

**List Of Antihepatitis Pharmaceutical Products  
(included to support Global Fund Policy for Co-Infections and Co-Morbidities)**

**Edition: Version 10 -16th of May 2018**

**List of A & B Products**

**As from the version 4, 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**

Ref. No	International Non-proprietary name	Strength/ Dose	Dosage form	Supplier/ Manufacturer(s)	Global Fund QA Standard	WHO Prequalification n/ SRA	Manufacturing site	Country	Material	Pack
18	Daclatasvir	30mg	Tablet	BMS Pharma UK	A-B	Yes	Astra Zeneca, Indiana Batch release:BMS Italy	USA	Blister	28 (2x14's)

	Daclatasvir (dihydrochloride)	30mg	Tablet	Bristol-Myers Squibb Company	A-B	HP007	Astra Zeneca Pharmaceuticals LP, 4601 Highway 62 East, Mount Vernon, Indiana, 47620, USA Bristol-Myers Squibb (BMS), Contrada Fontana del Ceraso, Anagni-Frosinone, 3012, Italy Bristol-Myers Squibb Manufacturing Company, State Road #3, Km 77.5, Humacao, 00791, Puerto Rico	USA	Blister, Alu/PVC-ACLAR	14x2, 28x1
	Daclatasvir (dihydrochloride)	60mg	Tablet	Bristol-Myers Squibb Company	A-B	HP008	Astra Zeneca Pharmaceuticals LP, 4601 Highway 62 East, Mount Vernon, Indiana, 47620, USA Bristol-Myers Squibb (BMS), Contrada Fontana del Ceraso, Anagni-Frosinone, 3012, Italy Bristol-Myers Squibb Manufacturing Company, State Road #3, Km 77.5, Humacao, 00791, Puerto Rico	USA	Blister, Alu/PVC-ACLAR	14x2, 28x1
19	Daclatasvir	60mg	Tablet	BMS Pharma UK	A-B	Yes	Astra Zeneca, Indiana Batch release:BMS Italy	USA	Blister	28 (2x14's)
	Daclatasvir (dihydrochloride)	90mg	Tablet	Bristol-Myers Squibb Company	B	EMEA/H/C/003768	Astra Zeneca Pharmaceuticals LP, 4601 Highway 62 East, Mount Vernon, Indiana, 47620, USA Bristol-Myers Squibb (BMS), Contrada Fontana del Ceraso, Anagni-Frosinone, 3012, Italy Bristol-Myers Squibb Manufacturing Company, State Road #3, Km 77.5, Humacao, 00791, Puerto Rico	USA	Blister, Alu/PVC-ACLAR	14x2, 28x1
1	Entecavir	0.5 mg	Tablet	Hetero labs Limited	A-B	HP005 ANDA 205740	Hetero labs Limited, Unit-V, Jadcherla, Mahaboobnagar-509301, Telangana State	India	HDPE Bottle ; Blister pack	30, 90 ; 10, 10*10

1	Entecavir	1.0 mg	Tablet	Hetero labs Limited	A-B	HP006 ANDA 205740	Hetero labs Limited, Unit-V, Jadcherla, Mahaboobnagar-509 301, Telangana State	India	HDPE Bottle ; Blister pack	30, 90 ; 10, 10*8
	Sofosbuvir	400 mg	Tablet	Mylan Laboratories Ltd	A	HP001	F4 & F12 Malegaon MIDC, Sinnar, Nashik District, Maharashtra, 422 113, India	India	HDPE Bottle -White or Blue	28
	Sofosbuvir	400 mg	Tablet	Cipla Ltd	A	HP004	Cipla, Unit 2, Plot A- 42 MIDC Industrial Area, Patalganga, Raigad District, Maharashtra, 410 220, India	India	Blister, Alu- PVC/PE/PVdC Bottle,HDPE	14x2; 28x1;84x1
	Sofosbuvir	400 mg	Tablet	Hetero labs Limited	A	HP002	Hetero labs Limited, Unit-V, Jadcherla, Mahaboobnagar-509 301, Telangana State	India	HDPE Bottle	28

## List Of Antihepatitis Pharmaceutical Products (included to support Global Fund Policy for Co-Infections and Co-Morbidities)

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### 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	Period Validity for ERP Review	Manufacturing site	Country	Material	Pack
	Sofosbuvir	400 mg	Tablet	European Egyptian Pharm. Ind.	ERP Reviewed	19-06-18	European Egyptian Pharm. Ind., Cairo Desert Road KM.25, El Manshia Alex, Amriya, Alexandria Egypt	Egypt	HDPE Bottle	28
	Sofosbuvir	400 mg	Tablet	Strides Shasun Ltd	ERP Reviewed	27-08-18	Strides Shasun Ltd- 36/7, Suragajakkanahalli Indlavadi Cross, Anekal Taluk Bangalore-562 106 India	India	HDPE Bottle	28
	Daclatasvir	30 mg	Tablet	Hetero Lab Ltd	ERP Reviewed	17-04-2019	V, TSIIC Formulation SEZ, Sy No. 439, 440, 441 & 458, Polepally Village, Jadcherla Mandal, Mahaboobnagar District, Telangana	India	HDPE Bottle	28
	Daclatasvir	60 mg	Tablet	Hetero Lab Ltd	ERP Reviewed	17-04-2019	V, TSIIC Formulation SEZ, Sy No. 439, 440, 441 & 458, Polepally Village, Jadcherla Mandal, Mahaboobnagar District, Telangana	India	HDPE Bottle	28

End of ERP Reviewed products list