

API Products

DDODUGTO	THERAPEUTIC	AVAILABLE STATUS ON								
PRODUCTS	CATEGORY	Tech pack	GMP	EUWC	US DMF	EDMF/ CEP	MEXICO/ BRAZIL DMF	TDMF	KDMF/ JDMF	PATENT
Anagrelide HCI	Antithrombocythemic	Α	WHO	Α	✓	√	√	✓	✓	-
Azithromycin Dihydrate	Macrolides	Α	WHO	Α	✓	√	√	√	√	-
Agomelatine Form II	Antidepressant	Α	WHO	Α	✓	✓	√	Α	✓	INDIA 851/MUM/2014
Aprepitant Form I And Form II (CEP 2019-093)	Anti-Emetic	Α	WHO	Α	✓	✓	√	Α	✓	India 20116210 09118
Bisoprolol Hemifumarate (CEP NO2013-342)	Anti Hypertensive	A	WHO	Α	√	Α	√	Α	√	-
Bazedoxifene Acetate Form A & B	Selective Estrogen Receptor Modulator	А	INDIA	2020	√	√	√	√	√	-
Chloramphenicol Base & Palmitate	Anti-Bacterial	Α	WHO	Α	✓	✓	√	✓	✓	-
Cinacalcet Hcl Form I	Calcimimetic	Α	WHO	Α	✓	✓	√	Α	✓	PCT/India IB2015 056205
Dipyridamol	Antiplatele	Α	INDIA	2019	✓	✓	✓	✓	✓	
Erythromycin Base - CEP NO RO-CEP 2009-267		Α	WHO	Α	√	Α	√	Α	√	
Erythromycin Ethyl Succinate CEP-2017-281	MACROLIDES	А	WHO	Α	✓	U/P	✓	√	✓	
Erythromycin Stearate			Α	WHO	Α	√	√	√	√	
Esmolol Hcl	Cardiology	Α	WHO	Α	✓	✓	✓	✓	✓	
Fluvoxamine Maleate	Antidepressant	Α	WHO	Α	✓	√	√	√	√	
Linagliptin Form A	Anti-diabetic	А	INDIA	2020	√	√	√	√	√	
Mirabegron Form α	Beta-3 adrenergic	А	INDIA	2020	✓	✓	✓	✓	✓	India 20162100 9117
Rivaroxaban Form I	Anticoagulant	Α	WHO	Α	√	✓	√	√	√	India PCT/IB20 16/053346

REMARKS - A : AVAILABLE ✓ - DOCUMENTS READY FOR FILING

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WHO

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Under Development

Vasodilator

Treprostinil Monohydrate

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PRODUCTS	THERAPEUTIC CATEGORY	DEVELOPMENT TIME LINE
Dabigatran Etexilate Mesylate	Anticoagulant	2019/2020
Dapagliflozin Propanediol Monohydrate	Antidiabetic	2018/2019
Empagliflozin	Antidiabetic	2019/2020
Edoxaban Tosylate Monohydrate	Anticoagulant	2019/2020

Under Evaluation

PRODUCTS	THERAPEUTIC CATEGORY
Apixaban	Anticoagulant
Luliconazole	Antifungal
Pazopanib HCI	Oncology
Pomalidomide	Immunomodulatory agent
Pirfenidone	Idiopathic Pulmonary Fibrosis
Sapropterin Di HCI	Phenylalanine Hydroxylase activator
Sorafenib Tosylate	Oncology
Tamsulocin HCI	Alpha-1a adrenergic antagonist
Teriflunomide	Immunomodulatory agent
Tofacitinib Citrate	Rheumatoid arthritis

The above products are offered as per BP/EP/USP/JP and FP and as per customers in-house Specifications.

Also available in Microfine

*Indian GMP- as per schedule M

*WHO GMP-Issued by Indian FDA to the format recommended by WHO

* EU-WC- EU Written confirmation

The above products are intended to supplied solely as per usage reasonably relating to the testing and development of information, regulatory submission, strictly according to the section 107A of the Indian Patent Act, 1970

DISCLAIMER

Mehta API has technical capabilities of manufacturing Linagliptin and Rivaroxaban and their Intermediates. However, these products will be offered only to the markets where product and process are not infringing. The quantities for the purpose of Research and Development of product for regulatory submission will be offered only to countries where such exemptions exists (Hatch Waxman Act/Bolar exemption) during the validity of the patent. While MAPL offers to work with the clients on status verification of patent, the ultimate responsibility vests with the buyer. Recipients of these APIs and intermediates are requested to make their independent evaluation and determination as to the patent status prior to the use of material and information in their respective jurisdiction. Products under patent offered only for exempted research, clinical and development purpose.

REFERENCE STANDARDS OF API & IMPURITIES AVAILABLE



Intermediate

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NAME OF THE INTERMEDIATES	CAS NO	END PRODUCT
7-Methoxy-1-naphthylacetonitrile	138113-08-3	Agomelatine
N-Methylcarbonyl-2-Chloroacetamidrazone	155742-64-6	Aprepitant
(2R,3S)-2-[(1R)-1-[3,5-is(trifluoromethyl)phenyl]ethoxy]- 3-(4-fluorophenyl)morpholine hydrochloride	171482-05-6	Aprepitant
1-[4-(2-Azepan-1-yl-ethoxy)-benzyl]-5-benzyloxy- 2-(4-benzyloxy -phenyl)-3-methyl-1h-indole	198480-21-6	Bazedoxifene
3-Acetyl-2-(aminosulfonyl)-5-chlorothiophene	160982-10-5	Brinzolamide
3-(2-Bromoacetyl)-5-chlorothiophene-2-sulfonamide,	160982-11-6	Brinzolamide
3-(3'-Trifluoromethylphenyl)propanol	78573-45-2	Cinacalcet
3-[(3-Amino-4-methylaminobenzoyl) pyridine-2-ylamino]propionic acid with ethyl ester	212322-56-0	Dabigatran
N-[[2-[[[4-(Aminoiminomethyl)phenyl]amino]methyl]-1-methyl-1H- benzimidazol- 5-yl]carbonyl]-N-(2-pyridinyl)-beta-alanine ethyl ester hydrochloride	211914-50-0	Dabigatran
1-(1,2,3,6-Tetrahydro-4-pyridyl)-2-Benzimidazolione	2147-83-3	Droperidol
1-{(4-methyl-quianazolin-2yl)methyl}-3-methyl-7- (2-butyn-1-yl)-8-bromo-xanthine	853029-57-9	Linagliptin
Tert-butyl (R)-piperidin-3-ylcarbamate/(R)-piperidin- 3-amine dihydrochloride	334618-23-4	Linagliptin
(1R)-2-{[2-(4-aminophenyl)ethyl]amino}-1-phenylethanol HCL	521284-22-0	Mirabegron
(S-1-decyn-O-tert dimethyl silyl-2-yl-5-ol		Prostaglandin
5-Bromo-2-(2-methyl-2H-tetrazol-5-yl)pyridine	380380-64-3	Tedizolid

Remarks:

Patent:All transactions are carried out in conformity with patent laws applicable in the user country, responsibility with respect to third parties rights in a specific country lies exclusively with the user.

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^{*} Under development/evaluation. ✓ Available.