

List of Antihepatitis Pharmaceutical Products (for Co-Infections and Co-Morbidities)

Edition: Version 26 - 31-Mar-2023

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/ SRA	Manufacturing site	Country	Material	Pack
H1	Daclatasvir(dihydrochloride)	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)	30 mg	Tablet	Mylan Laboratories Limited	A	HP015	F- 4 & F-12, MIDC, Malegaon, Sinnar, Nashik - 422 113 Maharashtra	India	HDPE bottle ; Alu-PVC/PVdC blister	28; 10x1
	Daclatasvir(dihydrochloride)	30 mg	Tablet	Hetero labs Limited	A	HP011	Unit 5, Survey No 439, 440, 441 & 458 TSIIC Formulation SEZ, Polepally Village, Jadcherla (M), Mahaboob Nagar District, Telangana, 509 301	India	Blister, Alu-PVC/Aclar ; Bottle, HDPE	10x10; 28x1
	Daclatasvir(dihydrochloride)	30 mg	Tablet	Cipla Ltd	A	HP021	Plot No. A-42 (Unit II), MIDC, Patalganga, District - Raigad, Maharashtra, Pin code: 410 220	India	HDPE bottle ; Alu-PVC/PE/PVDC blister	28; 14x2

	Daclatasvir(dihydrochloride)	30 mg	Tablet	Laurus Labs Limited, 2nd Floor, Serene Chambers, Road No. 7, Banjara Hills, Hyderabad, Telangana, 500 034, India	A	HP027	Laurus Labs Ltd, (Unit-2), Plot No:19, 20 & 21, Western Sector, APSEZ, Atchutapuram Mandal,Visakhapatnam- District, Andhra Pradesh, 531011, India	India	Bottle, HDPE	28x1, 500x1
H2	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	USA	Blister, Alu/PVC-ACLAR	14x2, 28x1
	Daclatasvir(dihydrochloride)	60mg	Tablet	BMS Pharma UK	A-B	Yes	Astra Zeneca, Indiana Batch release:BMS Italy	USA	Blister	28 (2x14's)
	Daclatasvir(dihydrochloride)	60 mg	Tablet	Mylan Laboratories Limited	A	HP016	F- 4 & F-12, MIDC, Malegaon, Sinnar, Nashik - 422 113 Maharashtra	India	HDPE bottle ; Alu- PVC/PVdC blister	28; 10x1
	Daclatasvir(dihydrochloride)	60 mg	Tablet	Hetero labs Limited	A	HP012	Unit 5, Survey No 439, 440, 441 & 458 TSIIC Formulation SEZ, Polepally Village, Jadcherla (M), Mahaboob Nagar District, Telangana, 509 301	India	Blister, Alu-PVC/Aclar ; Bottle, HDPE	10x10; 28x1
	Daclatasvir(dihydrochloride)	60 mg	Tablet	Cipla Ltd	A	HP022	Plot No. A-42 (Unit II), MIDC, Patalganga, District - Raigad, Maharashtra, Pin code: 410 220	India	HDPE bottle ; Alu- PVC/PE/PVDC blister	28; 14x2
	Daclatasvir(dihydrochloride)	60 mg	Tablet	Laurus Labs Limited, 2nd Floor, Serene Chambers, Road No. 7, Banjara Hills, Hyderabad, Telangana, 500 034, India	A	HP028	Laurus Labs Ltd, (Unit-2), Plot No:19, 20 & 21, Western Sector, APSEZ, Atchutapuram Mandal,Visakhapatnam- District, Andhra Pradesh, 531011, India	India	Bottle, HDPE	28x1, 500x1

H3	Daclatasvir (dihydrochloride)	90mg	Tablet	Bristol-Myers Squibb Company	B	EMA/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
H4	Entecavir	0.5 mg	Tablet	Hetero labs Limited	A-B	HP005 ANDA 205740	Hetero labs Limited, Unit-V, Jadcherla, Mahaboobnagar-509 301, Telangana State	India	HDPE Bottle ; Blister pack	30, 90 ; 10, 10*10
H5	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
H6	Ledipasvir+ sofosbuvir	90 mg+ 400 mg	Tablet, Film-coated	Mylan Laboratories Limited	A	HP019	F- 4 & F-12, MIDC, Malegaon, Sinnar, Nashik - 422 113 Maharashtra	India	HDPE Bottle	28
H7	Sofosbuvir/Velpatasvir	400mg+100mg	Tablet, Film-coated	Mylan Laboratories Limited	A	HP026	F- 4 & F-12, MIDC, Malegaon, Sinnar, Nashik - 422 113 Maharashtra	India	HDPE Bottle	28
	Sofosbuvir/Velpatasvir	400mg+100mg	Tablet, Film-coated	Gilead Sciences Ireland UC	A	HP024	IDA Business & Technology Park, Carrigtohill, County Cork, Ireland Patheon Inc, 2100 Syntex Court, Mississauga, Ontario, L5N 7K9	Canada	Bottle, HDPE	28x1
H8	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	Hetero labs Limited	A	HP002	Hetero labs Limited, Unit-V, Jadcherla, Mahaboobnagar-509 301, Telangana State	India	HDPE Bottle	28
	Sofosbuvir	400 mg	Tablet	Strides Pharma Science Limited	A	HP009	Oral Solid Dosage Forms Division, KRS Gardens, 36/7, Suragajakkanahalli, Indlawadi Cross, Anekal Taluk, Bangalore, Karnataka, 562 106	India	HDPE Bottle	28

H9	Daclatasvir+Sofosbuvir	60 mg+ 400 mg	Tablet, Film- coated	Mylan Laboratories Limited	A	HP025	F- 4 & F-12, MIDC, Malegaon, Sinnar, Nashik - 422 113 Maharashtra	India	HDPE Bottle	28
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End of A or B products list

List of Antihepatitis Pharmaceutical Products (for Co-Infections and Co-Morbidities)

Edition: Version 26 - 31-Mar-2023

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

End of ERP Reviewed products list