3. **List of new drugs approved in the year 2019 till date**

S.No.	Name of drug	indication	Date of issue
1	Fenspiride hydrochloride film coated extended release tablet 80 mg and fenspiride hydrochloride bulk	1. Acute Rhinosinusitis 2. moderate persistent asthma as an add- on therapy	04-02-2019
2	Bilastine tablets 20 mg and Bilastine bulk	For symptomatic treatment of allergic rhino-conjuctivitis (seasonal and perennial) and utricaria in adults	06-02-2019
3	Iguratimod film coated tablets 25 mg and iguratimod bulk	For the treatment of active rheumatoid arthritis symptoms	18-02-2019
4.	Fingolimod Capsules 0.5 mg and Fingolimod hydrochloride bulk	For the treatment of patients with relapsing forms of multiple sclerosis (MS) to reduce the frequency of clinical exacerbations and to delay the accumulation of physical disability.	25.03.2019
5	Remogliflozin etabonate bulk and Remogliflozin etabonate film coated tablets 100 mg	Indicated in adults aged 18 years and older with type 2 diabetes mellitus to improve glycemic control as:- • Monotherapy when diet and exercise alone do not provide adequate glyceamic control. • Add on therapy with metformin together with diet and exercise, when these do not provide adequate glyceamic control.	26.04.2019

05	45	Application for registrationof bioavailability and bioequivalence study centre	5,00,000
07	47	Reconsideration of application for Registration of bioavailability and bio-equivalence study centre	1,00,000
08	52	Application for permission to manufacture new drugs or investigational new drugs for clinical trial or bioavailability or bioequivalence study	5000 per product
09	53	Reconsideration of application to manufacture new drugs or investigational new drugs for clinical trial or bioavailability or bioequivalence study	2000 per product
10	59	Application for permission to manufacture unapproved active pharmaceutical ingredient for development of formulation for test or analysis or clinical trial or bioavailability or bioequivalence study	5000 per product
11	60	Reconsideration of permission to Manufacture unapproved active pharmaceutical ingredient for development of formulation for test or analysis or clinical trial or bioavailability or bioequivalence study	2000
12	67	Application for import of new drugs or investigational new drugs for clinical trial or bioavailability or bioequivalence study or for examination, test and analysis	5000 per product
13	68	Reconsideration of application for Import of new drugs or investigational new drugs for clinical trial or bioavailability or bioequivalence study or for examination, test and analysis	1000
14	75	Application for permission to import new drug (Finished Formulation) for marketing	5,00,000
15		Application for permission to import new Drug (Finished Formulation) already approved in the country for marketing	2,00,000
16		Application for permission to import new drug (Active Pharmaceutical Ingredient) for marketing	5,00,000

17		Application for permission to import new drug (Active Pharmaceutical Ingredient) already approved in the country for marketing	2,00,000
18		Application for permission to import approved new drug for new claims, new indication or new dosage form or new route of administration or new strength for marketing	3,00,000
19		Application for permission to import fixed dose combination having one or more of the ingredients as unapproved new molecules for marketing	5,00,000
20		Application for permission to import fixed Dose combination having approved ingredients for marketing	4,00,000
21		Application for permission to import fixed dose combination already approved for marketing	2,00,000
22		Application for permission to import fixed dose combination for new claims, new indication or new dosage form or new route of administration or new strength for marketing	3,00,000
23	76	Reconsideration of application for permission to import new drug for marketing	50,000

24	80	Application for permission to manufacture new drug (Finished Formulation or Active Pharmaceutical Ingredient) for sale or distribution	5,00.000
25		Application for permission to manufacture new drug (Active Pharmaceutical Ingredient) already approved in the country for sale or distribution	2,00.000
26		Application for permission to manufacture new drug (Finished Formulation) for sale or distribution	5,00.000
27		Application for permission to manufacture new drug (Finished Formulation) already approved in the country for sale or distribution	2,00.000
28		Application for permission to manufacture new drug (Active Pharmaceutical Ingredient) for sale or distribution	5,00.000

29		Application for permission to manufacture new drug (Active Pharmaceutical Ingredient) already approved in the country for sale or distribution	2,00,000
30		Application for permission to manufacture approved new drug for new claims, new indication or new dosage form or new route of administration or new strength for sale or distribution	3,00,000
31		Application for permission to manufacture fixed dose combination having one or more of the ingredients as unapproved new molecules for sale or distribution	5,00,000
32	80	Application for permission to manufacture fixed dose combination having approved ingredients for sale or distribution	3,00,000
33		Application for permission to manufacture fixed dose combination already approved for sale or distribution	2,00,000
34		Application for permission to manufacture fixed dose combination for new claims, new indication or new dosage form or new route of administration or new strength for sale or distribution	3,00,000
35	80	Application for permission to manufacture new drug (Active Pharmaceutical Ingredient) or to manufacture finished formulation	5,00,000
36		Application for permission to import or to manufacture phyto-pharmaceutical drugs	2,00,000
		Reconsideration of application for	
37	81	permission to manufacture new drug for sale or distribution	50,000
		Application for Import of unapproved new	
38	86	drug by Government hospital and medical institution	10,000
		Application for permission to manufacture unapproved new drug but under clinical	
39	91	trial, for treatment of patient of life threatening disease	5,000
40	98	Pre-submission meeting	5,00,000
41	99	Post-submission meeting	50000
42	-	Any other application which is not specified above	50000

1: No fee shall be chargeable in respect of application for conduct of clinical trial for orphan drugs as defined in se (x) of rule 2.

2: In case of application received from Micro Small Medium Enterprises (MSME) firms for conduct of clinical approval of new drug and pre and post submission meeting, the fee payable shall be half of the fee specified above.