

DEVA API PRODUCT LIST

Product name	Pharmaceutical Group	DMF Holder	DMF / CEP / Pharmacopoeias
Fingolimod Hydrochloride	Antineoplastic and Immunomodulating Agents	DEVA	DEVA EU DMF (AP+RP) available. 3.2.S: approved in EU (NL, DE); CEP: application done.
Imatinib Mesylate	Antineoplastic and Immunomodulating Agents	DEVA	R0-CEP 2016-299-Rev 00 DEVA EU DMF (AP+RP) and CEP available.
Lenalidomide	Antineoplastic and Immunomodulating Agents	DEVA	DEVA EU-DMF (AP+RP): approved in EU (NL, DE)
Sildenafil Citrate	Genito Urinary System and Sex Hormones	DEVA	NA
Pomalidomide	Antineoplastic and Immunomodulating Agents	DEVA	AP-DMF: available EU-DMF (AP+RP): under preparation
Indacaterol Maleate	Respiratory System	DEVA	AP-DMF: available EU-DMF (AP+RP): under preparation
Tiotropium Bromide Anhydrous	Respiratory System	DEVA	AP-DMF: available EU-DMF (AP+RP): can be prepared in case of demand If required, in case of demand, we can produce and have the capacity for monohydrate form.
Teriflunomide	Antineoplastic and Immunomodulating Agents	DEVA	AP-DMF: available EU-DMF (AP+RP): under preparation Published in Pharm. Europe Following
Dasatinib	Antineoplastic and Immunomodulating Agents	DEVA	AP-DMF: available EU-DMF (AP+RP): under preparation
Isoproterenol Hydrochloride	Respiratory System	DEVA	EP, USP; CEP: application is not planned.
Nilotinib Hydrochloride Dihydrate	Antineoplastic and Immunomodulating Agents	DEVA	EP describes monohydrate. Therefore, we cannot apply for CEP.
Nilotinib Dihydrochloride Dihydrate	Antineoplastic and Immunomodulating Agents	DEVA	EP describes monohydrate. Therefore, we cannot apply for CEP.

NA: Not Applicable.