

## Task Force on Repurposing of Drugs (TFORD) for COVID-19

### Patent status in India: by GNANLEX

#### Darunavir

#### A. Active patents

S.no.	Title	Assignee	Patent details	Type of patent	Remarks
1.	Modulators of pharmacokinetic properties of therapeutics	Gilead Sciences, Inc.	App no/Grant no: IN332719 (10487/DELNP/2008): Filing date: 18/12/2008 Grant date: 24/02/2020 Expected expiry date: 06/07/2027 Form 27: not yet worked in India	Pharmaceutical composition of Darunavir and Cobicistat.	No Patent Barrier
2.	Process for the preparation of (3r,3as, 6ar)-hexahydrofuro [2,3-b] furan-3-yl (1s,2r)-3-[[4-aminophenyl] sulfonyl] (sobutyl) amino]-1-benzyl-2-hydroxypropylcarbamate	Janssen Sciences Ireland UC	App no/Grant no: IN293069 (617/MUMNP/2011) Filing date: 30/03/2011 Grant date: 20/02/2018 Expected expiry date: 01/09/2029 Form 27: not yet worked in India	Darunavir process patent	Patent Barrier. However, can be worked around.
3.	A process for preparation of darunavir	Laurus Labs Limited	App no/Grant no: IN299050 (3021/CHE/2012) Filing date: 24/07/2012 Grant date: 20/07/2018 Expected expiry date: 24/07/2032 Form 27: not yet worked in India	Darunavir process patent	Patent Barrier. However, can be worked around.
4.	Process for preparation of darunavir	Hetero Research Foundation	App no/Grant no: IN308174 (9759/CHENP/2012): Filing date: 19/11/2012 Grant date: 27/02/2019 Expected expiry date: 20/05/2030 Form 27: not yet worked in India	Darunavir process patent	Patent Barrier. However, can be worked around.
5.	An improved process for the preparation of darunavir	Micro Labs Limited	App no/Grant no: IN311671 (2451/CHE/2014): Filing date: 16/05/2014 Grant date: 26/04/2019 Expected expiry date: 16/05/2034 Form 27: not yet worked in India	Darunavir process patent	Patent Barrier. However, can be worked around.

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#### B. Pending applications

S.no.	Title	Assignee	Application details	Type of patent	Remarks
1.	A novel process for preparation of darunavir	Lupin Limited	App no: 1303/KOL/2009 Filing date: 30/10/2009 Status: Under prosecution	Darunavir API process	Can be worked around even if granted
2.	Anti-retroviral combination	Cipla Limited	App no: 1399/MUMNP/2010 Filing date: 30/06/2010 Status: Under prosecution (Reply to First examination report filled on 27/10/2015)	A single unitary multilayer tablet comprising of ritonavir and darunavir	Can be worked around even if granted
3.	An improved process for preparing darunavir	Aurobindo Pharma Ltd	App no: 199/CHE/2012 Filing date: 18/01/2012 Status: Under prosecution (Response to hearing notice filled on 04/02/2020)	Darunavir process preparation	Can be worked around even if granted
4.	Novel solvates of darunavir	Aurobindo Pharma Ltd	App no: 2314/CHE/2012 Filing date: 11/06/2012 Status: Under prosecution (correspondence to hearing notice on 11/11/2019)	Darunavir process preparation	Can be worked around even if granted
5.	Darunavir polymorph and process for preparation thereof	Cipla Limited	App no: 1875/MUMNP/2012 Filing date: 31/07/2012 Status: Under prosecution (Reply to First Examination Report filled on 13/04/2018)	Darunavir process preparation	Can be worked around even if granted
6.	A pharmaceutical composition comprising a solid dosage.	Cipla Limited	App no: 201628006782 Filing date: 26/02/2016 Status: Under prosecution (First examination report on 27/11/2019)	Pharmaceutical composition of darunavir	Can be worked around even if granted
7.	A simplified procedure for the preparation of darunavir	Janssen Sciences Ireland Unlimited Company	App no: 201917019679 Filing date: 17/05/2019 Status: Under prosecution (correspondence on 13/11/2019)	Darunavir process preparation	Can be worked around even if granted

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#### C. Expired/Lapsed applications

S.no.	Title	Assignee	Application details	Type of patent	Remarks
1.	Combination of cytochrome p450 dependent protease inhibitors	Tibotec Pharmaceuticals Ltd.	App No: 1647/DELNP/2004 Filing Date: 11/06/2004 Status: Patent application withdrawn on 14/05/2013	Darunavir API	No patent barrier
2.	Ethanolate and hydrate pseudopolymorphs of a hiv protease inhibitor	Tibotec Pharmaceuticals Ltd.	App no: 3598/DELNP/2004 Filing Date: 17/11/2004 Status: Patent application appears to be abandoned for not submitting reply to First examination report	Darunavir API	No patent barrier
3.	A process for preparing compound of formula (6)	Janssen Sciences Ireland Uc	App No: 2122/DELNP/2006 Filing Date: 16/04/2006 Status: Patent application has been refused u/s 15	Darunavir API. process	No patent barrier
4.	Methods for the preparation of (3R,3AS, 6AR) hexahydro-furo [2,3-B] furan-3-ol	Tibotec Pharmaceuticals Ltd.	App No: 5301/DELNP/2006 Filing Date: 13/09/2006 Status: Patent application has been refused u/s 25 (1)	Darunavir API process	No patent barrier
5.	Modulators of pharmacokinetic properties of therapeutics	Gilead Sciences, Inc.	App No: 5324/DELNP/2009 Filing Date: 19/08/2009 Status: Patent application appears to be abandoned for not submitting reply to examination report on 15/04/2017 u/s 21(1)	Combination of Darunavir/Cobicistat.	No patent barrier
6.	Combination formulations comprising darunavir and etravirine	Tibotec Pharmaceuticals	App No: 35/MUMNP/2010 Filing Date: 07/01/2010 Status: Patent application deemed to be abandoned u/s 21(1)	Combination of darunavir and etravirine.	No patent barrier
7.	Anti-HIV tablet formulations comprising darunavir	Tibotec Pharmaceuticals	App No: 357/MUMNP/2010 Filing Date: 24/02/2010 Status: Patent application appears to be abandoned for not submitting reply to examination report on	Tablet formulation comprising darunavir.	No patent barrier

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			28/06/2016		
8.	Polymorphs of darunavir	Mapi Pharma Hk Limited	App No: 7790/DELNP/2010 Filing Date: 03/11/2010 Status: Application deemed to be abandoned u/s 21(1) for not submitting the reply to First Examination Report (FER) on 01/02/2018	Darunavir API polymorph	No patent barrier
9.	Process for the preparation of darunavir and darunavir intermediates	Mapi Pharma Ltd	App No: 2226/DELNP/2011 Filing Date: 25/03/2011 Status: Patent application appears to be withdrawn	Process preparation of darunavir and its intermediates.	No patent barrier
10.	Improved process for preparation of carbamic acid, n-[(1s, 2r)-3-[[4-aminophenyl) sulfonyl] (2-methylpropyl) amino]-2-hydroxy-1-(phenylmethyl) propyl]-, (3r, 3as, 6ar)-hexahydrofuro [2, 3-b] furan-3-yl ester and novel intermediate use in the preparation thereof	Sandoz AG	App No: 1226/MUM/2011 Filing Date: 15/04/2011 Status: Application appears to be abandoned	Process preparation of darunavir and its intermediates.	No patent barrier
11.	Novel crystalline darunavir and process for its preparation	Mylan Laboratories Ltd	App No: 4206/CHE/2011 Filing Date: 05/12/2011 Status: Application deemed to be abandoned u/s 21(1) for not submitting the reply to First Examination Report (FER) on 11/01/2018	Process preparation of crystalline darunavir	No patent barrier
12.	A new process for the synthesis of HIV protease inhibitors	Council Of Scientific Industrial Research	App No: 82/DEL/2012 Filing Date: 10/01/2012 Status: Application deemed to be abandoned u/s 21(1) on 25/09/2019	Process preparation of darunavir	No patent barrier
13.	Polymorphs of darunavir	Hetero Research Foundation	App No: 4069/CHENP/2012 Filing Date: 08/05/2012 Status: Application appears to be abandoned	Process preparation of amorphous darunavir	No patent barrier
14.	Pharmaceutical composition of	Cipla Limited	App No: 1994/MUM/2012	Darunavir composition	No patent barrier

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	darunavir		Filing Date: 10/07/2012 Status: Application appears to be abandoned (correspondence on 23/12/2014)		
15.	Darunavir combination formulations	1 Janseen sciences Ireland 2. Gilead sciences inc.	App No: 115/MUMNP/2014 Filing Date: 20/01/2014 Status: Application deemed to be abandoned u/s 21(1) for not submitting the reply to First Examination Report (FER) on 27/09/2018	Darunavir combination	No patent barrier
16.	Darunavir formulations	Janssen Sciences Ireland UC	App No: 114/MUMNP/2014 Filing Date: 20/01/2014 Status: Application deemed to be abandoned u/s 21(1) for not submitting the reply to First Examination Report (FER) on 21/01/2019	Darunavir composition	No patent barrier
17.	Solvates of HIV protease inhibitor and processes for preparation thereof	Lupin Limited	App No: 999/MUM/2014 Filing Date: 02/10/2015 Status: Application appears to be abandoned (correspondence on 18/11/2015)	Process preparation of darunavir	No patent barrier
18.	Combination therapy comprising tenofovir alafenamide hemifumarate and cobicistat for use in the treatment of viral infections	Gilead Sciences Inc.	App No: 7100/DELNP/2014 Filing Date: 22/08/2014 Status: Application deemed to be abandoned u/s 21(1) on 21/09/2019	Combination therapy comprising tenofovir alafenamide hemifumarate and cobicistat	No patent barrier
19.	A novel process to prepare intermediates of HIV-protease inhibitors thereof	ZCL Chemicals Ltd	App No: 2958/MUM/2014 Filing Date: 16/09/2014 Status: Application deemed to be abandoned u/s 21(1) on 18/02/2020	Process preparation of darunavir	No patent barrier
20.	Crystalline form of darunavir and process for preparing thereof	Cadila Healthcare Limited	App No: 3027/MUM/2014 Filing Date: 22/09/2014 Status: Application appears to be abandoned	Process preparation of darunavir	No patent barrier

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			(correspondence on 19/11/2015)		
21.	Darunavir n-propanol solvate and process for preparation thereof	Lupin Limited	App No: 3990/MUM/2014 Filing Date: 12/12/2014 Status: Application appears to be abandoned (correspondence on 10/04/2018)	Process preparation of darunavir	No patent barrier
22.	A novel process for the preparation of HIV protease inhibitor and intermediates thereof	Granules India Limited	App No: 201641025234 Filing Date: 22/07/2016 Status: Patent application appears to be withdrawn	Process preparation of darunavir	No patent barrier
23.	A high drug loaded tablet composition for treating HIV	Hetero Research Foundation	App No: 201641026995 Filing Date: 08/08/2016 Status: Patent application appears to be withdrawn	Tablet composition of darunavir	No patent barrier
24.	A multi-class anti-retroviral composition	Hetero Research Foundation	App No: 201641026996 Filing Date: 08/08/2016 Status: Patent application appears to be withdrawn	Combination composition of darunavir, dolutegravir and cobicistat	No patent barrier
25.	Anti-retroviral compositions	Hetero Research Foundation	App No: 201641026997 Filing Date: 08/08/2016 Status: Patent application appears to be withdrawn	Combination composition of darunavir and dolutegravir	No patent barrier
26.	Process for the preparation of darunavir	Amneal Pharmaceuticals Company GMBH	App No: 201727045657 Filing Date: 19/12/2017 Status: Current status not available on ipairs	Process preparation of darunavir	No patent barrier

#### Disclaimer:

Search results are up to 11<sup>th</sup> April 2020

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