

Anti Diabetic

MOLECULE	API	BE REFERENCE PRODUCT	COUNTRIES REGISTERED IN	COUNTRIES COMMERCIALIZED IN
Products with CTD Dossiers (DMF, International BE)				
Gliclazide 30/60 mg ER Tablets	DMF	Diamcron® Gliclazide MR Tablets 60 mg (Servier, France)	Malaysia (under registration), Vietnam (under registration), Uzbekistan (under registration)	-
Metformin HCl 500 mg SR Tablets	DMF	Glucophage® Metformin HCl XR Tablets 500 mg (BMS, US)	US (Filed 2010) UAE (Under registration) Zimbabwe (Under registration) South Africa (Under registration)	US (2013)
Metformin HCl 750 mg SR Tablets	DMF	Glucophage® Metformin HCl XR Tablets 750 mg (Merck, Malaysia)	Guatemala (2014), Philippines (2016), Malaysia (Under registration), Peru (2016), Vietnam (2016), Kazakhstan (Under registration)	Guatemala (2014) Vietnam (2017)
Metformin HCl 1000 mg SR Tablets	DMF	Glucophage® Metformin HCl SR Tablets 1000 mg (Merck, UK)	Zimbabwe (Under registration) Malaysia (Under registration)	-
Sitagliptin + Metformin 50/500, 50/1000 mg Tablets	DMF	Janumet® (Merck & Co, US)	Under Development	Under Development
Sitagliptin + Metformin ER 50/500, 50/1000, 100/1000 mg Tablets	DMF	Janumet® XR (Merck & Co, US)	Under Development	Under Development
Dapagliflozin 5mg/ 10mg Tablets	DMF	Farxiga® (AstraZeneca, US)	Under Development	Under Development
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), Ghana (2011), Nigeria (2012), Cambodia (2012), Uzbekistan (2012), Guatemala (2014), Kenya (2014), Dominican Republic (2015), Sri Lanka (2012), Uganda (2015), Tanzania (2015), Peru (2016), Trinidad (Under registration), Kazakhstan (Under registration)	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)
Products with CTD Dossiers				
Metformin HCl 1000 mg SR Tablets	Non DMF	NA	Nigeria (2009), Myanmar (2010), Jamaica (2012), CIS (2010), India (2002), Cambodia (2012), Ghana (2011), Kenya (2010), Mongolia, Philippines (2012), Vietnam (2009), Thailand (2010), Guatemala (2015), Uganda (2015), Peru (2016), Dominican Republic (2016), Tanzania (under registration), Malaysia (Under registration), Kazakhstan (Under registration)	India (2003), Vietnam (2009), Kenya (2010), Myanmar (2010), Thailand (2010), Ghana (2011), Nigeria (2011), Cambodia (2012), Uzbekistan (2013), Philippines (2015), Guatemala (2016), Uganda (2015)
Metformin HCl 500 mg SR + Glimperide 1/2 mg Tablets	Non DMF	Glucophage® Metformin HCl XR Tablets 500 mg (BMS, USA)+ Amaryl®2 Glimperide Tablets 2 mg (Aventis, India)	India (2004), Philippines (2011), Malaysia (2012), Kenya, Myanmar (2009), Nigeria (2011), Vietnam (2010), Uzbekistan (2015), Jamaica (2012), Dominican Republic (2016), Cambodia (2015), Venezuela (Under registration), Uzbekistan (2016), Ghana (Under registration)	India (2004), Vietnam (2010), Nigeria (2011), Philippines (2011), Malaysia (2013), Kenya (2013), Myanmar (2009), Jamaica (2016)

Anti Diabetic continued



MOLECULE	API	BE REFERENCE PRODUCT	COUNTRIES REGISTERED IN	COUNTRIES COMMERCIALIZED IN
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), Ghana (2011), Kenya (2012), Nigeria (2010), Philippines (2010)	India (2004), Nigeria (2010), Ghana (2011), Kenya (2012), Jamaica (2016), Philippines (2011)
Metformin HCl 1000 mg SR + Glimepiride 1/2 mg Tablets	Non DMF	NA	India (2007), Venezuela (under registration), Nigeria (2016), Ghana (Under registration)	India (2007)
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)
Metformin HCl 500 mg SR + Glibenclamide 5mg Tablets	Non DMF	Glucophage® XR 500 Metformin HCl XR Tablets 500 mg (BMS, US) + Daonil® 5 Glibenclamide Tablets 5 mg (Aventis, India)	Jamaica (2011), Lebanon (2008)	Lebanon (2008)
Semi Finished Formulations				
Gliclazide SR DC Granules 18.18% w/w	DMF	Diamicon® Gliclazide MR Tablets 60 mg (Servier, France)	-	-
Gliclazide SR DC Granules 18.18% w/w	Non DMF	NA	Bangladesh (2008)	Bangladesh (2008)
Metformin SR DC Granules 60% 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 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 EC Capsules	DMF	Prevacid® Lansoprazole DR Capsules 30 mg (Takeda, US)	US (Filed 2013)	-
Mesalamine 1.2 g DR Tablets	DMF	Lialda (Shire,US)	Under Development	-
Products with CTD Dossiers				
Rabeprazole 20 mg Buffer Tablets	Non DMF	Parit® Rabeprazole Tablets 20 mg (GlaxoSmithKline, India)	India (2007), Sri Lanka (2012), Myanmar (2013), Vietnam (2015), Malaysia (under registration), Nigeria (Under registration), Lebanon (Under registration), Zimbabwe (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), Mongolia, Myanmar (2009), Nigeria (2009), Ukraine (2009), Uzbekistan (2010), Vietnam (2009), Philippines (2010), Thailand (2010), Uganda (under registration), Rwanda (under registration), Moldova (under registration)	Kenya (2009), Nigeria (2009), Myanmar (2009), Ukraine (2009), Vietnam (2009), Ghana (2010), Philippines (2010), Thailand (2010), Uzbekistan (2010)
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), Nigeria (2013), Myanmar (2014)	India (2005), Philippines (2010), Nigeria (2013)
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)
Rabeprazole 20 mg Tablets	Non DMF	NA	Under Development	Under Development
Semi Finished Formulations				
Domperidone SR Pellets 30% w/w	Non DMF	NA	India (2013)	India (2013)
Domperidone SR Pellets 40% w/w	Non DMF	NA	-	-
Esomeprazole EC Pellets 22.5% w/w	Non DMF	NA	Bangladesh (2007), Pakistan (2008)	Bangladesh (2007), Pakistan (2008)
Esomeprazole EC Pellets 8.5% w/w	Non DMF	NA	Bangladesh (2004), Pakistan (2008)	Bangladesh (2004), Pakistan (2008)
Itopride SR Pellets 60% w/w	Non DMF	NA	Pakistan (2009)	Pakistan (2009)
Lansoprazole EC Pellets 8.1% w/w	Non DMF	NA	-	-
Lansoprazole EC Pellets 8.5% w/w	Non DMF	NA	Bangladesh (2004), Korea (2006)	Bangladesh (2004), Korea (2006)
Omeprazole EC Pellets 22.22% w/w	Non DMF	NA	Bangladesh (2008), Pakistan (2012)	Bangladesh (2008), Pakistan (2012)
Omeprazole EC Pellets 8.5% w/w	Non DMF	NA	Bangladesh (2004), Pakistan (2009), Vietnam (2008)	Bangladesh (2004), Pakistan (2009), Vietnam (2008)
Ondansetron TM Granules 2.96% w/w	Non DMF	NA	Bangladesh (2009)	Bangladesh (2009)
Pantoprazole EC Pellets 21% w/w	Non DMF	NA	-	-
Rabeprazole EC Pellets 13.33% w/w	Non DMF	Pariet® Rabeprazole EC Tablets 20 mg (Eisai, India)	-	-

Cardiovascular



MOLECULE	API	BE REFERENCE PRODUCT	COUNTRIES REGISTERED IN	COUNTRIES COMMERCIALIZED IN
Products with CTD Dossiers (DMF, International BE)				
Felodipine 2.5/5/10 mg ER Tablets	DMF	Plendil® Felodipine ER Tablets 10 mg (AstraZeneca LP,US)	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) Sri Lanka (under registration)	-
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)	-
Telmisartan 20/40/80 mg Tablets	DMF	Micardis® Telmisartan Tablets 80 mg (Boehringer Ingelham, US)	US (Filed 2015) Vietnam (under registration) UAE (Under registration)	-
Telmisartan + Hydrochlorthiazide 40/12.5, 80/12.5, 80/25mg Tablets	DMF	Micardis HCT® Telmisartan 80 mg & Hydrochlorthiazide Tablets 25 mg (Boehringer Ingelham, US)	US (Filed 2014) Kazakhstan (under registration)	-
Ezetimibe 10 mg Tablets	DMF	Zetia® (MSD, EU/US)	Under Development	Under Development
Semi Finished Formulations				
Fenofibrate Granules 20.55% w/w	Non DMF	Tricor® Fenofibrate Tablets 145 mg (Abbott, US)	Lebanon (2009)	Lebanon (2011)
ISMN SR Pellets 40% w/w	Non DMF	Imdur® Isosorbide Mononitrate Tablets 60 mg BID (Astra, India)	-	-
ISMN SR Pellets 17.34% w/w	Non DMF	NA	Bangladesh (2006)	Bangladesh (2006)
ISMN SR Pellets 18.5% w/w	Non DMF	NA	Bangladesh (2010)	Bangladesh (2010)

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MOLECULE	API	BE REFERENCE PRODUCT	COUNTRIES REGISTERED IN	COUNTRIES COMMERCIALIZED IN
Products with CTD Dossiers (DMF, International BE)				
Duloxetine 20/30/60 mg DR Capsules	DMF	Cymbalta® Duloxetine HCl DR Capsules 60 mg (Eli Lilly, US)	US (2015)	-
Duloxetine 30/60 mg DR Capsules	EUDMF	Cymbalta® Duloxetine HCl DR Capsules 60 mg (Eli Lilly, Netherland)	Europe (2015) UAE (Under registration)	-
Iloperidone 1/2/4/6/8/10/12 mg Tablets	DMF	Fanapt® Iloperidone Tablets 1 mg (Novartis, US)	US (Filed 2014)	-
Paliperidone 1.5/3/6/9 mg ER Tablets	DMF	Invega® Paliperidone ER Tablet 6 mg (Janssen L.P., US)	US (Filed 2012)	-
Venlafaxine 37.5/75/150 mg SR Capsules	DMF	Effexor® Venlafaxine HCl XR 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),
Pregabalin 75/150/300 mg SR Tablets	Non DMF	Lyrica® Pregabalin Capsules 150 mg (Pfizer, Germany)	India (2009), Kenya (2014), Guatemala (2014), Colombia (2015), Uganda (Under registration)	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), Lebanon (Under registration), Uganda (Under registration)	India (2008), Kenya (2015)
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	Non DMF	Effexor® 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 (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)	Guatemala (2014)	-
Products with ACTD Dossiers				
Tapentadol 50/100/150/200 mg SR Tablets	Non DMF	Tapenta® Tapentadol Tablets 100 mg (Zuventus, India)	India (under registration)	-
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				
Aceclofenac SR Pellets 60% w/w	Non DMF	NA	Pakistan (2010)	Pakistan (2010)
Eperisone SR Pellets 50% w/w	Non DMF	Epry® Eperisone Tablets 50 mg (Eisai Co., Japan)	-	-
Ketoprofen SR Pellets 70% w/w	Non DMF	NA	Bangladesh (2004), Nigeria (2008)	Bangladesh (2004), Nigeria (2008)
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)	-
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)	-
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), Malaysia (under registration)	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 (under registration)	-
Tamsulosin 0.2/0.4 mg ER Capsules	Non DMF	NA	Guatemala (2012)	Guatemala (2014)
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 (under registration)	-
Semi Finished Formulations				
Tamsulosin ER Pellets 0.14%w/w	Non DMF	NA	Bangladesh (2006)	Bangladesh (2006)
Tolterodine Tartrate ER Pellets 2% w/w	Non DMF	Detrol® Tolterodine ER Capsules 4 mg (LA of Pharmacia Upjohn of Pfizer NY, US)	Bangladesh (2011)	Bangladesh (2011)

Anti Infective



MOLECULE	API	BE REFERENCE PRODUCT	COUNTRIES REGISTERED IN	COUNTRIES COMMERCIALIZED IN
Products with ACTD Dossiers				
Linezolid 1200 mg SR Tablets	Non DMF	Lizolid® Linezolid Tablets 600 mg (Glenmark, India)	India (2013)	India (2013)
Semi Finished Formulations				
Ciprofloxacin Taste Masked Pellets 20% w/w	Non DMF	NA	Bangladesh (under registration)	-

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), Malaysia (under registration), Zimbabwe (Under registration)	India (2005), Sri Lanka (2012), Myanmar (2013), Colombia (2014), Guatemala (2013)