

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

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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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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

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

CEFOTAXIME SODIUM

INJECTABLE;INJECTION  
 CEFOTAXIME  
 RX HIKMA EQ 500MG BASE/VIAL A065072 001 Nov 20, 2002 RLD: N050547  
 RX EQ 1GM BASE/VIAL A065072 002 Nov 20, 2002 RLD: N050547  
 RX EQ 2GM BASE/VIAL A065072 003 Nov 20, 2002 RLD: N050547  
 RX EQ 10GM BASE/VIAL A065071 001 Nov 20, 2002 RLD: N050547

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

DOXORUBICIN HYDROCHLORIDE

INJECTABLE, LIPOSOMAL; INJECTION  
 DOXORUBICIN HYDROCHLORIDE (LIPOSOMAL)  
 RX SUN PHARMA GLOBAL 20MG/10ML (2MG/ML) A203263 001 Feb 04, 2013 RLD: N050718  
 RX 50MG/25ML (2MG/ML) A203263 002 Feb 04, 2013 RLD: N050718

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ERYTHROMYCIN

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

ESOMEPRAZOLE SODIUM

INJECTABLE; INTRAVENOUS  
ESOMEPRAZOLE SODIUM  
RX AUROBINDO PHARMA EQ 40MG BASE/VIAL A204657 002 Aug 10, 2016 RLD: N021689  
LTD

FAMCICLOVIR

TABLET; ORAL  
FAMCICLOVIR  
RX TEVA PHARMS 500MG A077487 003 Aug 24, 2007 RLD: N020363

FEXOFENADINE HYDROCHLORIDE

SUSPENSION; ORAL  
FEXOFENADINE HYDROCHLORIDE  
RX ACTAVIS MID 30MG/5ML A201311 001 Jul 25, 2012 RLD: N021963  
ATLANTIC

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 10-100mCi/ML A203771 001 Aug 31, 2015 RLD: N021768  
PET

FLUOXETINE HYDROCHLORIDE

TABLET; ORAL  
FLUOXETINE HYDROCHLORIDE  
RX MYLAN EQ 20MG BASE A075755 002 Aug 02, 2001 RLD: N020974

FLUPHENAZINE HYDROCHLORIDE

TABLET; ORAL  
FLUPHENAZINE HYDROCHLORIDE  
RX MYLAN 10MG A089804 001 Aug 12, 1988 RLD: N011751

FLUTAMIDE

CAPSULE; ORAL  
FLUTAMIDE  
RX CIPLA LTD 125MG A075780 001 Sep 19, 2001 RLD: N018554

FLUTICASONE PROPIONATE

SPRAY, METERED; NASAL  
FLUTICASONE PROPIONATE  
RX WEST-WARD PHARMS 0.05MG/SPRAY A076504 001 Feb 22, 2006 RLD: N020121  
INT

GALANTAMINE HYDROBROMIDE

SOLUTION; ORAL  
GALANTAMINE HYDROBROMIDE  
RX WEST-WARD PHARMS 4MG/ML A078185 001 Jan 30, 2009 RLD: N021224  
INT

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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

GLYBURIDE; METFORMIN HYDROCHLORIDE

TABLET; ORAL  
 GLYBURIDE AND METFORMIN HYDROCHLORIDE  
 RX AUROBINDO PHARMA 2.5MG; 500MG A077870 002 Nov 14, 2007 RLD: N021178

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

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SOLUTION; ORAL					
LEVOFLOXACIN					
RX	HI TECH PHARMA	250MG/10ML	A091678	001	Jun 20, 2011 RLD: N021721
<u>LEVONORGESTREL</u>					
TABLET; ORAL					
LEVONORGESTREL					
RX	PERRIGO R AND D	0.75MG	A090740	001	Dec 30, 2010 RLD: N021045
OTC		0.75MG	A090740	001	Dec 30, 2010 RLD: N021045
<u>LIDOCAINE HYDROCHLORIDE</u>					
SOLUTION; ORAL					
LIDOCAINE HYDROCHLORIDE VISCOUS					
RX	LANNETT CO INC	2%	A040708	001	Feb 27, 2007 RLD: N009470
<u>LOPERAMIDE HYDROCHLORIDE</u>					
CAPSULE; ORAL					
LOPERAMIDE HYDROCHLORIDE					
RX	MYLAN	2MG	A072741	001	Sep 18, 1991 RLD: N017694
<u>LOPERAMIDE HYDROCHLORIDE; SIMETHICONE</u>					
TABLET, CHEWABLE; ORAL					
LOPERAMIDE HYDROCHLORIDE AND SIMETHICONE					
OTC	PERRIGO	2MG;125MG	A076029	001	Aug 30, 2002 RLD: N020606
<u>MEFLOQUINE HYDROCHLORIDE</u>					
TABLET; ORAL					
MEFLOQUINE HYDROCHLORIDE					
RX	BARR	250MG	A076392	001	Dec 29, 2003 RLD: N019591
<u>METHSCOPOLAMINE BROMIDE</u>					
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
<u>METHYLERGONOVINE MALEATE</u>					
TABLET; ORAL					
METHYLERGONOVINE MALEATE					
RX	NOVEL LABS INC	0.2MG	A091577	001	May 02, 2011 RLD: N006035
<u>METHYLPHENIDATE HYDROCHLORIDE</u>					
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
<u>METOPROLOL TARTRATE</u>					
TABLET; ORAL					
METOPROLOL TARTRATE					
RX	MYLAN	100MG	A076704	003	Jan 16, 2004 RLD: N017963
<u>MOEXIPRIL HYDROCHLORIDE</u>					
TABLET; ORAL					
MOEXIPRIL HYDROCHLORIDE					
RX	TEVA	15MG	A076204	002	May 08, 2003 RLD: N020312
<u>MOXIFLOXACIN HYDROCHLORIDE</u>					
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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NAFTIFINE HYDROCHLORIDE

CREAM; TOPICAL  
 NAFTIFINE HYDROCHLORIDE  
 RX TARO PHARMS 1% A205975 001 Sep 08, 2016 RLD: N019599

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

PRILOCAINE HYDROCHLORIDE

INJECTABLE; INJECTION  
 PRILOCAINE HYDROCHLORIDE  
 RX SEPTODONT INC 4% A079235 001 Sep 29, 2010 RLD: N021382

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 CO INC 5MG A077152 002 Mar 25, 2005 RLD: N017849

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TERCONAZOLE

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

TESTOSTERONE

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

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

VINBLASTINE SULFATE

INJECTABLE; INJECTION  
VINBLASTINE SULFATE  
RX WEST-WARD PHARMS 10MG/VIAL A089395 001 Apr 09, 1987 RLD: N012665  
INT