

Anti Diabetic

MOLECULE	API	BE REFERENCE PRODUCT	COUNTRIES REGISTERED IN	COUNTRIES COMMERCIALIZED IN
Products with CTD Dossiers (DMF, International BE)				
Gliclazide 30/60 mg MR Tablets	CEP	Diamicon® Gliclazide MR Tablets 30, 60 mg (Servier, UK)	Under Development	-
Metformin HCl 500 mg ER USP Tablets	DMF	Glucophage® Metformin HCl XR Tablets 500 mg (BMS, US)	US (2012), UAE (2018), South Africa (Under registration)	US (2013)
Metformin HCl 750 mg ER USP Tablets	DMF	Glucophage® Metformin HCl XR Tablets 750 mg (Merck, Malaysia)	Guatemala (2014), Philippines (2016), Malaysia (Under registration), Peru (2016), Vietnam (2016), Kazakhstan (2018), Myanmar (2017), Tanzania (2019), Uganda (Under registration)	Guatemala (2014), Vietnam (2017), Peru (2017), Myanmar (2018)
Metformin HCl 500 mg PR Tablets	CEP	Glucophage® Metformin HCl SR Tablets 500 mg PR (Merck, UK)	UK (Under registration), Italy (Under registration) Netherlands (Under registration), Poland (Under registration)	-
Metformin HCl 750 mg PR Tablets	CEP	Glucophage® Metformin HCl SR Tablets 750 mg PR (Merck, UK)	UK (Under registration), Italy (Under registration) Netherlands (Under registration), Poland (Under registration)	-
Metformin HCl 1000 mg PR Tablets	CEP	Glucophage® Metformin HCl SR Tablets 1000 mg PR (Merck, UK)	UK (Under registration), Italy (Under registration) Netherlands (Under registration), Poland (Under registration)	-
Metformin 500 / 1000 mg ER Tablets	DMF	Glumetza Metformin HCL ER Tablets (Valeant Pharmaceutical International, Inc.,US)	Under Development	-
Metformin 500 / 1000 mg ER Tablets	DMF	Fortamet Metformin HCL ER Tablets (Actavis Laboratories FL, Inc.,US)	Under Development	-
Dapagliflozin 5mg/ 10 mg Tablets	DMF	Farxiga® Dapagliflozin Tablets 10mg (AstraZeneca, US)	US (Tentative approval received 2019)	-
Products with CTD Dossiers (Non DMF, International BE)				
Metformin HCl 500 mg SR Tablets	Non DMF	Glucophage® Metformin HCl XR Tablets 500 mg (BMS, US)	India (2006), Vietnam (2006), Philippines (2010), Malaysia (2010), Myanmar (2011), Jamaica (2011), Nigeria (2012), Cambodia (2012), Uzbekistan (2012), Guatemala (2014), Kenya (2014), Dominican Republic (2015), Sri Lanka (2012),Uganda (2015), Tanzania (2015), Peru (2016), Ethiopia (2018), Yemen (Under registration) Trinidad (Under registration), Kazakhstan(2018)	India (2006), Vietnam (2006), Philippines (2010), Malaysia (2010), Myanmar (2012), Cambodia (2012), Guatemala (2014), Kenya (2014), Sri Lanka (2012), Uzbekistan (2012), Nigeria (2012), Tanzania (2015), Uganda (2015), Peru (2017)

Anti Diabetic continued



MOLECULE	API	BE REFERENCE PRODUCT	COUNTRIES REGISTERED IN	COUNTRIES COMMERCIALIZED IN
Products with CTD Dossiers				
Metformin HCl 500 mg SR + Glimepiride 1/2 mg Tablets	Non DMF	Glucophage® Metformin HCl XR Tablets 500 mg (BMS, USA)+ Amaryl®2 Glimepiride Tablets 2 mg (Aventis, India)	India (2004), Philippines (2011), Malaysia (2012), Kenya (2013), Myanmar (2009), Nigeria (2011), Vietnam (2010), Uzbekistan (2015), Jamaica (2012), Dominican Republic (2016), Cambodia (2015), Venezuela (Under registration), Uzbekistan (2016), Guatemala (2019) Ethiopia (Under registration) Yemen (Under registration) ,Peru (Under registration)	India (2004), Vietnam (2010), Nigeria (2011), Philippines (2011), Malaysia (2013), Kenya (2013), Myanmar (2009), Jamaica (2016)
Products with ACTD Dossiers				
Metformin HCl 500 mg SR + Pioglitazone HCl 15/30 mg Tablets	Non DMF	Glucophage® Metformin HCl XR Tablets 500 mg (BMS, US) + Actos® Pioglitazone HCl Tablets 30 mg (Takeda, US)	India (2004), Jamaica (2012),	India (2004), Jamaica (2016)
Metformin HCl 1000 mg SR + Glimepiride 1/2 mg Tablets	Non DMF	NA	India (2007), Venezuela (under registration), Nigeria (2016), Ghana (Under registration), Guatemala (2019)	India (2007), Nigeria (2018)
Metformin HCl 500 mg SR + Voglibose 0.2/0.3 mg Tablets	Non DMF	Glucophage® Metformin HCl XR Tablets 500 mg (BMS, US) + Volix® Voglibose Tablets 0.3 mg (Ranbaxy, India)	India (2011)	India (2011)
Semi Finished Formulations				
Dapagliflozin Granules 4%w/w	DMF	Farxiga® Dapagliflozin Tablets 10mg (AstraZeneca, US)	-	-
Gliclazide SR DC Granules 18.18% w/w	CEP	Diamicron® Gliclazide MR Tablets 30, 60 mg (Servier, France)	-	-
Metformin SR DC Granules 59.88% w/w	Non DMF	Glucophage® Metformin HCl XR Tablets 500 mg (BMS, US)	Bangladesh (2004), Lebanon (2011)	Bangladesh (2004), Lebanon (2011)
Metformin SR DC Granules 65.22% w/w	DMF	Glucophage® Metformin HCl XR Tablets 750 mg (Merck, Malaysia)	-	-
Metformin SR DC Granules 72.72% w/w	Non DMF	NA	Lebanon (2011), Bangladesh (2015)	Lebanon (2011), Bangladesh (2015)

Gastrointestinal

MOLECULE	API	BE REFERENCE PRODUCT	COUNTRIES REGISTERED IN	COUNTRIES COMMERCIALIZED IN
Products with CTD Dossiers (DMF, International BE)				
Lansoprazole 15/30 mg DR Capsules	DMF	Prevacid® Lansoprazole DR Capsules 30 mg (Takeda, US)	US (2017)	US (2018)
Mesalamine 1.2 g DR Tablets	DMF	Lialda® Mesalamine DR Tablets 1.2 g (Shire, US)	Under Development	-
Products with CTD Dossiers				
Rabeprazole 20 mg Buffer Tablets	Non DMF	Pariet® Rabeprazole Tablets 20 mg (GlaxoSmithKline, India)	India (2007), Sri Lanka (2012), Myanmar (2013), Vietnam (2015), Nigeria (Under registration), Uganda (Under registration),	India (2007), Sri Lanka (2012), Myanmar (2013), Cambodia (2014), Vietnam (2015)
Products with ACTD Dossiers				
Omeprazole 20 mg + Domperidone 30 mg SR Capsules	Non DMF	Omez® Omeprazole Tablets 20 mg (Dr.Reddy's Lab, India) + Domstal OD® Domperidone SR Tablets 30 mg (Torrent, India)	Ghana (2010), Kenya (2009), Myanmar (2009), Nigeria (2009), Ukraine (2009), Uzbekistan (2010), Philippines (2010), Thailand (2010), Rwanda (2016), Uganda (2016), Moldova (under registration), Ethiopia (2019)	Kenya (2009), Nigeria (2009), Myanmar (2009), Ukraine (2009), Ghana (2010), Philippines (2010), Thailand (2010), Uzbekistan (2010), Uganda (2017) Rwanda (2018)
Pantoprazole 40 mg + Domperidone 30 mg SR Capsules	Non DMF	Pantocid® Pantoprazole EC Tablets 40 mg (Sun Pharma, India) + Domstal OD® Domperidone SR Tablets 30 mg (Torrent, India)	India (2005), Philippines (2010), Myanmar (2014), Ecuador (2018)	India (2005), Philippines (2010),
Rabeprazole 20 mg + Domperidone 30 mg SR Capsules	Non DMF	Domstal OD® Domperidone SR Tablets 30 mg (Torrent, India) + Pariet® Rabeprazole Tablets 20 mg (Eisai, Japan)	India (2004), Myanmar (2012)	India (2004), Myanmar (2013)
Semi Finished Formulations				
Lansoprazole EC Pellets 8.1% w/w	Non DMF	NA	-	-
Lansoprazole DR Pellets 9.1% w/w	DMF	NA	-	-

Cardiovascular



MOLECULE	API	BE REFERENCE PRODUCT	COUNTRIES REGISTERED IN	COUNTRIES COMMERCIALIZED IN
Products with CTD Dossiers (DMF, International BE)				
Amlodipine + Telmisartan 5/40, 5/80, 10/40, 10/80 mg Tablets	CEP+ASMF	Twynsta® Tablets (Boehringer Ingelheim, Austria)	Under Development	-
Chlorthalidone Tablets 25mg / 50 mg	DMF	Chlorthalidone Tablets (Mylan, US)	US (Filed 2018)	-
Colesevelam Hydrochloride Tablets 625mg	DMF	Welchol Colesevelam HCL (Daiichi Sankyo, US)	US (Filed 2018)	-
Felodipine 2.5/5/10 mg ER Tablets	DMF	Plendil® Felodipine ER Tablets 10 mg (AstraZeneca LP, UK)	Vietnam (under registration)	-
Metoprolol 25/50/100/200 mg ER Tablets	DMF	Toprol XL® Metoprolol ER Tablets 200 / 50 mg (AstraZeneca, US)	US (Filed 2013)	-
Olmesartan Medoxomil 5 / 20 / 40 mg Tablets	DMF	Benicar® Olmesartan Medoxomil Tablets 40 mg (Daiichi Sankyo, US)	US (Filed 2015)	-
Rosuvastatin 5 /10 /20/40 mg Tablets	DMF	Crestor® Rosuvastatin Tablets 40 mg (Astra Zeneca, US)	US (Filed 2014) Chile (Under Registration)	-
Telmisartan 20/40/80 mg Tablets	DMF	Micardis® Telmisartan Tablets 80 mg (Boehringer Ingelheim, US)	US (2015), UAE (2018), India (2018)	US (2016), India (2018)
Telmisartan + Hydrochlorothiazide 40/12.5, 80/12.5, 80/25 mg Tablets	DMF	Micardis HCT® Telmisartan 80 mg & Hydrochlorothiazide Tablets 25 mg (Boehringer Ingelheim, US)	US (Filed 2016) Kazakhstan (Under registration)	-
Rivaroxaban 2.5 / 10 / 15 / 20 mg Tablets	ASMF	Xarelto® Rivaroxaban Film-Coated Tablets 10 & 20 mg (Bayer Pharma, UK)	Under Development	-
Semi Finished Formulations				
Fenofibrate Granules 20.55% w/w	Non DMF	Tricor® Fenofibrate Tablets 145 mg (Abbott, US)	Lebanon (2009)	Lebanon (2011)
Rosuvastatin Calcium 3.33% w/w	DMF	Crestor® Rosuvastatin Calcium Tablets 40 mg (Astra Zeneca, US)	-	-
Rosuvastatin Calcium 6.67% w/w	DMF	Crestor® Rosuvastatin Calcium Tablets 40 mg (Astra Zeneca, US)	-	-
Rosuvastatin Calcium 13.33 % w/w	DMF	Crestor® Rosuvastatin Calcium Tablets 40 mg (Astra Zeneca, US)	-	-

MOLECULE	API	BE REFERENCE PRODUCT	COUNTRIES REGISTERED IN	COUNTRIES COMMERCIALIZED IN
Products with CTD Dossiers (DMF, International BE)				
Buspirone HCl Tablets 5 / 7.5 / 10 / 15 / 30 mg	DMF	Buspirone HCl Tablets (Teva, US)	US (2018)	US (2018)
Carbamazepine ER Tablets 100 / 200 / 400 mg	DMF	Tegretol® ER Tablets (Novartis, US)	Under Development	-
Duloxetine 30/60 mg GR Capsules	EUDMF	Cymbalta® Duloxetine HCl GR Capsules 60 mg (Eli Lilly, Netherland)	UK and Malta (Filed 2015), Spain and Portugal (Filed 2019) UAE (Under registration), Chile (Under registration),	UK (2018)
Fluoxetine Tablets 60 mg	DMF	Fluoxetine Tablets, USP (Edgemont, US)	US (2017)	US (2018)
lloperidone 1/2/4/6/8/10/12 mg Tablets	DMF	Fanapt® Iloperidone Tablets 1 mg (Novartis, US)	US (2016)	-
Paliperidone 1.5/3/6/9 mg ER Tablets	DMF	Invega® Paliperidone ER Tablet 6 mg (Janssen L.P., US)	US (2019)	-
Venlafaxine 37.5/75/150 mg ER Capsules	DMF	Effxor® Venlafaxine HCl ER Capsules 150 mg (Pfizer, US)	US (Filed 2011)	-
Products with CTD Dossiers (Non DMF, International BE)				
Duloxetine 30/60 mg DR Capsules	Non DMF	Cymbalta® Duloxetine HCl DR Capsules 60 mg (Eli Lilly, US)	Guatemala (2012), Venezuela (2014), Trinidad (2014), Dominican Republic (2015), Philippines (2016)	Guatemala (2013), Trinidad (2014), Dominican Republic (2015), Venezuela (2014), Philippines (2018)
Pregabalin 75/150/300 mg SR Tablets	Non DMF	Lyrica® Pregabalin Capsules 150 mg (Pfizer, Germany)	India (2009), Kenya (2014), Guatemala (2014), Colombia (2015),	India (2009), Guatemala (2014), Kenya (2015), Colombia (2016)
Products with ACTD Dossiers				
Pregabalin 75/150/300 mg SR + Methylcobalamin 1500 mcg Tablets	Non DMF	PEG SR® Pregabalin SR Tablet 300 mg (Ipca, India) + Nuroday® Methylcobalamin Tablet 1500 mg (Wockhardt, India)	India (2008), Kenya (2015), Myanmar (2015),	India (2008), Kenya (2015), Myanmar (2016)
Semi Finished Formulations				
Duloxetine DR Pellets 16% w/w	DMF	Cymbalta® Duloxetine HCl DR Capsules 60 mg (Eli Lilly, US)	Brazil (2015),	Brazil (2015)
Venlafaxine SR Pellets 33% w/w	DMF	Effxor® Venlafaxine HCl XR Capsules 150 mg (Pfizer, US)	Brazil (2004), Mexico (2008), Korea (2009)	Brazil (2004), Mexico (2008), Korea (2009)

Pain Management

MOLECULE	API	BE REFERENCE PRODUCT	COUNTRIES REGISTERED IN	COUNTRIES COMMERCIALIZED IN
Products with CTD Dossiers (DMF, International BE)				
Cyclobenzaprine HCl 15 mg, 30 mg ER Capsules	DMF	Amrix® Cyclobenzaprine HCl ER Capsules 30 mg (Cephalon, US)	US (Filed 2018)	-
Etoricoxib 30 mg, 60 mg, 90 mg, 120 mg Tablets	ASMF	Arcoxia Etoricoxib film coated Tablets 30mg, 60mg, 90mg and 120mg (MSD SHARP & DOHME GMBH, Germany)	Under Development	-
Products with CTD Dossiers (Non DMF, International BE)				
Eperisone 150 mg SR Capsules	Non DMF	Epry® Eperisone Tablets 50 mg (Eisai Co., Japan)	India (2011), Myanmar (2015), Sri Lanka (Under registration)	India (2011), Myanmar (2016)
Products with CTD Dossiers				
Eperisone 150 mg SR + Diclofenac Sodium 100 mg SR Capsules	Non DMF	Epry® Eperisone Tablets 50 mg (Eisai Co., Japan) + Voveran® Diclofenac Sodium SR Tablets 100 mg (Novartis, India)	India (2011)	India (2011)
Thiocolchicoside 8/16 mg SR Capsules	Non DMF	Myoril® Thiocolchicoside Capsules 8 mg (Sanofi Aventis, India)	India (2011), Guatemala (2014)	-
Products with ACTD Dossiers				
Thiocolchicoside 8/16 mg SR + Diclofenac Sodium 100 mg SR Capsules	Non DMF	Myoril® Thiocolchicoside Capsules 8 mg (Sanofi Aventis, India) + Voveran® Diclofenac Sodium SR Tablets 100 mg (Novartis, India)	India (2011)	-
Thiocolchicoside 8/16 mg SR + Aceclofenac 200 mg SR Capsules	Non DMF	Myoril® Thiocolchicoside Capsules 8 mg (Sanofi Aventis, India) + Zerodol® Aceclofenac Tablets 100 mg (Ipca, India)	India (2010), Kenya (2015), Uganda (Under registration)	India (2010), Kenya (2015)
Semi Finished Formulations				
Cyclobenzaprine HCl ER Pellets 15.79% w/w	DMF	Amrix® Cyclobenzaprine HCl ER Capsules 30 mg (Cephalon, US)	-	-
Eperisone SR Pellets 50% w/w	Non DMF	Epry® Eperisone Tablets 50 mg (Eisai Co., Japan)	-	-
Thiocolchicoside SR Pellets 10% w/w	Non DMF	Myoril® Thiocolchicoside Capsules 8 mg (Sanofi Aventis, India)	-	-

Urinogenital

MOLECULE	API	BE REFERENCE PRODUCT	COUNTRIES REGISTERED IN	COUNTRIES COMMERCIALIZED IN
Products with CTD Dossiers (DMF, International BE)				
Darifenacin Hydrobromide 7.5/15 mg ER Tablets	DMF	Enablex® Darifenacin ER Tablets 15 mg (Novartis, US)	US (Filed 2013), Colombia (Under Registration)	-
Tolterodine Tartrate 2/4 mg ER Capsules	DMF	Detrol® Tolterodine ER Capsules 4 mg (LA by Pharmacia Upjohn of Pfizer NY,US)	US (Filed 2012)	-
Nitrofurantoin Macrobid Capsule 75:25	DMF	Macrobid® Capsules (Alvogen Inc, US)	US (Filed 2018)	-
Nitrofurantoin 100mg Prolonged Release Capsules	ASMF	Macrobid Prolonged-Release Capsules 100mg (Mercury Pharmaceuticals Ltd, UK)	Under Development	-
Products with CTD Dossiers (Non DMF, International BE)				
Sildenafil 50 mg Orodispersible Tablets	Non DMF	Viagra® Sildenafil Tablets 50 mg (Pfizer Labs, France)	Chile (2009), Myanmar (2011), Sri Lanka (2011), Guatemala (2012), Togo (2012), Kenya (2014), Benin (2015),	Sri Lanka (2012), Myanmar (2013), Guatemala (2013), Chile (2009), Kenya (2015)
Products with ACTD Dossiers				
Dapoxetine 30/60 mg Mouth Dissolving Tablets	Non DMF	Duralast® Dapoxetine Tablets 60 mg (Sun Pharma, India)	Sri Lanka (2017)	Sri Lanka (2017)
Tolterodine Tartrate 2/4 mg ER Capsules	Non DMF	Detrol® Tolterodine ER Capsules 4 mg (LA by Pharmacia Upjohn of Pfizer NY, US)	Sri Lanka (Under registration), Peru (2018), Colombia (Under registration)	-
Semi Finished Formulations				
Tolterodine Tartrate ER Pellets 2% w/w	DMF	Detrol® Tolterodine ER Capsules 4 mg (LA of Pharmacia Upjohn of Pfizer NY, US)	-	-

Anti Infective

MOLECULE	API	BE REFERENCE PRODUCT	COUNTRIES REGISTERED IN	COUNTRIES COMMERCIALIZED IN
PRODUCTS WITH CTD DOSSIERS (DMF, INTERNATIONAL BE)				
Posaconazole Delayed Release Tablet 100 mg	DMF	Noxafil® DR Tablets (Merck & Co)	Under Development for US	-
Posaconazole 100 mg GR Tablets	DMF	Noxafil® GR Tablets (Merck & Co, Germany, UK)	Under Development for EU	-

Respiratory



MOLECULE	API	BE REFERENCE PRODUCT	COUNTRIES REGISTERED IN	COUNTRIES COMMERCIALIZED IN
Products with ACTD Dossiers				
Levocetirizine HCl 5 mg Mouth Dissolving Tablets	Non DMF	NA	India (2005), Guatemala (2011), Sri Lanka (2011), Myanmar (2012), Togo (2012), Senegal (2013), Colombia (2014), Benin (2015), Peru (2016), Uzbekistan (2016),	India (2005), Sri Lanka (2012), Myanmar (2013), Guatemala (2013), Colombia (2014) -

Heavy metal chelator



MOLECULE	API	BE REFERENCE PRODUCT	COUNTRIES REGISTERED IN	COUNTRIES COMMERCIALIZED IN
Products With CTD Dossiers (DMF, International BE)				
Deferasirox 90 / 180 / 360 mg Film Coated Tablets	DMF, ASMF	Exjade Deferasirox Film coated 90 mg, 180 mg & 360 mg Tablets (Novartis Europharm Limited)	Under Development	-

Smoking cessation

MOLECULE	API	REFERENCE PRODUCT	COUNTRIES REGISTERED IN	COUNTRIES COMMERCIALIZED IN
Products With CTD Dossiers (DMF, Permeability)				
Varenicline Tartrate 0.5 / 1 mg Tablets	CEP	Champix (Pfizer, EU)	Under Development for EU	-
Varenicline Tartrate 0.5 / 1 mg Tablets	DMF	Chantix (Pfizer, US)	Under Development for US	-