	Recipharm Pharmaservices private Ltd	India	HDPE Bottle Blister	188 24
11	Clofazimine *	50mg	Capsule	Novartis, Switzerland	B	Yes	Sandoz, Kalwe	India	HDPE Bottle	100
	Clofazimine *	100mg	Capsule	Novartis, Switzerland	B	Yes	Sandoz, Kalwe	India	HDPE Bottle	100
	Cycloserine	125 mg	Capsule	Macleods Pharmaceutical Ltd	A	TB330	Unit 2, Plot No 25-27, Survey No 366, Premier Industrial Estate, Kachigam, Daman, 396 210	India	Alu/Alu blister; Alu/Alu strip	10x10
12	Cycloserine	250 mg	Capsule	Macleods Pharmaceutical Ltd	A	Yes	Kachigam, Daman Solan Himachal Pradesh	India	Al Strip	10
	Cycloserine	250 mg	Capsule	Dong-A Pharmaceutical Co Ltd	A	Yes	Dong-A Pharmaceutical Co Ltd Cheonan, Chungcheongnam-do	Republic of Korea	Alu/Alu strip	10x10
	Cycloserine	250 mg	Capsule	Chao Centre	B	Yes	Chao Centre Indiana	USA	HDPE Bottle	40
	Cycloserine	250 mg	Capsule	Biocom JSC	A	Yes	Stavropol	Russia	HDPE Bottle	100
	Cycloserine	250 mg	Capsule	Cipla Ltd	A	Yes	Verna Salcette, Goa	India	HDPE Bottle	40

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
	Cycloserine	250 mg	Capsule	Strides Shasun Ltd	A	TB306	Strides Shasun Ltd, Unit II, RS No 32-34, PIMS Road, Periyakalpet, Puducherry, 605 014	India	Bottle HDPE Blister Alu/Alu	40x1 10x10
	Cycloserine	250 mg	Capsule	Mylan Laboratories Ltd	A	TB304	Plot No H-12 & H13 MIDC Waluj Industrial Area, Aurangabad, Maharashtra, 431 136	India	Bottle HDPE; Blister Alu/Alu	100x1; 10x1
13	Delamanid *	50mg	Tablet	Otsuka Novel Products GmbH, Germany	B	Yes	AndersonBrecon (UK) Ltd.	UK	HDPE Bottle Alu/Alu strip	50, 300 5x8tab(40) 6x8 tab(48)
14	Ethambutol	100 mg	Tablet	Labatec Pharma	B	Yes	Meyrin, Geneva	Switzerland	PVC/Alu Blister HDPE Bottle	10*10 100
	Ethambutol	100 mg	Tablet	SW Pharma GmbH (Former FATOL-(RIEMSER) Arzneimittel)	B	Yes	Schiffweiler, Germany	Germany	PVC/Aclar/PVC /Alu blister	50, 100, 500
	Ethambutol	100 mg	Tablet	Macleods Pharmaceutical Ltd	A	Yes	Kachigam Damam	India	Al/PVC/PVDC blister	10 x 10, 24 x 28; HDPE bottle 1000
	Ethambutol	100mg	disp tablet	Macleods Pharmaceutical Ltd	A	TB334	Unit II, Plot No. 25-27 Sr. No. 366, Kachigam, Daman	India	Blister pack Alu/Alu strip pack	10x10 6x10
15	Ethambutol	250 mg	Film coated tablet	SW Pharma GmbH (Former FATOL-(RIEMSER) Arzneimittel)	B	Yes	Schiffweiler, Germany	Germany	PVC/Alu blister	100, 500
16	Ethambutol	400 mg	Tablet	Cadila Pharmaceuticals Ltd	A	Yes	Dholka, Ahmedabad,	India	Alu/PVC/PVdC Blister ; HDPE bottle	10, 28; 1000
	Ethambutol	400 mg	Tablet	Macleods Pharmaceutical Ltd	A	Yes	Kachigam, Daman	India	Blister; HDPE Bottle	10, 28; 1000
	Ethambutol	400 mg	Tablet	OlainFarm JSC	B	Yes	Olaine	Latvia	HDPE Bottle	1000
	Ethambutol	400 mg	Tablet	Lupin India Ltd	A	Yes	Chikalhana, Aurangabad Bari Brahmana, Jammu (J & K)	India	PVC/PVDC/Alu blister ; HDPE bottles	28,10; 100, 500, 1000
	Ethambutol	400 mg	Tablet	Labatec Pharma	B	Yes	Meyrin, Geneva	Switzerland	PVC/Alu Blister	10*10
	Ethambutol	400 mg	Tablet	Svizera Europe BV	B	Yes	Svizera Labs Pvt Ltd, Plot No D16/6 TTC Industrial Area, MIDI, Turbhe, Navi Mumbai, 400 703	India	HDPE Bottle Blister	1000; 28x24, 100

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
	Ethambutol	400 mg	Film coated tablet	SW Pharma GmbH (Former FATOL-(RIEMSER) Arzneimittel)	B	Yes	Schiffweiler, Germany	Germany	PVC/Alu blister	100, 500
	Ethambutol	400 mg	Tablet	S.C. Antibiotice S.A	A	Yes	Lasi	Romania	AluPVC Blister	2x10 150x10
17	Ethambutol	500 mg	Film coated tablet	SW Pharma GmbH (Former FATOL-(RIEMSER) Arzneimittel)	B	Yes	Schiffweiler, Germany	Germany	PVC/Alu blister	100, 500
19	Ethambutol + Isoniazid + Rifampicin	275 mg+75 mg+150 mg	Tablets	Macleods Pharmaceutical Ltd	A	Yes	Kachigam, Daman; Oxalis lab, Solan, Baddi	India	HDPE container; Alu/PVC/PVdc Blister	1000; 10, 28
	Ethambutol + Isoniazid +Rifampicin	275mg +75mg +150mg	Tablet	Lupin India Ltd	A	Yes	Aurangabad	India	HDPE Bottle Alu/PVC/PVDC blister	1000 28
	Ethambutol + Isoniazid +Rifampicin	275mg +75mg +150mg	Tablet	Svizera Europe BV	A	TB192	Svizera Labs Pvt Ltd, Plot No D16/6 TTC Industrial Area, MIDI, Turbhe, Navi Mumbai, 400 703	India	Bottle HDPE; Blister Alu/PVC/PVdC	1000x1; 28x24
20	Ethambutol + Isoniazid + Pyrazinamide + Rifampicin	275 mg + 75 mg + 400 mg + 150 mg	Tablet	Lupin India Ltd	A	Yes	Chikalthana Aurangabad	India	Blister; HDPE bottle	4, 28;672 100, 500, 1000
	Ethambutol + Isoniazid + Pyrazinamide + Rifampicin	275 mg + 75 mg + 400 mg + 150 mg	Film coated Tablet	Macleods Pharmaceutical Ltd	A	Yes	Kachigam, Daman; Oxalis lab, Solan, Baddi	India	HDPE container; Alu/PVC/PVdc Blister	500, 1000; 10, 28
	Ethambutol Hydrochloride+ Isoniazid + Pyrazinamide + Rifampicin	275 mg + 75 mg + 400 mg + 150 mg	Tablet	Svizera Europe BV	A	TB193	Svizera Labs Pvt Ltd, Plot No D16/6 TTC Industrial Area, MIDI, Turbhe, Navi Mumbai, 400 703	India	Bottle HDPE; Blister Alu/PVC/PVdC	1000x1; 28x24
	Ethambutol Hydrochloride+ Isoniazid + Pyrazinamide + Rifampicin	275 mg + 75 mg + 400 mg + 150 mg	Tablet, Film-coated	Sandoz Pvt Ltd, India	A	TB090	Sandoz Pvt Ltd, K-3 MDT-TB, Plot No 8 A/2 & 8-B, TTC Industrial Area, MIDC, Kalwe Block, Dighe Village, Navi Mumbai, Thane District, Maharashtra, 400 708 Strides Pharma Science Limited, Oral Solid Dosage Forms Division, KRS Gardens, 36/7, Suragajakkanahalli, Indlawadi Cross, Anekal Taluk, Bangalore, Karnataka, 562 106 Panacea Biotech Ltd, Malpur, Baddi, Tehsil Nalagarh, Solan District, Himanchal Pradesh, 173 205	India	Blister Alu/PVC/PE/PVdC; Bottle PP; Bottle HDPE	30,60,120,24 0,672,1000; 500X1,1000x1; 500X1
	Ethambutol Hydrochloride+ Isoniazid + Pyrazinamide + Rifampicin	275 mg + 75 mg + 400 mg + 150 mg			A	TB223		India		

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
	Ethionamide	125 mg	Tablet	Macleods Pharmaceutical Ltd, Mumbai (India)	A	TB314	Kachigam, Daman	India	Alu/Alu strip	10x10
	Ethionamide	125 mg	Dispersible Tablet	Macleods Pharmaceutical Ltd, Mumbai (India)	A	TB333	Kachigam, Daman	India	Alu/Alu strip	6x5
	Ethionamide	125 mg	Tablet	Micro Labs Ltd	A	TB331	Unit 03, 92 Sipcot Industrial Complex, Hosur, Tamil Nadu	India	Bottle Alu/PVC-PVdC Blister	100x1; 10x10;10x14
	Ethionamide	125 mg	disp tablet	Micro Labs Ltd	A	TB352	(Unit-03) 92, Sipcot Industrial Complex, Hosur - 635126, Tamilnadu	India	Alu/Alu strips; Alu-PVC/PE/PVdC blisters	10 x 3, 10x10, 14x10
21	Ethionamide	250 mg	Tablet	Macleods Pharmaceutical Ltd	A	Yes	Kachigam, Daman Oxalis lab, Solan, Baddi	India	HDPE; Strip	100; 10
	Ethionamide	250mg	Film coated tablet	Cipla Ltd	A	Yes	Patalganga	India	HDPE Bottle; Alu/PVC/PVdC Blsiter	100; 10
	Ethionamide	250mg	Tablet	Lupin India Ltd	A	Yes	Aurangabad	India	HDPE Bottle ; AL/AL Strip	100; 5x 10
	Ethionamide	250mg	Tablet	Micro Labs Ltd	A	Yes	Hosur, Tamilnadu	India	HDPE Bottle ; PVDC/PVC/AL Strip	100; 10
22	Imipenum+Cilastatin	250mg/250mg	Powder for solution for infusion	Fresenius Kabi	B	Yes	Runcorn, Cheshire	UK	Glass vial	10x 20ml
23	Imipenum+Cilastatin	500mg/500mg	Powder for Injection	Labatec Pharma	B	Yes	Anfarm Facta Farmaceutici ACS Dobfar	Greece Italy Italy	Glass vials in carton box	10
	Imipenum+Cilastatin	500mg/500mg	Powder for Injection	DEMO SA Pharmaceutical Industry	B	Yes	Attiki	Greece	Glass vial in carton box	1;10;50
	Imipenum+Cilastatin	500mg/500mg	Powder for solution for infusion	Fresenius Kabi	B	Yes	Runcorn, Cheshire	UK	Glass vial	10x 20ml
	Imipenum+Cilastatin	500mg/500mg	Powder for solution for infusion	Sun Pharmaceutical Industries Ltd	B	Yes	Madhya Pradesh	India	Glass vial	10x 30ml
	Imipenum+Cilastatin	500mg/500mg	Powder for solution for infusion	PANMEDICA, France	B	Yes	FACTA FARMACEUTICI S.p.A	Italy	Glass vial 20ml	1, 10, 25
24	Isoniazid	50 mg	Tablet	SW Pharma GmbH (Former FATOL-(RIEMSER) Arzneimittel)	B	Yes	Schiffweiler, Germany	Germany	PVC/Aclar/PVC /Alu blister	100, 500

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
	Isoniazid	50 mg	Dispersible Tablet	Micro Labs Ltd	A	TB347	Unit 3, 92 Sipcot Industrial Complex, Hosur, Tamil Nadu, 635 126	India	Strip, Alu/Alu	10x10, 24x28
	Isoniazid	100 mg	Dispersible Tablet	Micro Labs Ltd	A	TB348	Unit 3, 92 Sipcot Industrial Complex, Hosur, Tamil Nadu, 635 126	India	Strip, Alu/Alu	10x10, 24x28
25	Isoniazid	100 mg	Tablet	Macleods Pharmaceutical Ltd	A	Yes	Kachigam, Daman Oxalis lab, Solan, Baddi	India	HDPE Container; PVC/PVdc Blister	1000; 10, 28
	Isoniazid	100 mg	Tablet	SW Pharma GmbH (Former FATOL-(RIEMSER) Arzneimittel)	B	Yes	Schiffweiler, Germany	Germany	PVC/Aclar/PVC /Alu blister	100, 500
	Isoniazid	100mg	Tablet	Micro Labs Ltd	A	Yes	Hosur, Tamilnadu	India	HDPE Container	1000
	Isoniazid	100mg	Tablet	Lupin India Ltd	A	Yes	Chikalhana, Aurangabad,	India	Al/PVC/PVDC blister HDPE bottle	10*10 (100) 100, 1000
	Isoniazid	100mg	Tablet	Labatec Pharma	B	Yes	Meyrin, Geneva	Switzerland	PVC/Alu Blister HDPE Bottle	10*10 100
	Isoniazid	100mg	Tablet	S.C. Antibiotice S.A	A	Yes	Lasi	Romania	AluPVC Blister	2x10 150x10
	Isoniazid	100mg	Tablet	Mylan Laboratories Ltd	A	TB308	Plot No H-12 & H13 MIDC Waluj Industrial Area, Aurangabad, Maharashtra, 431 136	India	Bottle, HDPE ; Alu/PVC/PVDC blister	100x1; 10x10
26	Isoniazid	200 mg	Tablet	SW Pharma GmbH (Former FATOL-(RIEMSER) Arzneimittel)	B	Yes	Schiffweiler, Germany	Germany	PVC/Aclar/PVC /Alu blister	100, 500
27	Isoniazid	300 mg	Tablet	Macleods Pharmaceutical Ltd	A	Yes	Kachigam, Daman Oxalis lab, Solan, Baddi	India	HDPE Container ; PVC/PVdC/Alu Blister	1000; 10, 28
	Isoniazid	300 mg	Tablet	Micro Labs Ltd	A	Yes	Hosur, Tamilnadu	India	HDPE Container	1000
	Isoniazid	300mg	Tablet	S.C. Antibiotice S.A	A	Yes	Lasi	Romania	AluPVC Blister	3x10 150x10
	Isoniazid	300mg	Tablet	Cadila Pharmaceuticals Ltd	A	Yes	Dholka, Ahmedabad	India	PVC-PVDC/Alu blister ; HDPE bottle	10x10,24x28 500, 1000

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
	Isoniazid	300mg	Tablet	Mylan Laboratories Ltd	A	TB285	Plot No H-12 & H13 MIDC Waluj Industrial Area, Aurangabad, Maharashtra, 431 136	India	Bottle, HDPE	Bo 30x1, 1000x1 (with desiccant); 30x1, 1000x1 (without desiccant)
	Isoniazid + Rifampicin	50mg +75mg	Disp tablet	Macleods	A	TB302	Phase II, Unit II, Plot No. 25-27, Premier Ind. Estate, Kachigam, Daman (U.T). Oxalis Labs, Vill. Theda, P.O. Lodhimajra, Baddi, Dist. Solan (H.P.)	India	container pack Alu/Alu strip pack	100 10 (10x10), 28
30	Isoniazid + Rifampicin	75 mg + 150 mg	Tablet	Lupin India Ltd	A	Yes	Chikalthana Aurangabad	India	Blister ; HDPE bottle	15; 100, 500, 1000
	Isoniazid + Rifampicin	75 mg + 150 mg	Tablet	Macleods Pharmaceutical Ltd	A	Yes	Kachigam, Daman; Oxalis lab, Solan, Baddi	India	HDPE Bottle; Alu/PVC/PVdc Blister	500, 1000; 10, 28
	Isoniazid + Rifampicin	75 mg + 150 mg	Tablet, coated	Sandoz Pvt Ltd, India	A	TB085	Panacea Biotech Ltd, Malpur, Baddi, Tehsil Nalagarh, Solan District, Himanchal Pradesh, 173 205 Panacea Biotech Ltd, Malpur, Baddi, Tehsil Nalagarh, Solan District, Himanchal Pradesh, 173 205, Strides Pharma Science Limited, Oral Solid Dosage Forms Division, KRS Gardens, 36/7, Suragajakkanahalli, Indlawadi Cross, Anekal Taluk, Bangalore, Karnataka, 562 106, Sandoz Pvt Ltd, K-3 MDT-TB, Plot No 8 A/2 & 8-B, TTC Industrial Area, MIDC, Kalwe Block, Dighe Village, Navi Mumbai, Thane District, Maharashtra, 400 708	India	Blister Alu/PVC/PE/PVDC ; Bottle PP/HDPE	30, 60, 120, 240, 672, 1000 ; 500x1
	Isoniazid + Rifampicin	75 mg + 150 mg	Tablet	Svizera Europe BV	A	TB189	Svizera Labs Pvt Ltd, Plot No D16/6 TTC Industrial Area, MIDI, Turbhe, Navi Mumbai, 400 703	India	Bottle HDPE; Blister Alu/PVC/PVdC	1000x1; 28x24
32	Isoniazid + Rifampicin	150 mg + 300 mg	Tablet	Groupo Lepetit	B	Yes	Anagni	Italy	Blister	8, 24
	Isoniazid + Rifampicin	150 mg + 300 mg	Film coated Tablet	Remedica	B	Yes	Limassol	Cyprus	PP/PE Bottle	100
	Isoniazid + Rifampicin	150 mg + 300 mg	Film coated tablet	SW Pharma GmbH (Former FATOL-(RIEMSER) Arzneimittel)	B	Yes	Schiffweiler, Germany	Germany	PVC/Alu blister	100, 500
	Isoniazid + Rifampicin	150 mg + 300 mg	Capsule	S.C. Antibiotice S.A	A	Yes	Lasi	Romania	AluPVC Blister	1x10 100x10

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
	Isoniazid + Rifampicin	150 mg + 300 mg	Tablet	Macleods Pharmaceutical Ltd	A	TB231	Kachigam, Daman	India	HDPE Bottle; PVC/PVDC/ Alu blister	1000,500; 10x10, 3x28, 24x28
	Isoniazid + Pyrazinamide+Rifampicin	50 mg+ 150 mg+75mg	Dispersible Tablet	Macleods Pharmaceutical Ltd	A	TB309	Unit 2, Plot No 25-27, Survey No 366, Premier Industrial Estate, Kachigam, Daman, 396 210; Oxalis Labs, Vill. Theda, P.O.lodhimajra, Baddi, Distt. Solan	India	Strip Alu/Alu, HDPE Bottle	10x10, 100
	Levofloxacin	100mg	Dispersible Tablet	Macleods	A	TB326	Block N2 Village Theda, P.O. Lodhimajra, Tehsil Baddi, District:-Solan Himachal Pradesh	India	Blister pack Alu/Alu strip pack	10x10 10x10
	Levofloxacin	100mg	disp tablet	Micro Labs Ltd	A	TB356	(Unit-03) 92, Sipcot Industrial Complex, Hosur – 635126, Tamilnadu	India	Alu/Alu strips; Alu-PVC/PE/PVdC blisters	10X10 ; 10x2
36	Levofloxacin	250mg	Tablet	Cipla Ltd	A	Yes	Goa	India	HDPE Bottle; Alu/PVC Blister	50; 10*10
	Levofloxacin	250mg	Tablet	Hetero Labs Ltd	B	Yes	Hetero Labs Limited UNIT- V, TSIIC Formulation SEZ, Sy No. 439, 440, 441 & 458, Polepally Village, Jadcherla Mandal, Mahaboobnagar District, Telangana	India	Alu/PVC Blister	3*1, 5*1, 7*1, 10*1,14*1, 50*1, 200*1
	Levofloxacin	250mg	Tablet	Micro Labs Ltd	A	Yes	Hosur, Tamilnadu	India	PVC/Alu blister	10x10
	Levofloxacin	250mg	Tablet	Denk Pharma GmbH & Co	B	Yes	Rottendorf Pharma GmbH, Ennigerloh,	Germany	Blister	3, 5, 7,10
	Levofloxacin	250mg	Tablet	Medochemie	B	Yes	Limassol	Cyprus	Blister	3,5,7,10 Box (10x10)
	Levofloxacin	250mg	Tablet	Macleods Pharmaceutical Ltd	A	Yes	Solan, Himachal Pradesh, India	India	Alu/PVC blister	5's x 20 tablet
	Levofloxacin	250mg	Tablet	HEC Pharm GmbH, Germany	B	Yes	Sunshine Lake Pharma Co., Ltd.	China	PVC/PVDC/AL U-Blister	6'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
	Levofloxacin	250mg	tablet, Film-coated	MSN Laboratories Private Limited	A	TB338	Formulations Division, Unit-II, Survey Nos. 1277, 1319 to 1324, Nandigama (Village & Mandal), Rangareddy (District), Telangana, 509228	India	Blister,Alu/PVC ; Bottle,HDPE	1x1, 10x1; 50x1
37	Levofloxacin	500mg	Tablet	Cipla Ltd	A	Yes	Goa	India	HDPE Bottle; Alu/PVC Blister	50; 1*10
	Levofloxacin	500mg	Tablet	Micro Labs Ltd	A	Yes	Hosur, Tamilnadu	India	PVC/Alu blister	10x10
	Levofloxacin	500mg	Tablet	Denk Pharma GmbH & Co	B	Yes	Rottendorf Pharma GmbH, Ennigerloh	Germany	Blister	5, 7, 10
	Levofloxacin	500mg	Tablet	Medochemie	B	Yes	Limassol	Cyprus	Blister	3,5,7,10 Box (8x10)
	Levofloxacin	500mg	Tablet	Macleods Pharmaceutical Ltd	A	Yes	Solan, Himachal Pradesh, India	India	Alu/PVC blister	5's x 20 tablet
	Levofloxacin	500mg	Tablet	HEC Pharm GmbH, Germany	B	Yes	Sunshine Lake Pharma Co., Ltd.	China	PVC/PVDC/ALU-Blister	10's
	Levofloxacin	500mg	Tablet	Hetero Labs Ltd	B	Yes	Hetero Labs Limited UNIT- V, TSIC Formulation SEZ, Sy No. 439, 440, 441 & 458, Polepally Village, Jadcherla Mandal, Mahaboobnagar District, Telangana	India	Alu/PVC Blister	1*1, 5*1, 7*1, 10*1,14*1, 50*1, 500*1
	Levofloxacin	500mg	Film-coated Tablet	PT. Kalbe Farma Tbk.	A	TB354	Kawasan Industri Delta Silicon, Jl.M.H.Thamrin Blok A3-1, Lippo Cikarang, Bekasi, 17550	Indonesia	Strip, Alu/Alu	10x3
	Levofloxacin	500mg	Film-coated Tablet	MSN Laboratories Private Limited	A	TB339	Formulations Division, Unit-II, Survey Nos. 1277, 1319 to 1324, Nandigama (Village & Mandal), Rangareddy (District), Telangana, 509228	India	Blister,Alu/PVC ; Bottle,HDPE	1x1, 10x1; 50x1
	Levofloxacin	750mg	Tablet	Macleods Pharmaceutical Ltd	A	Yes	Solan, Himachal Pradesh, India	India	Alu/PVC blister	10's x 10 tablet

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
	Levofloxacin	750mg	Tablet	Hetero Labs Ltd, India	B	Yes	Hetero Unit V Andra Pradesh	India	Blister	5,10
	Levofloxacin	750mg	Film-coated Tablet	MSN Laboratories Private Limited	A	TB340	Formulations Division, Unit-II, Survey Nos. 1277, 1319 to 1324, Nandigama (Village & Mandal), Rangareddy (District), Telangana, 509228	India	Blister,Alu/PVC ; Bottle,HDPE	1x1, 10x1; 20x1
39	Linezolid	600mg	Tablet	Hetero Europe SL Spain	B	Yes	Hetero Unit V Andra Pradesh	India	Blister	5,10
	Linezolid	600mg	Tablet, Film-coated	Mylan Laboratories Ltd	A	TB365	Plot No 11, 12 & 13, Indore Special Economic Zone, Pharma Zone, Phase II, Sector III, Pithampur, District Dhar, Madya Pradesh, 454 775	India	Bottle, HDPE	30x1, 100x1, 200x1
	Linezolid	600mg	Tablet	Pharmacia UK	B	Yes	Pfizer, Puurs,	Belgium	Blister HDPE Bottle	1x10, 2x10, 3x10, 5x10, 6x10 30,60
	Linezolid	600mg	Tablet	Teva Pharma S.L.U, Zaragoza, Spain	B	Yes	Teva Pharmaceutical Works, Debrecen	Hungary	Blister	10
	Linezolid	600mg	Tablet	Cipla Ltd, India	A	TB321	Indore, SEZ, Pithampur, Dist Dhar (M.P.), India	India	Alu/PVC blister HDPE Bottle	10x2 20x1
	Linezolid	600mg	Tablet	Hetero Labs Ltd, India	A	TB299	Mahaboob Nagar District, Andhra Pradesh	India	HDPE Bottle	20 tablets & 100 tablets

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
	Linezolid	600mg	Tablet	Dr.Reddy's Laboratories (UK) Limited	B	Yes	Bulk Production Polpharma S.A ul.Pelplinska 19, 83-200 Starogard Gdanski, Poland	Poland	oPA/Al/PVC/Al blister	10 units per pack in 10; 20; 30; 50; 60; 100
	Linezolid	600mg	Tablet	Macleods Pharmaceuticals Ltd	A	TB297	Block No. N2, Village Theda, P.O. Lodhi Majra, Tehsil Baddi, District Solan, Himachal Pradesh, 174 101	India	Blister Alu/PVC Strip Alu/Alu	10x10;10x10, 4x5
	Linezolid	600mg	Film coated tablet	Lupin Ltd	A	TB350	Lupin Ltd, EPIP, SIDCO Industrial Complex, Kartholi, Bari Brahmna, Jammu & Kashmir, 181 133	India	Alu/PVC Blister; Alu/PVC/PVdC Blister	10x10
	Linezolid	600mg	Film coated tablet	Celltrion Inc.	A	TB351	82, 2 Sandan-ro, Ochang-eup, Cheongwon-gu, Cheongju-si, Chungcheongbuk-do, 28117	Republic of Korea	Bottle, HDPE ; Blister, Alu/PVC/PVdC	10x1, 20x1, 30x1; 10x1, 10x2, 10x3, 10x6, 10x10
	Linezolid	600mg	Film coated tablet	Micro Labs Ltd	A	TB323	Unit 3, 92 Sipcot Industrial Complex, Hosur, Tamil Nadu, 635 126	India	Strip,Alu/Alu	4x1
40	Linezolid	100 mg/5 ml	Granules for Oral Suspension	Pharmacia UK	B	Yes	Pfizer, Puurs,	Belgium	Glass bottle	5x240ml (66 g per bottle) 10x240ml (66 g per bottle)
41	Linezolid	2mg/ml	Intra Venous Infusion	Pharmacia UK	B	Yes	Fresenius Kabi Norge AS	Norway	Infusion bag	5x300ml 10x300ml 20x 300ml
42	Meropenem	1g	Powder for Intra Venous injection/Infusion	Vianex, Greece	B	Yes	Vianex Plant D Patra, Axaia	Greece	Glass vial	1 vial 1x10 vials
	Meropenem	1g	Powder for Intra Venous injection	PANMEDICA, France	B	Yes	FacTA FARMACEUTICI S.p.A, Teramo	Italy	Glass vial	1 vial 1x10 vials

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
	Meropenem	1g	Powder for Intra Venous injection	DEMO SA Pharmaceutical Industry Greece	B	Yes	DEMO SA Pharmaceutical Industry	Greece	Glass vial	1 vial 1x10 vials
	Meropenem	1g	Powder for solution for injection	Venus Pharma GmbH Venus Pharma GmbH, Am Bahnhof 1-3, 59368 Werne, Germany	A	TB384	ill Top Industrial Estate, Jharmajri EPIP, Phase-1 (Extn.), Bhatoli Kalan, Baddi, Distt. Solan (Himachal Pradesh), 173205	India	20ml Clear glass vial with 20mm grey butyl rubber stopper 10 vials x1	1vial of 20ml 1x10 vials
	Moxifloxacin(as hydrochloride)	100mg	disp tablet	Micro Labs Ltd	A	TB349	Micro Labs Ltd, Unit 03, 92 Sipcot Industrial Complex, Hosur, Tamil Nadu, 635 126;	India	Alu-Alu strips; Alu-PVC/PE/PVDC blisters	10x10; 10x1, 14x1
	Moxifloxacin(as hydrochloride)	100mg	disp tablet	Macleods Pharmaceuticals Ltd	A	TB342	Macleods Pharmaceuticals Ltd, Block No. N2, Village Theda, P.O. Lodhi Majra, Tehsil Baddi, District Solan, Himachal Pradesh, 174 101	India	Alu/Alu blister	10x10
	Moxifloxacin	400mg	Tablet	Bayer Schering AG	B	Yes	Bayer Schering AG Leverkusen	Germany	Blister	5
	Moxifloxacin	400mg	Tablet	Macleods Pharmaceutical Ltd	A	Yes	Kachigam, Damam; Solan, Baddi	India	Alu/Alu cold form blister Alu/Alu strip	5, 10, 20
	Moxifloxacin	400mg	Tablet	Sun Pharmaceutical Industries Ltd	A	Yes	MSN Laboratories Ltd, Medak District, Andhra Pradesh, India	India	Alu/PVC/PVDC blister	1 x 5, 1 x 10, 10x10
	Moxifloxacin	400mg	Tablet	Hetero Europe SL	B	Yes	Hetero Unit V Andra Pradesh	India	Blister	5,7,10
	Moxifloxacin (as hydrochloride)	400 mg	Tablet	Mylan Laboratories Limited	A	TB286	Sinnar, Nashik, Maharashtra, India	India	Alu/PVC/PVDC blister HDPE Bottle	10x10 100
	Moxifloxacin (as hydrochloride)	400 mg	Tablet	Micro Labs Ltd, India	A	TB263	Hosur, Tamilnadu	India	PVC/PE/PVDC /Alu blister; Alu/Alu blister; HDPE bottle	10x10; 10 x 10; 30, 100

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
	Moxifloxacin (as hydrochloride)	400 mg	Tablet	MSN Laboratories Private Limited	A	TB341	Formulations Division, Unit-II, Survey Nos. 1277, 1319 to 1324, Nandigama (Village & Mandal), Rangareddy (District), Telangana, 509216	India	HDPE Bottle; Blister;Alu/PVC /PVdC	30x1, 500x1;; 5x3, 7x5, 10x3
	Moxifloxacin (as hydrochloride)	400 mg	Tablet	Hetero Labs Ltd, India	A	TB315	Unit 5, Survey No 439, 440, 441 & 458 TSIC Formulation SEZ, Polepally Village, Jadcherla (M), Mahaboob Nagar District, Telangana, 509 301	India	Alu/Alu Blister	10x1
	Moxifloxacin (as hydrochloride)	400 mg	Tablet	Zhejiang Hisun Pharmaceutical Co Ltd	A	TB289	1 Haizheng Avenue, Taizhou, Jiaojiang District, Zhejiang, 318 000	China	Alu-PVC/PVdC	10x3
	Moxifloxacin (as hydrochloride)	400 mg	Film coated Tablet	Getz Pharma Pvt Ltd	A	TB311	29-30/27 Korangi Industrial Area, Karachi, 74900	Pakistan	Blister	Blister Alu/Alu 5x1
46	Para-aminosalicylate sodiam	60% w/w	Delayed Release Granules	Macleods Pharmaceutical Ltd	A	Yes	Kachigam, Daman Solan, Himachal Pradesh	India	HDPE container; Sachet	100g; 9.2g
47	Para-aminosalicylic Acid sodiam	4g	Powder for oral solution	OlainFarm JSC	A-B	Yes	Olaine	Latvia	Box	25, 300
	Para-AminoSalicylic Acid	4g	Granules	Jacobus	B	Yes	New Jersey	USA	Box	30
	Pretomanid*	200mg	Tablet	Mylan Ireland Limited	B	NDA212862	Mylan Laboratories Limited, Plot No. H-12 & H-13, M.I.D.C. Waluj, Aurangabad-431136, Maharashtra	India	HDPE Bottle; PVC/PVDC Blister	26's count; 14's count
48	Prothionamide	250mg	Tablet	OlainFarm JSC	B	Yes	Olaine	Latvia	HDPE	1000

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
	Prothionamide	250mg	Tablet	SW Pharma GmbH (Former FATOL-(RIEMSER) Arzneimittel)	A-B	TB345	Schiffweiler	Germany	PVC/AL blister	50, 100
	Prothionamide	250mg	Tablet	Micro Labs Ltd	A	Yes	Hosur	India	Blister; Bottle	14; 100
	Prothionamide	250mg	Tablet	Lupin India Ltd	A	Yes	Chikalhana, Aurangabad	India	HDPE bottle	50
	Prothionamide	250mg	Film coated Tablet	Micro Labs Ltd	A	TB324	Plot No 11, 12 & 13, Indore Special Economic Zone, Pharma Zone, Phase II, Sector III, Pithampur, District Dhar, Madhya Pradesh, 454 775	India	Blister: Alu/PVC ; Bottle HDPE	10x1, 10x10; 60x1
49	Pyrazinamide	150mg	Dispersible tablets	Macleods Pharmaceutical Ltd	A	TB307	Solan, Himachal Pradesh	India	triple laminated bag further packed in HDPE bottle	100
	Pyrazinamide	150mg	Dispersible tablets	Micro Labs Ltd	A	TB335	Unit 3, 92 Sipcot Industrial Complex, Hosur, Tamil Nadu, 635 126	India	Bottle,HDPE ; Strip, Alu/Alu	100x1,500x1, 1000x1; 10x10
50	Pyrazinamide	400 mg	Tablet	Cadila Pharmaceuticals Ltd	A	Yes	Dholka, Ahmedabad	India	Blister ; HDPE bottle	10, 28; 1000
	Pyrazinamide	400 mg	Tablet	Macleods Pharmaceutical Ltd	A	Yes	Kachigam,Daman Oxalis lab, Solan, Baddi	India	HDPE Bottle; Alu/PVC/PVdc Blister	1000; 10,28
	Pyrazinamide	400 mg	Tablet	Micro Labs Ltd	A	Yes	Hosur, Tamilnadu	India	HDPE container	1000
51	Pyrazinamide	500 mg	Tablet	Micro Labs Ltd	A	Yes	Hosur, Tamilnadu	India	HDPE container Alu/PVC/PVdc Blister	1000 10
	Pyrazinamide	500 mg	Film coated tablet	SW Pharma GmbH (Former FATOL-(RIEMSER) Arzneimittel)	B	Yes	Schiffweiler, Germany	Germany	PVC/Alu blister	100, 500
	Pyrazinamide	500 mg	Tablet	OlainFarm JSC	B	Yes	Olaine	Latvia	HDPE Bottle	1000
	Pyrazinamide	500 mg	Tablet	Labatec Pharma	B	Yes	Meyrin, Geneva	Switzerlan d	Blister	10x10
	Pyrazinamide	500 mg	Tablet	Macleods Pharmaceutical Ltd	A	Yes	Kachigam Damam Oxalis lab, Solan, Baddi	India	Alu/PVC blister HDPE bottle	3 x 10, 10 x 10, 3 x 28, 24 x 28; 1000
	Pyrazinamide	500 mg	Tablet	S.C. Antibiotice S.A	A	Yes	Lasi	Romania	AluPVC Blister	2x10 150x10

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
52	Rifabutin	150mg	Capsule	Lupin India Ltd	A-B	Yes	Chikalthana, Aurangabad	India	HDPE Bottle	100
53	Rifapentine	150mg	Tablet	Sanofi Aventis, USA	A-B	TB366	Sanofi SpA, Anagni	Italy	Blister	24 (3 x 8's)
54	Rifampicin	100 mg/5ml	Granule for Syrup	Avantis Pharma	B	Yes	Gruppo Lepanti, Anagni	Italy	Glass Bottle;	120ml
	Rifampicin	100 mg / 5 ml	Granulate for oral suspension	SW Pharma GmbH (Former FATOL-(RIEMSER) Arzneimittel)	B	Yes	Lomapharm, Germany	Germany	Glass bottle	100ml
55	Rifampicin	150 mg	Capsule	Labatec Pharma	B	Yes	Meyrin, Geneva	Switzerland	PVC/Alu Blister	10*8's
	Rifampicin	150 mg	Capsule	Avantis Pharma	B	Yes	Gruppo Lepanti, Anagni	Italy	Glass Bottle; Blister	100; 100
	Rifampicin	150 mg	Film coated tablet	SW Pharma GmbH (Former FATOL-(RIEMSER) Arzneimittel)	B	Yes	Schiffweiler, Germany	Germany	PVC/Aclar/PVC /Alu blister	100, 500
	Rifampicin	150 mg	Capsule	Remedica	B	Yes	Limassol	Cyprus	Alu/PVC blister	10 (10*10 caps in carton box)
	Rifampicin	150 mg	Capsule	S.C. Antibiotice S.A	A	Yes	Lasi	Romania	AluPVC Blister	2x10 100x10
	Rifampicin	150 mg	Capsule	Macleods Pharmaceutical Ltd	A	TB259	Kachigam, Daman	India	HDPE Bottle; Alu/Alu strip	100; 10*10
	Rifampicin	300 mg	Capsule	Macleods Pharmaceutical Ltd	A	TB332	Unit 2, Plot No 25-27, Survey No 366, Premier Industrial Estate, Kachigam, Daman, 396 210	India	Blister, Alu/PVC ; Strip, Alu/Alu ; LDPE Bag	10x10; 100x1,
56	Rifampicin	300 mg	Capsule	Labatec Pharma	B	Yes	Meyrin, Geneva	Switzerland	PVC/Alu Blister	10*4's
	Rifampicin	300 mg	Capsule	Avantis Pharma	B	Yes	Gruppo Lepanti, Anagni	Italy	Glass Bottle; Blister	100; 100
	Rifampicin	300 mg	Film coated tablet	SW Pharma GmbH (Former FATOL-(RIEMSER) Arzneimittel)	B	Yes	Schiffweiler, Germany	Germany	PVC/Aclar/PVC /Alu blister	100, 500
	Rifampicin	300 mg	Capsule	S.C. Antibiotice S.A	A	Yes	Lasi	Romania	AluPVC Blister	1x10 100x10
	Rifampicin	300 mg	Capsule	Remedica	B	Yes	Limassol	Cyprus	Alu/PVC blister	10 (10*10 caps in carton box)
57	Rifampicin	450 mg	Capsule	Avantis Pharma	B	Yes	Gruppo Lepanti, Anagni	Italy	Glass Bottle; Blister	30; 8
	Rifampicin	450 mg	Film coated tablet	SW Pharma GmbH (Former FATOL-(RIEMSER) Arzneimittel)	B	Yes	Schiffweiler, Germany	Germany	PVC/Aclar/PVC /Alu blister	100, 500
58	Rifampicin	600 mg	Film coated tablet	SW Pharma GmbH (Former FATOL-(RIEMSER) Arzneimittel)	B	Yes	Schiffweiler, Germany	Germany	PVC/Aclar/PVC /Alu blister	100, 500
59	Streptomycin	1g	Powder for injection	Panpharma Laboratory	B	Yes	Fougeres	France	Bottle	50

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
	Streptomycin	1g	Powder for injection-IM	Reig Jofre	B	Yes	Laboratorio Reig Jofré, S.A. Madrid B. Braun Medical, S.A. Jaén	Spain	Glass Vial	100
	Streptomycin (sulfate) sterile	1 g	Powder for injection	NCPC International Corp.	A	TB296	North China Pharmaceutical Co Ltd, New Preparation Branch Factory, No. 115 Hainan Road, Shijiazhuang, Hebei	China (People's Republic of)	Vial, Type III glass	1x10
	Streptomycin (sulfate) sterile	1 g	Powder for injection	Macleods Pharmaceuticals Ltd	A	TB214	Unit 2, Plot No 25-27, Survey No 366, Premier Industrial Estate, Kachigam, Daman, 396 210	India	Vial, Type III glass	1x1
60	Terizidone	250mg	Capsule	SW Pharma GmbH (Former FATOL-(RIEMSER) Arzneimittel)	A-B	TB346	Schiffweiler	Germany	Blister	50
	Terizidone	250mg	Capsule	Macleods Pharmaceuticals Ltd	A	TB303	Macleods Pharmaceuticals Ltd, Unit 2, Plot No 25-27, Survey No 366, Premier Industrial Estate, Kachigam, Daman, 396 210, India	India	Container, HDPE Strip, Alu/Alu	100x1 ; 10x10
*	<p align="center">Conditions to be observed before procuring the products:</p> <p>* Bedaquiline: Procurement of this item is subject to compliance with WHO recommendations (as confirmed by WHO) concerning management of this item. See relevant WHO guidance at : http://apps.who.int/iris/bitstream/10665/84879/1/9789241505482_eng.pdf?ua=1</p> <p>* Delamanid: Procurement of this item is subject to compliance with WHO recommendations (as confirmed by WHO) concerning management of this item. See relevant WHO guidance at: http://apps.who.int/iris/bitstream/10665/137334/1/WHO_HTM_TB_2014.23_eng.pdf?ua=1&ua=1</p> <p>* Clofazimine : Procurement of this item is subject to receipt by GDF of named prescriptions from practitioners authorized to prescribe the medicine for this indication and signed Disclaimer for the use of this product</p> <p>*Pretomanid : Limited Population: Pretomanid Tablet is an antimycobacterial indicated, as part of a combination regimen with bedaquiline and linezolid for the treatment of adults with pulmonary extensively drug resistant (XDR), treatment-intolerant or nonresponsive multidrug-resistant (MDR) tuberculosis (TB). Approval of this indication is based on limited clinical safety and efficacy data. This drug is indicated for use in a limited and specific population of patients.</p>									

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

Edition: Version 101 - 06th July 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
	Clofazimine *	50mg	tablet	Macleods Pharmaceutical Ltd	ERP reviewed	30-09-20	Macleods Pharmaceuticals Limited, At, Oxalis Labs Village Theda, P.O Lodhimajra, Baddi, Distt. Solan, Himachal Pradesh, 174101	India	Al/PVC/PVD C blister or Al/Al strip; HDPE Bottle	28x10's OR 10x10's; 100
	Clofazimine *	100mg	tablet	Macleods Pharmaceutical Ltd	ERP reviewed	30-09-20	Macleods Pharmaceuticals Limited, At, Oxalis Labs Village Theda, P.O Lodhimajra, Baddi, Distt. Solan, Himachal Pradesh, 174101	India	Al/PVC/PVD C blister or Al/Al strip; HDPE Bottle	28x10's or 8x6's; 100

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
	Clofazimine *	100mg	soft capsule	Dong-A ST Co., Ltd.	ERP reviewed	27-01-21	1. Suheung Co.Ltd. 61, Osongsaengmyeong-ro, Osong-eup, Heungdeok-gu, Ceongjusi, Chungcheongbuk-do 2. Dong-A ST Co., Ltd. Cheonan Plant 200-23, Baekseokgongdan 1-ro, Seobuk-gu, Cheonan-si, Chungcheongnam-do, Korea 2F Section B, 3F, 4F Section B)	Republic of Korea	HDPE bottle	100'
	Rifapentine+Isoniazid	300mg+300 mg	tablet FDC	Macleods Pharmaceutical Ltd	ERP reviewed	08-11-2020	Oxalis Labs Village Theda, P.O Lodhimajra, Baddi, Distt. Solan, Himachal Pradesh, 174101	India	Alu/OPA/PVC-Alu blister; Alu-Alu strip	12, 3x12 and 10x12 Blister Pack 7x6 and 3x12 Strip Pack
	Rifampin+Isoniazid	75mg+50 mg	disp tablet FDC	Lupin Ltd	ERP reviewed	31-07-20	A-28/1, MIDC Area, Chikalhana, Aurangabad,Aurangabad- 431210	India	Alu-Alu Strip; Alu-Alu Blister	28x3, 14x6 10x10, 18x5, 25 x10

End of ERP Reviewed products list