

**Approved Drug Product List - Orange Book**  
**Reference Listed Drugs by ANDA Reference Standard List**

March 2018

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**DESCRIPTION**

This list refers to drug products approved under an Abbreviated New Drug Application (ANDA) that FDA has selected as reference standards and the associated reference listed drugs (RLDs). The purpose of this list is to assist applicants submitting an ANDA to seek approval of a generic drug in identifying an RLD when an ANDA RS has been selected. If the applicant has a question about which listed drug it should refer to as the RLD, the applicant may consult with FDA (refer to section 1.4 Reference Listed Drug and Reference Standard of the Orange Book Preface for more information).

This list is updated monthly. Information in this list is sorted by Active Ingredient(s), Dosage Form, Route, Trade Name, Applicant Name and Strength. Additional information included are marketing status (RX, OTC, DISCN), Application Number, Product Number, and approval date of the Reference Standard.

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ADAPALENE

SOLUTION; TOPICAL  
ADAPALENE  
RX CALL INC 0.1% A204593 001 Jan 05, 2016 RLD: N020338

AMIODARONE HYDROCHLORIDE

TABLET; ORAL  
AMIODARONE HYDROCHLORIDE  
RX SANDOZ 200MG A075315 001 Dec 23, 1998 RLD: N018972

AMOXICILLIN

TABLET, CHEWABLE; ORAL  
AMOXICILLIN  
RX TEVA 250MG A064013 001 Dec 22, 1992 RLD: N050542

AMOXICILLIN; CLAVULANATE POTASSIUM

TABLET; ORAL  
AMOXICILLIN AND CLAVULANATE POTASSIUM  
RX SANDOZ 250MG; EQ 125MG BASE A065189 001 Aug 23, 2005 RLD: N050564  
RX SANDOZ INC 500MG; EQ 125MG BASE A065117 001 Nov 27, 2002 RLD: N050564

ARIPIPIRAZOLE

SOLUTION; ORAL  
ARIPIPIRAZOLE  
RX AMNEAL PHARMS 1MG/ML A203906 001 Aug 14, 2015 RLD: N021713

ATORVASTATIN CALCIUM; EZETIMIBE

TABLET; ORAL  
EZETIMIBE AND ATORVASTATIN CALCIUM  
RX WATSON LABS TEVA EQ 80MG BASE; 10MG A206084 004 Apr 26, 2017 RLD: N200153

BISOPROLOL FUMARATE

TABLET; ORAL  
BISOPROLOL FUMARATE  
RX MYLAN 10MG A075831 002 Dec 14, 2005 RLD: N019982

BROMFENAC SODIUM

SOLUTION/DROPS; OPHTHALMIC  
BROMFENAC SODIUM  
RX APOTEX INC EQ 0.09% ACID A202435 001 Jun 19, 2014 RLD: N021664

BROMOCRIPTINE MESYLATE

CAPSULE; ORAL  
BROMOCRIPTINE MESYLATE  
RX MYLAN EQ 5MG BASE A077226 001 Apr 04, 2005 RLD: N017962  
TABLET; ORAL  
BROMOCRIPTINE MESYLATE  
RX PADDOCK LLC EQ 2.5MG BASE A077646 001 Oct 01, 2008 RLD: N017962

BUPROPION HYDROCHLORIDE

TABLET; ORAL  
BUPROPION HYDROCHLORIDE  
RX APOTEX INC 100MG A076143 002 Jan 17, 2006 RLD: N018644

CALCITONIN SALMON

SPRAY, METERED; NASAL  
CALCITONIN-SALMON  
RX APOTEX INC 200 IU/SPRAY A076396 001 Nov 17, 2008 RLD: N020313

CETIRIZINE HYDROCHLORIDE

SYRUP; ORAL  
CETIRIZINE HYDROCHLORIDE  
RX PERRIGO R AND D 5MG/5ML A078398 001 Jun 17, 2008 RLD: N020346

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CHLOROQUINE PHOSPHATE

TABLET; ORAL  
 CHLOROQUINE PHOSPHATE  
 RX NATCO PHARMA LTD EQ 300MG BASE A090612 001 Jan 21, 2011 RLD: N006002

CHLORZOXAZONE

TABLET; ORAL  
 CHLORZOXAZONE  
 RX MIKART INC 250MG A207483 001 Jun 24, 2016 RLD: N011300

CIPROFLOXACIN

INJECTABLE; INJECTION  
 CIPROFLOXACIN  
 RX BAXTER HLTHCARE 200MG/20ML (10MG/ML) A078062 001 Apr 29, 2008 RLD: N019847  
 CORP  
 RX 400MG/40ML (10MG/ML) A078062 002 Apr 29, 2008 RLD: N019847  
 CIPROFLOXACIN IN DEXTROSE 5% IN PLASTIC CONTAINER  
 RX HOSPIRA 200MG/100ML A077753 001 Mar 18, 2008 RLD: N019857  
 RX 400MG/200ML A077753 002 Mar 18, 2008 RLD: N019857

CLOBETASOL PROPIONATE

OINTMENT; TOPICAL  
 CLOBETASOL PROPIONATE  
 RX FOUGERA PHARMS 0.05% A074407 001 Feb 23, 1996 RLD: N019323

CYTARABINE

INJECTABLE; INJECTION  
 CYTARABINE  
 RX FRESENIUS KABI USA 100MG/ML A076512 001 Jan 15, 2004 RLD: N016793  
 RX HOSPIRA 20MG/ML A071868 001 Jun 04, 1990 RLD: N016793

DACARBAZINE

INJECTABLE; INJECTION  
 DACARBAZINE  
 RX FRESENIUS KABI USA 100MG/VIAL A075371 001 Aug 27, 1999 RLD: N017575  
 RX 200MG/VIAL A075371 002 Aug 27, 1999 RLD: N017575

DESOGESTREL; ETHINYL ESTRADIOL

TABLET; ORAL-28  
 DESOGESTREL AND ETHINYL ESTRADIOL  
 RX DURAMED PHARMS 0.15MG;0.03MG A075256 002 Aug 12, 1999 RLD: N020301  
 BARR

DICLOFENAC SODIUM

TABLET, EXTENDED RELEASE; ORAL  
 DICLOFENAC SODIUM  
 RX DEXCEL LTD 100MG A076201 001 Nov 06, 2002 RLD: N020254

DICYCLOMINE HYDROCHLORIDE

SYRUP; ORAL  
 DICYCLOMINE HYDROCHLORIDE  
 RX MIKART 10MG/5ML A040169 001 Mar 24, 2005 RLD: N007961

DOCETAXEL

INJECTABLE; INJECTION  
 DOCETAXEL  
 RX JIANGSU HENGRUI 40MG/ML A203170 001 Feb 15, 2017 RLD: N020449  
 MED

ERYTHROMYCIN

SOLUTION; TOPICAL  
 ERYTHROMYCIN  
 RX PERRIGO NEW YORK 2% A063038 001 Jan 11, 1991 RLD: A062405

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ESOMEPRAZOLE SODIUM

INJECTABLE; INTRAVENOUS  
ESOMEPRAZOLE SODIUM

RX	AUROBINDO PHARMA LTD	EQ 40MG BASE/VIAL	A204657	002	Aug 10, 2016	RLD: N021689
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FAMCICLOVIR

TABLET; ORAL  
FAMCICLOVIR

RX	TEVA PHARMS	500MG	A077487	003	Aug 24, 2007	RLD: N020363
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FLUCONAZOLE

INJECTABLE; INJECTION  
FLUCONAZOLE IN DEXTROSE 5% IN PLASTIC CONTAINER

RX	HOSPIRA	200MG/100ML (2MG/ML)	A076304	001	Jul 29, 2004	RLD: N019950
RX		400MG/200ML (2MG/ML)	A076304	002	Jul 29, 2004	RLD: N019950

FLUCONAZOLE IN SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER

RX	INFORLIFE	200MG/100ML (2MG/ML)	A079104	001	Jul 30, 2009	RLD: N019950
RX		400MG/200ML (2MG/ML)	A079104	002	Jul 30, 2009	RLD: N019950

FLUDEOXYGLUCOSE F-18

INJECTABLE; INTRAVENOUS  
FLUDEOXYGLUCOSE F18

RX	QUEEN HAMAMATSU PET	10-100mCi/ML	A203771	001	Aug 31, 2015	RLD: N021768
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FLUOXETINE HYDROCHLORIDE

TABLET; ORAL  
FLUOXETINE HYDROCHLORIDE

RX	MYLAN	EQ 20MG BASE	A075755	002	Aug 02, 2001	RLD: N020974
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FLUPHENAZINE HYDROCHLORIDE

TABLET; ORAL  
FLUPHENAZINE HYDROCHLORIDE

RX	MYLAN	10MG	A089804	001	Aug 12, 1988	RLD: N011751
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FLUTAMIDE

CAPSULE; ORAL  
FLUTAMIDE

RX	CIPLA LTD	125MG	A075780	001	Sep 19, 2001	RLD: N018554
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FLUTICASONE PROPIONATE

SPRAY, METERED; NASAL  
FLUTICASONE PROPIONATE

RX	WEST-WARD PHARMS INT	0.05MG/SPRAY	A076504	001	Feb 22, 2006	RLD: N020121
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GALANTAMINE HYDROBROMIDE

SOLUTION; ORAL  
GALANTAMINE HYDROBROMIDE

RX	WEST-WARD PHARMS INT	4MG/ML	A078185	001	Jan 30, 2009	RLD: N021224
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GLIMEPIRIDE; ROSIGLITAZONE MALEATE

TABLET; ORAL  
ROSIGLITAZONE MALEATE AND GLIMEPIRIDE

RX	TEVA PHARMS USA	1MG; 4MG	A078709	001	Apr 01, 2016	RLD: N021700
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GLYBURIDE; METFORMIN HYDROCHLORIDE

TABLET; ORAL  
GLYBURIDE AND METFORMIN HYDROCHLORIDE

RX	AUROBINDO PHARMA	2.5MG; 500MG	A077870	002	Nov 14, 2007	RLD: N021178
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GLYCOPYRROLATE

INJECTABLE; INJECTION  
 GLYCOPYRROLATE  
 RX HIKMA FARMACEUTICA 0.2MG/ML A090963 001 Sep 21, 2011 RLD: N017558

HYDROCHLOROTHIAZIDE; MOEXIPRIL HYDROCHLORIDE

TABLET; ORAL  
 MOEXIPRIL HYDROCHLORIDE AND HYDROCHLOROTHIAZIDE  
 RX TEVA 25MG;15MG A076980 002 Mar 07, 2007 RLD: N020729

HYDROCODONE BITARTRATE; IBUPROFEN

TABLET; ORAL  
 HYDROCODONE BITARTRATE AND IBUPROFEN  
 RX AMNEAL PHARMS NY 7.5MG;200MG A076642 001 Oct 12, 2004 RLD: N020716

IMIPRAMINE PAMOATE

CAPSULE; ORAL  
 IMIPRAMINE PAMOATE  
 RX WEST-WARD PHARMS EQ 75MG HCL A091099 001 Apr 16, 2010 RLD: N017090  
 INT

IPRATROPIUM BROMIDE

SPRAY, METERED; NASAL  
 IPRATROPIUM BROMIDE  
 RX WEST-WARD PHARMS 0.021MG/SPRAY A076664 001 Nov 05, 2003 RLD: N020393  
 INT  
 RX 0.042MG/SPRAY A076598 001 Nov 05, 2003 RLD: N020394

ISOSULFAN BLUE

INJECTABLE; INJECTION  
 ISOSULFAN BLUE  
 RX MYLAN 1% A090874 001 Jul 20, 2010 RLD: N018310  
 INSTITUTIONAL

ISRADIPINE

CAPSULE; ORAL  
 ISRADIPINE  
 RX WATSON LABS TEVA 5MG A077317 002 Jan 05, 2006 RLD: N019546

KETOTIFEN FUMARATE

SOLUTION/DROPS; OPHTHALMIC  
 KETOTIFEN FUMARATE  
 OTC ALCON PHARMS LTD EQ 0.025% BASE A077200 001 Sep 02, 2008 RLD: N021066

LACTULOSE

SOLUTION; ORAL  
 LACTULOSE  
 RX HI TECH PHARMA 10GM/15ML A074076 001 Jul 03, 1995 RLD: N017884

LEVOFLOXACIN

INJECTABLE; INJECTION  
 LEVOFLOXACIN IN DEXTROSE 5% IN PLASTIC CONTAINER  
 RX INFORLIFE EQ 250MG/50ML (EQ 5MG/ML) A090343 001 Jul 07, 2011 RLD: N020635  
 RX EQ 500MG/100ML (EQ 5MG/ML) A090343 002 Jul 07, 2011 RLD: N020635  
 RX EQ 750MG/150ML (EQ 5MG/ML) A090343 003 Jul 07, 2011 RLD: N020635  
 SOLUTION; ORAL  
 LEVOFLOXACIN  
 RX HI TECH PHARMA 250MG/10ML A091678 001 Jun 20, 2011 RLD: N021721

LEVONORGESTREL

TABLET; ORAL  
 LEVONORGESTREL  
 OTC PERRIGO R AND D 0.75MG A090740 001 Dec 30, 2010 RLD: N021045  
 RX 0.75MG A090740 001 Dec 30, 2010 RLD: N021045

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LIDOCAINE HYDROCHLORIDE

SOLUTION;ORAL  
 LIDOCAINE HYDROCHLORIDE VISCOUS  
 RX VINTAGE 2% A040708 001 Feb 27, 2007 RLD: N009470

LOPERAMIDE HYDROCHLORIDE

CAPSULE;ORAL  
 LOPERAMIDE HYDROCHLORIDE  
 RX MYLAN 2MG A072741 001 Sep 18, 1991 RLD: N017694

LOPERAMIDE HYDROCHLORIDE; SIMETHICONE

TABLET, CHEWABLE;ORAL  
 LOPERAMIDE HYDROCHLORIDE AND SIMETHICONE  
 OTC PERRIGO 2MG;125MG A076029 001 Aug 30, 2002 RLD: N020606

MEFLOQUINE HYDROCHLORIDE

TABLET;ORAL  
 MEFLOQUINE HYDROCHLORIDE  
 RX BARR 250MG A076392 001 Dec 29, 2003 RLD: N019591

METFORMIN HYDROCHLORIDE; REPAGLINIDE

TABLET;ORAL  
 REPAGLINIDE AND METFORMIN HYDROCHLORIDE  
 RX LUPIN LTD 500MG;2MG A200624 002 Jul 15, 2015 RLD: N022386

METHSCOPOLAMINE BROMIDE

TABLET;ORAL  
 METHSCOPOLAMINE BROMIDE  
 RX VINTAGE PHARMS 2.5MG A040624 001 Dec 28, 2006 RLD: N008848  
 RX 5MG A040624 002 Dec 28, 2006 RLD: N008848

METHYLERGONOVINE MALEATE

TABLET;ORAL  
 METHYLERGONOVINE MALEATE  
 RX NOVEL LABS INC 0.2MG A091577 001 May 02, 2011 RLD: N006035

METHYLPHENIDATE HYDROCHLORIDE

CAPSULE, EXTENDED RELEASE;ORAL  
 METHYLPHENIDATE HYDROCHLORIDE  
 RX MAYNE PHARMA 60MG A078458 004 Jun 23, 2016 RLD: N021284  
 TABLET, CHEWABLE;ORAL  
 METHYLPHENIDATE HYDROCHLORIDE  
 RX NOVEL LABS INC 10MG A204115 003 Feb 25, 2015 RLD: N021475  
 TABLET, EXTENDED RELEASE;ORAL  
 METHYLPHENIDATE HYDROCHLORIDE  
 RX OSMOTICA 72MG A205327 005 Jul 28, 2017 RLD: N021121

METOPROLOL TARTRATE

TABLET;ORAL  
 METOPROLOL TARTRATE  
 RX MYLAN 100MG A076704 003 Jan 16, 2004 RLD: N017963

MOEXIPRIL HYDROCHLORIDE

TABLET;ORAL  
 MOEXIPRIL HYDROCHLORIDE  
 RX TEVA 15MG A076204 002 May 08, 2003 RLD: N020312

MOXIFLOXACIN HYDROCHLORIDE

SOLUTION;IV (INFUSION)  
 MOXIFLOXACIN HYDROCHLORIDE IN SODIUM CHLORIDE 0.8% IN PLASTIC CONTAINER  
 RX MYLAN LABS LTD 400MG/250ML (1.6MG/ML) A205833 001 May 05, 2017 RLD: N021277

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NALTREXONE HYDROCHLORIDE

TABLET;ORAL  
 NALTREXONE HYDROCHLORIDE  
 RX SPECGX LLC 50MG A076264 002 Mar 22, 2002 RLD: N018932

NIZATIDINE

SOLUTION;ORAL  
 NIZATIDINE  
 RX AMNEAL PHARMS 15MG/ML A090576 001 Nov 18, 2009 RLD: N021494

OFLOXACIN

SOLUTION/DROPS;OTIC  
 OFLOXACIN  
 RX BAUSCH AND LOMB 0.3% A076128 001 Mar 17, 2008 RLD: N020799

OMEPRAZOLE

CAPSULE, DELAYED REL PELLETS;ORAL  
 OMEPRAZOLE  
 RX SANDOZ 20MG A075757 002 Jan 28, 2003 RLD: N019810  
 RX 40MG A076515 001 Jan 21, 2009 RLD: N019810

OXALIPLATIN

INJECTABLE;IV (INFUSION)  
 OXALIPLATIN  
 RX QILU PHARM CO LTD 200MG/40ML (5MG/ML) A204368 003 Jun 07, 2016 RLD: N021759

PANCURONIUM BROMIDE

INJECTABLE;INJECTION  
 PANCURONIUM BROMIDE  
 RX TEVA PHARMS USA 1MG/ML A072759 001 Jul 31, 1990 RLD: N017015  
 RX 2MG/ML A072760 001 Jul 31, 1990 RLD: N017015

PARICALCITOL

CAPSULE;ORAL  
 PARICALCITOL  
 RX TEVA PHARMS USA 4MCG A090829 003 Sep 27, 2013 RLD: N021606

PENTOXIFYLLINE

TABLET, EXTENDED RELEASE;ORAL  
 PENTOXIFYLLINE  
 RX APOTEX 400MG A075191 001 Jun 09, 1999 RLD: N018631

PHENTERMINE HYDROCHLORIDE

TABLET;ORAL  
 LOMAIRA  
 RX AVANTHI INC 8MG A203495 001 Sep 12, 2016 RLD: N012737

SODIUM POLYSTYRENE SULFONATE

POWDER;ORAL, RECTAL  
 KALEXATE  
 RX KVK TECH 454GM/BOT A040905 001 Mar 30, 2009 RLD: N011287

TERBUTALINE SULFATE

TABLET;ORAL  
 TERBUTALINE SULFATE  
 RX LANNETT 5MG A077152 002 Mar 25, 2005 RLD: N017849

TERCONAZOLE

CREAM;VAGINAL  
 TERCONAZOLE  
 RX TARO 0.8% A075953 001 Apr 06, 2004 RLD: N019964

TESTOSTERONE

SOLUTION, METERED;TRANSDERMAL  
 TESTOSTERONE  
 RX PERRIGO ISRAEL 30MG/1.5ML ACTUATION A204255 001 Feb 28, 2017 RLD: N022504

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THIOTHIXENE

CAPSULE;ORAL

THIOTHIXENE

RX MYLAN 5MG A071093 004 Jun 23, 1987 RLD: N016584

TIMOLOL MALEATE

SOLUTION/DROPS;OPHTHALMIC

TIMOLOL MALEATE

RX SANDOZ INC EQ 0.25% BASE A074261 001 Apr 28, 1995 RLD: N018086

RX EQ 0.5% BASE A074262 001 Apr 28, 1995 RLD: N018086

VERAPAMIL HYDROCHLORIDE

TABLET, EXTENDED RELEASE;ORAL

VERAPAMIL HYDROCHLORIDE

RX GLENMARK GENERICS 180MG A090700 002 Aug 03, 2011 RLD: N019152