

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

April 2022

Page 1 of 15

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.

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

April 2022

Page 2 of 15

ACETAMINOPHEN

SOLUTION; INTRAVENOUS
 ACETAMINOPHEN
 RX SANDOZ INC 1GM/100ML (10MG/ML) A204052 001 Mar 22, 2016 RLD: N022450

ACETAMINOPHEN; BUTALBITAL

TABLET; ORAL
 BUTAPAP
 RX MIKART 325MG; 50MG A089987 001 Oct 26, 1992 RLD: A087550

ACETAMINOPHEN; BUTALBITAL; CAFFEINE

CAPSULE; ORAL
 BUTALBITAL, ACETAMINOPHEN AND CAFFEINE
 RX MAYNE PHARMA INC 325MG; 50MG; 40MG A089007 001 Mar 17, 1986 RLD: A088825

TABLET; ORAL
 BUTALBITAL, ACETAMINOPHEN AND CAFFEINE
 RX STRIDES PHARMA 325MG; 50MG; 40MG A040511 001 Aug 27, 2003 RLD: A088616

ACETAMINOPHEN; CODEINE PHOSPHATE

TABLET; ORAL
 ACETAMINOPHEN AND CODEINE PHOSPHATE
 RX SPECGX LLC 300MG; 15MG A040419 001 May 31, 2001 RLD: A085055
 RX 300MG; 30MG A040419 002 May 31, 2001 RLD: A085055

ACETAMINOPHEN; OXYCODONE HYDROCHLORIDE

TABLET; ORAL
 PERCOET
 RX VINTAGE PHARMS LLC 325MG; 5MG A040330 002 Jun 25, 1999 RLD: A085106

ACYCLOVIR

CREAM; TOPICAL
 ACYCLOVIR
 RX PADAGIS ISRAEL 5% A208702 001 Feb 04, 2019 RLD: N021478

ALBUTEROL SULFATE; IPRATROPIUM BROMIDE

SOLUTION; INHALATION
 ALBUTEROL SULFATE AND IPRATROPIUM BROMIDE
 RX NEPHRON EQ 0.083% BASE; 0.017% A076749 001 Dec 31, 2007 RLD: N020950

ALMOTRIPTAN MALATE

TABLET; ORAL
 ALMOTRIPTAN MALATE
 RX AJANTA PHARMA LTD EQ 12.5MG BASE A205523 002 Mar 03, 2016 RLD: N021001

AMINOCAPROIC ACID

TABLET; ORAL
 AMINOCAPROIC ACID
 RX SUNNY 1GM A209060 002 Nov 27, 2018 RLD: N015197

AMIODARONE HYDROCHLORIDE

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

AMLODIPINE BESYLATE; TELMISARTAN

TABLET; ORAL
 TELMISARTAN AND AMLODIPINE
 RX MYLAN EQ 10MG BASE; 80MG A202516 004 Aug 26, 2014 RLD: N022401

AMOXICILLIN

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

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

April 2022

Page 3 of 15

AMOXICILLIN; CLARITHROMYCIN; LANSOPRAZOLE

CAPSULE, TABLET, CAPSULE, DELAYED REL PELLETS;ORAL
 LANSOPRAZOLE, AMOXICILLIN AND CLARITHROMYCIN (COPACKAGED)
 RX RISING 500MG;500MG;30MG A206006 001 Oct 07, 2016 RLD: N050757

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

AMPHETAMINE SULFATE

TABLET;ORAL
 EVEKEO
 RX ARBOR PHARMS LLC 10MG A200166 002 Aug 09, 2012 RLD: A083901

ARIPIPIRAZOLE

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

ARSENIC TRIOXIDE

INJECTABLE;INJECTION
 ARSENIC TRIOXIDE
 RX FRESENIUS KABI USA 1MG/ML A208231 001 Aug 31, 2018 RLD: N021248

ASPIRIN; BUTALBITAL; CAFFEINE

TABLET;ORAL
 BUTALBITAL, ASPIRIN AND CAFFEINE
 RX STRIDES PHARMA 325MG;50MG;40MG A204195 001 Sep 22, 2016 RLD: A086162

BETHANECHOL CHLORIDE

TABLET;ORAL
 BETHANECHOL CHLORIDE
 RX AMNEAL PHARM 10MG A040855 002 Nov 21, 2007 RLD: A088440
 RX 25MG A040855 003 Nov 21, 2007 RLD: A088441

BIMATOPROST

SOLUTION/DROPS;OPHTHALMIC
 BIMATOPROST
 RX ALEMBIC PHARMS LTD 0.03% A210263 001 Apr 12, 2019 RLD: N021275

BISMUTH SUBSALICYLATE; METRONIDAZOLE; TETRACYCLINE HYDROCHLORIDE

TABLET, CHEWABLE, TABLET, CAPSULE;ORAL
 BISMUTH SUBSALICYLATE, METRONIDAZOLE AND TETRACYCLINE HYDROCHLORIDE
 RX AILEX PHARMS LLC 262.4MG, N/A, N/A;N/A, 250MG, N/A;N/A, N/A, 500MG A202584 001 Nov 30, 2018 RLD: N050719

BRETYLIUM TOSYLATE

INJECTABLE;INJECTION
 BRETYLIUM TOSYLATE
 RX BRECKENRIDGE 50MG/ML A204386 001 Dec 21, 2018 RLD: N019030

BROMOCRIPTINE MESYLATE

CAPSULE;ORAL
 BROMOCRIPTINE MESYLATE
 RX MYLAN EQ 5MG BASE A077226 001 Apr 04, 2005 RLD: N017962
 TABLET;ORAL
 BROMOCRIPTINE MESYLATE
 RX PADAGIS US 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

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

April 2022

Page 4 of 15

CABERGOLINE

TABLET;ORAL
 CABERGOLINE
 RX INGENUS PHARMS LLC 0.5MG A204735 001 Aug 01, 2018 RLD: N020664

CAFFEINE; ERGOTAMINE TARTRATE

TABLET;ORAL
 ERGOTAMINE TARTRATE AND CAFFEINE
 RX MIKART 100MG;1MG A040590 001 Sep 16, 2005 RLD: A084294

CALCITONIN SALMON

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

CARBOPLATIN

INJECTABLE;INTRAVENOUS
 CARBOPLATIN
 RX ACCORD HLTHCARE 1GM/100ML (10MG/ML) A206775 005 Apr 06, 2020 RLD: N020452

CEFAZOLIN SODIUM

INJECTABLE;INJECTION
 CEFAZOLIN SODIUM
 RX QILU EQ 10GM BASE/VIAL A209217 001 Oct 17, 2018 RLD: N050461

CEFIXIME

CAPSULE;ORAL
 CEFIXIME
 RX ALKEM LABS LTD 400MG A210574 001 Oct 09, 2018 RLD: N203195

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 PADAGIS US 5MG/5ML A078398 001 Jun 17, 2008 RLD: N020346

CHLOROQUINE PHOSPHATE

TABLET;ORAL
 CHLOROQUINE PHOSPHATE
 RX NATCO PHARMA LTD 250MG A091621 001 Jan 21, 2011 RLD: A083082
 RX 500MG A090612 001 Jan 21, 2011 RLD: N006002

CHLORPROMAZINE HYDROCHLORIDE

CONCENTRATE;ORAL
 CHLORPROMAZINE HYDROCHLORIDE
 RX GENUS 30MG/ML A214542 001 Jun 02, 2021 RLD: N009149
 RX 100MG/ML A214542 002 Jun 02, 2021 RLD: N009149

CHLORZOXAZONE

TABLET;ORAL
 CHLORZOXAZONE
 RX MIKART 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

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

April 2022

Page 5 of 15

INJECTABLE; INJECTION						
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
<u>CLINDAMYCIN PHOSPHATE</u>						
INJECTABLE; INJECTION						
CLINDAMYCIN PHOSPHATE IN 5% DEXTROSE IN PLASTIC CONTAINER						
RX	SANDOZ INC	EQ 6MG BASE/ML	A201692	001	May 31, 2012	RLD: N050639
RX		EQ 12MG BASE/ML	A201692	002	May 31, 2012	RLD: N050639
RX		EQ 18MG BASE/ML	A201692	003	May 31, 2012	RLD: N050639
<u>CLOBETASOL PROPIONATE</u>						
OINTMENT; TOPICAL						
CLOBETASOL PROPIONATE						
RX	FOUGERA PHARMS	0.05%	A074407	001	Feb 23, 1996	RLD: N019323
<u>CYCLOBENZAPRINE HYDROCHLORIDE</u>						
TABLET; ORAL						
CYCLOBENZAPRINE HYDROCHLORIDE						
RX	RUBICON	10MG	A208170	003	May 31, 2017	RLD: N017821
<u>CYTARABINE</u>						
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
RX	WEST-WARD PHARMS	2GM/VIAL	A074245	002	Aug 31, 1994	RLD: N016793
	INT					
<u>DACARBAZINE</u>						
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
<u>DARIFENACIN HYDROBROMIDE</u>						
TABLET, EXTENDED RELEASE; ORAL						
DARIFENACIN						
RX	MACLEODS PHARMS	EQ 15MG BASE	A207302	002	Jul 28, 2017	RLD: N021513
	LTD					
<u>DESMOPRESSIN ACETATE</u>						
SPRAY, METERED; NASAL						
DESMOPRESSIN ACETATE (NEEDS NO REFRIGERATION)						
RX	SUN PHARM	0.01MG/SPRAY	A078271	001	Dec 23, 2013	RLD: N017922
<u>DESOGESTREL; ETHINYL ESTRADIOL</u>						
TABLET; ORAL-28						
DESOGESTREL AND ETHINYL ESTRADIOL						
RX	DURAMED PHARMS	0.15MG; 0.03MG	A075256	002	Aug 12, 1999	RLD: N020301
	BARR					
<u>DESONIDE</u>						
GEL; TOPICAL						
DESONIDE						
RX	CINTEX SVCS	0.05%	A202470	001	May 11, 2020	RLD: N021844
<u>DEXAMETHASONE SODIUM PHOSPHATE</u>						
INJECTABLE; INJECTION						
DEXAMETHASONE SODIUM PHOSPHATE PRESERVATIVE FREE						
RX	FRESENIUS KABI USA	EQ 10MG PHOSPHATE/ML	A040491	001	Apr 11, 2003	RLD: N014694

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

April 2022

Page 6 of 15

DICLOFENAC POTASSIUM

TABLET;ORAL
 DICLOFENAC POTASSIUM
 RX RK PHARMA 50MG A075463 001 Jul 26, 1999 RLD: N020142

DICLOFENAC SODIUM

GEL;TOPICAL
 DICLOFENAC SODIUM
 RX TARO 3% A206298 001 Apr 28, 2016 RLD: N021005
 TABLET, EXTENDED RELEASE;ORAL
 DICLOFENAC SODIUM

RX DEXCEL LTD 100MG A076201 001 Nov 06, 2002 RLD: N020254

DICYCLOMINE HYDROCHLORIDE

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

DIMENHYDRINATE

INJECTABLE;INJECTION
 DIMENHYDRINATE
 RX FRESENIUS KABI USA 50MG/ML A040519 001 Jun 23, 2004 RLD: A080615

DISULFIRAM

TABLET;ORAL
 DISULFIRAM
 RX HIKMA 500MG A202652 002 Feb 05, 2014 RLD: A088483

DOXORUBICIN HYDROCHLORIDE

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

DYCLONINE HYDROCHLORIDE

SOLUTION;TOPICAL
 DYCLOPRO
 RX NOVOCOL INC 0.5% A200480 001 Nov 20, 2018 RLD: N009925
 RX 1% A200480 002 Nov 20, 2018 RLD: N009925

EPTIFIBATIDE

INJECTABLE;INJECTION
 EPTIFIBATIDE
 RX MYLAN LABS LTD 2MG/ML A203258 001 Jul 20, 2018 RLD: N020718
 RX 75MG/100ML A203258 002 Jul 20, 2018 RLD: N020718

ESOMEPRAZOLE SODIUM

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

ESTRADIOL

TABLET;ORAL
 ESTRADIOL
 RX BARR LABS INC 2MG A040197 003 Oct 22, 1997 RLD: A084500

ETHINYL ESTRADIOL; NORETHINDRONE

TABLET;ORAL-28
 BALZIVA-28
 RX BARR 0.035MG;0.4MG A076238 001 Apr 22, 2004 RLD: N017716

ETHINYL ESTRADIOL; NORETHINDRONE ACETATE

TABLET;ORAL-28
 CHABELINA FE
 RX NOVAST LABS 0.02MG,0.03MG,0.035MG;1MG,1MG,1 A202962 001 Apr 15, 2020 RLD: N020130
 MG

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

April 2022

Page 7 of 15

ETHINYL ESTRADIOL; NORGESTIMATE

TABLET;ORAL-28

NORGESTIMATE AND ETHINYL ESTRADIOL

RX	GLENMARK PHARMS	0.025MG,0.025MG,0.025MG;0.18MG, 0.215MG,0.25MG	A204057	001	Feb 23, 2016	RLD: N021241
----	-----------------	---	---------	-----	--------------	--------------

FAMCICLOVIR

TABLET;ORAL

FAMCICLOVIR

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

FAMOTIDINE

TABLET;ORAL

FAMOTIDINE

RX	AUROBINDO PHARMA LTD	40MG	A206530	002	Dec 22, 2015	RLD: N019462
----	-------------------------	------	---------	-----	--------------	--------------

FLUCONAZOLE

INJECTABLE;INJECTION

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
----	------------------------	--------------	---------	-----	--------------	--------------

FLUNISOLIDE

SPRAY, METERED;NASAL

FLUNISOLIDE

RX	BAUSCH AND LOMB	0.025MG/SPRAY	A074805	001	Feb 20, 2002	RLD: N018148
----	-----------------	---------------	---------	-----	--------------	--------------

FLUOXETINE HYDROCHLORIDE

TABLET;ORAL

FLUOXETINE HYDROCHLORIDE

RX	DR REDDYS	EQ 20MG BASE	A076006	002	Apr 23, 2018	RLD: N020974
RX	TORRENT	EQ 20MG BASE	A206937	002	Oct 21, 2016	RLD: N021860

FLUTICASONE PROPIONATE

SPRAY, METERED;NASAL

FLUTICASONE PROPIONATE

RX	HIKMA	0.05MG/SPRAY	A076504	001	Feb 22, 2006	RLD: N020121
OTC		0.05MG/SPRAY	A207957	001	May 26, 2016	RLD: N205434

FOLIC ACID

TABLET;ORAL

FOLIC ACID

RX	AMNEAL PHARM	1MG	A040625	001	Jul 21, 2005	RLD: A080680
----	--------------	-----	---------	-----	--------------	--------------

GALANTAMINE HYDROBROMIDE

SOLUTION;ORAL

GALANTAMINE HYDROBROMIDE

RX	HIKMA	4MG/ML	A078185	001	Jan 30, 2009	RLD: N021224
----	-------	--------	---------	-----	--------------	--------------

GANCICLOVIR SODIUM

INJECTABLE;INJECTION

GANCICLOVIR SODIUM

RX	PHARMASCIENCE INC	EQ 500MG BASE/VIAL	A207645	001	Dec 08, 2017	RLD: N019661
----	-------------------	--------------------	---------	-----	--------------	--------------

GLYBURIDE; METFORMIN HYDROCHLORIDE

TABLET;ORAL

GLYBURIDE AND METFORMIN HYDROCHLORIDE

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

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

April 2022

Page 8 of 15

GLYCOPYRROLATE

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

HYDRALAZINE HYDROCHLORIDE; HYDROCHLOROTHIAZIDE

CAPSULE; ORAL
 HYDRA-ZIDE
 RX STRIDES PHARMA 50MG; 50MG A088946 001 Oct 21, 1985 RLD: A084810

HYDROCHLOROTHIAZIDE; MOEXIPRIL HYDROCHLORIDE

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

HYDROCODONE BITARTRATE

CAPSULE, EXTENDED RELEASE; ORAL
 HYDROCODONE BITARTRATE
 RX ALVOGEN 10MG A206986 001 Jan 21, 2020 RLD: N202880

HYDROCODONE BITARTRATE; IBUPROFEN

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

HYDROCORTISONE

CREAM; TOPICAL
 HYDROCORTISONE
 RX FOUGERA PHARMS INC 2.5% A089414 001 Dec 16, 1986 RLD: A087457

HYDROMORPHONE HYDROCHLORIDE

TABLET, EXTENDED RELEASE; ORAL
 HYDROMORPHONE HYDROCHLORIDE
 RX OSMOTICA PHARM US 32MG A205629 004 Jul 07, 2016 RLD: N021217

HYDROXYCHLOROQUINE SULFATE

TABLET; ORAL
 HYDROXYCHLOROQUINE SULFATE
 RX ACCORD HLTHCARE 400MG A213342 004 Aug 18, 2021 RLD: N009768

HYDROXYPROGESTERONE CAPROATE

SOLUTION; INTRAMUSCULAR
 HYDROXYPROGESTERONE CAPROATE
 RX ASPEN GLOBAL INC 1250MG/5ML (250MG/ML) A200271 001 Aug 24, 2015 RLD: N016911

IBANDRONATE SODIUM

TABLET; ORAL
 IBANDRONATE SODIUM
 RX DR REDDYS LABS LTD EQ 150MG BASE A078997 001 Apr 30, 2012 RLD: N021455

IMIPRAMINE PAMOATE

CAPSULE; ORAL
 IMIPRAMINE PAMOATE
 RX HIKMA EQ 75MG HYDROCHLORIDE A091099 001 Apr 16, 2010 RLD: N017090

INDOMETHACIN SODIUM

INJECTABLE; INJECTION
 INDOMETHACIN SODIUM
 RX NAVINTA LLC EQ 1MG BASE/VIAL A206561 001 Jul 19, 2017 RLD: N018878

IPRATROPIUM BROMIDE

SPRAY, METERED; NASAL
 IPRATROPIUM BROMIDE
 RX HIKMA 0.021MG/SPRAY A076664 001 Nov 05, 2003 RLD: N020393
 RX 0.042MG/SPRAY A076598 001 Nov 05, 2003 RLD: N020394

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

April 2022

Page 9 of 15

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
 ZADITOR
 OTC ALCON PHARMS LTD EQ 0.025% BASE A077200 001 Sep 02, 2008 RLD: N021066

LABETALOL HYDROCHLORIDE

INJECTABLE; INJECTION
 LABETALOL HYDROCHLORIDE
 RX HOSPIRA 5MG/ML A075239 001 Nov 29, 1999 RLD: N018686
 TABLET; ORAL
 LABETALOL HYDROCHLORIDE
 RX SANDOZ 200MG A075113 002 Aug 04, 1998 RLD: N018687

LACTULOSE

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

LEVOCETIRIZINE DIHYDROCHLORIDE

TABLET; ORAL
 LEVOCETIRIZINE DIHYDROCHLORIDE
 RX GLENMARK GENERICS 5MG A090385 001 Feb 24, 2011 RLD: N022064

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 AKORN 250MG/10ML A091678 001 Jun 20, 2011 RLD: N021721

LEVOLEUCOVORIN CALCIUM

SOLUTION; INTRAVENOUS
 LEVOLEUCOVORIN CALCIUM
 RX GLAND PHARMA LTD EQ 175MG BASE/17.5ML (EQ 10MG A210892 001 Sep 14, 2018 RLD: N020140
 BASE/ML)
 RX EQ 250MG BASE/25ML (EQ 10MG A210892 002 Sep 14, 2018 RLD: N020140
 BASE/ML)

LEVONORGESTREL

TABLET; ORAL
 LEVONORGESTREL
 OTC L PERRIGO CO 0.75MG A090740 001 Dec 30, 2010 RLD: N021045
 RX 0.75MG A090740 001 Dec 30, 2010 RLD: N021045

LEVORPHANOL TARTRATE

TABLET; ORAL
 LEVORPHANOL TARTRATE
 RX SENTYNL THERAPS 3MG A074278 003 Jun 18, 2018 RLD: N008720
 INC

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

April 2022

Page 10 of 15

LIDOCAINE HYDROCHLORIDE

SOLUTION;TOPICAL

LIDOCAINE HYDROCHLORIDE

RX	HIKMA	4%	A088803	001	Apr 03, 1985	RLD: N010417
----	-------	----	---------	-----	--------------	--------------

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
-----	---------	-----------	---------	-----	--------------	--------------

MAFENIDE ACETATE

FOR SOLUTION;TOPICAL

MAFENIDE ACETATE

RX	PAR FORM	5%	A201511	001	Feb 12, 2013	RLD: N019832
----	----------	----	---------	-----	--------------	--------------

MEFLOQUINE HYDROCHLORIDE

TABLET;ORAL

MEFLOQUINE HYDROCHLORIDE

RX	BARR	250MG	A076392	001	Dec 29, 2003	RLD: N019591
----	------	-------	---------	-----	--------------	--------------

MELOXICAM

CAPSULE;ORAL

MELOXICAM

RX	LUPIN LTD	10MG	A209487	002	Jun 01, 2020	RLD: N207233
----	-----------	------	---------	-----	--------------	--------------

MELPHALAN

TABLET;ORAL

MELPHALAN

RX	ALVOGEN	2MG	A207809	001	Mar 22, 2017	RLD: N014691
----	---------	-----	---------	-----	--------------	--------------

MEPERIDINE HYDROCHLORIDE

INJECTABLE;INJECTION

MEPERIDINE HYDROCHLORIDE PRESERVATIVE FREE

RX	WEST-WARD PHARMS	10MG/ML	A081002	001	Jul 30, 1993	RLD: A088432
----	------------------	---------	---------	-----	--------------	--------------

INT

MEPROBAMATE

TABLET;ORAL

MEPROBAMATE

RX	ALEMBIC PHARMS LTD	200MG	A090122	001	Feb 18, 2009	RLD: A083304
----	--------------------	-------	---------	-----	--------------	--------------

RX		400MG	A090122	002	Feb 18, 2009	RLD: A083308
----	--	-------	---------	-----	--------------	--------------

METFORMIN HYDROCHLORIDE

TABLET, EXTENDED RELEASE;ORAL

METFORMIN HYDROCHLORIDE

RX	ALKEM LABS LTD	750MG	A206145	002	Oct 22, 2018	RLD: N021202
----	----------------	-------	---------	-----	--------------	--------------

METHADONE HYDROCHLORIDE

TABLET;ORAL

METHADONE HYDROCHLORIDE

RX	SPECGX LLC	5MG	A040517	001	Apr 27, 2004	RLD: N006134
----	------------	-----	---------	-----	--------------	--------------

RX		10MG	A040517	002	Apr 27, 2004	RLD: N006134
----	--	------	---------	-----	--------------	--------------

METHENAMINE HIPPURATE

TABLET;ORAL

METHENAMINE HIPPURATE

RX	AUROBINDO PHARMA	1GM	A205661	001	Jul 05, 2016	RLD: N017681
----	------------------	-----	---------	-----	--------------	--------------

LTD

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

April 2022

Page 11 of 15

METHOCARBAMOL

TABLET; ORAL		METHOCARBAMOL					
RX	AUSTARPHARMA LLC	1GM		A200958	003	Dec 06, 2021	RLD: N011011
RX	GRANULES	500MG		A209312	001	May 07, 2018	RLD: N011011
RX		750MG		A209312	002	May 07, 2018	RLD: N011011

METHOTREXATE SODIUM

INJECTABLE; INJECTION		METHOTREXATE SODIUM PRESERVATIVE FREE					
RX	ACCORD HLHCARE	EQ 250MG BASE/10ML (EQ 25MG BASE/ML)		A040768	001	Apr 30, 2007	RLD: A088760
TABLET; ORAL		METHOTREXATE SODIUM					
RX	HIKMA	EQ 2.5MG BASE		A040054	001	Aug 01, 1994	RLD: N008085

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	ASCENT PHARMS INC	10MG		A210354	003	Dec 29, 2017	RLD: N021475
TABLET, EXTENDED RELEASE; ORAL		METHYLPHENIDATE HYDROCHLORIDE					
RX	OSMOTICA	72MG		A205327	005	Jul 28, 2017	RLD: N021121

METHYLTESTOSTERONE

CAPSULE; ORAL		METHYLTESTOSTERONE					
RX	IMPAX LABS INC	10MG		A204851	001	Sep 21, 2015	RLD: A083976

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

MOMETASONE FUROATE

SPRAY, METERED; NASAL		MOMETASONE FUROATE					
RX	APOTEX INC	0.05MG/SPRAY		A091161	001	Mar 22, 2016	RLD: N020762

MOXIFLOXACIN HYDROCHLORIDE

SOLUTION; INTRAVENOUS		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

NAFTIFINE HYDROCHLORIDE

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

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

April 2022

Page 12 of 15

NALMEFENE HYDROCHLORIDE

SOLUTION; INTRAMUSCULAR, INTRAVENOUS, SUBCUTANEOUS
 NALMEFENE HYDROCHLORIDE
 RX PURDUE PHARMA LP EQ 2MG BASE/2ML (EQ 1MG BASE/ML) A212955 001 Feb 08, 2022 RLD: N020459

NALTREXONE HYDROCHLORIDE

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

NATEGLINIDE

TABLET; ORAL
 NATEGLINIDE
 RX ZYDUS PHARMS 120MG A205248 002 Jul 06, 2016 RLD: N021204

NIACIN

TABLET; ORAL
 NIACOR
 RX AVONDALE PHARMS 500MG A040378 001 May 03, 2000 RLD: A083823

NICARDIPINE HYDROCHLORIDE

CAPSULE; ORAL
 NICARDIPINE HYDROCHLORIDE
 RX EPIC PHARMA 30MG A074928 002 Mar 19, 1998 RLD: N019488

NIFEDIPINE

TABLET, EXTENDED RELEASE; ORAL
 NIFEDIPINE
 RX NOVAST LABS 60MG A202987 002 Aug 25, 2016 RLD: N020198
 RX 90MG A202987 003 Aug 25, 2016 RLD: N020198

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; INTRAVENOUS
 OXALIPLATIN
 RX QILU PHARM HAINAN 200MG/40ML (5MG/ML) A204368 003 Jun 07, 2016 RLD: N021759

OXYBUTYNIN CHLORIDE

TABLET, EXTENDED RELEASE; ORAL
 OXYBUTYNIN CHLORIDE
 RX ACCORD HLTHCARE 15MG A207138 003 Feb 29, 2016 RLD: N020897

PALONOSETRON HYDROCHLORIDE

INJECTABLE; INTRAVENOUS
 PALONOSETRON HYDROCHLORIDE
 RX DR REDDYS EQ 0.25MG BASE/5ML (EQ 0.05MG BASE/ML) A201533 002 Apr 21, 2016 RLD: N021372

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

April 2022

Page 13 of 15

PANCURONIUM BROMIDE

INJECTABLE; INJECTION

PANCURONIUM BROMIDE

RX	DR REDDYS	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
----	--------	-------	---------	-----	--------------	--------------

PHENOXYBENZAMINE HYDROCHLORIDE

CAPSULE; ORAL

PHENOXYBENZAMINE HYDROCHLORIDE

RX	PAR PHARM INC	10MG	A204522	001	Jan 24, 2017	RLD: N008708
----	---------------	------	---------	-----	--------------	--------------

PHENTERMINE HYDROCHLORIDE

TABLET; ORAL

LOMAIRA

RX	AVANTHI INC	8MG	A203495	001	Sep 12, 2016	RLD: N012737
----	-------------	-----	---------	-----	--------------	--------------

PHENYLEPHRINE HYDROCHLORIDE; PROMETHAZINE HYDROCHLORIDE

SYRUP; ORAL

PHENYLEPHRINE HYDROCHLORIDE AND PROMETHAZINE HYDROCHLORIDE

RX	PHARM ASSOC	5MG/5ML; 6.25MG/5ML	A040654	001	Dec 07, 2006	RLD: A088761
----	-------------	---------------------	---------	-----	--------------	--------------

PHYTONADIONE

INJECTABLE; INJECTION

PHYTONADIONE

RX	CIPLA	1MG/0.5ML	A212424	001	Apr 22, 2022	RLD: N012223
RX		10MG/ML	A212424	002	Apr 22, 2022	RLD: N012223

PIPERACILLIN SODIUM; TAZOBACTAM SODIUM

INJECTABLE; INJECTION

PIPERACILLIN AND TAZOBACTAM

RX	WOCKHARDT BIO AG	EQ 2GM BASE/VIAL; EQ 250MG BASE/VIAL	A206996	001	Mar 22, 2017	RLD: N050684
RX		EQ 3GM BASE/VIAL; EQ 375MG BASE/VIAL	A206996	002	Mar 22, 2017	RLD: N050684
RX		EQ 4GM BASE/VIAL; EQ 500MG BASE/VIAL	A206996	003	Mar 22, 2017	RLD: N050684
RX		EQ 36GM BASE/VIAL; EQ 4.5GM BASE/VIAL	A207146	001	Mar 17, 2017	RLD: N050684

POTASSIUM CHLORIDE

TABLET, EXTENDED RELEASE; ORAL

KLOR-CON M20

RX	UPSHER SMITH LABS	20MEQ	A074726	001	Nov 20, 1998	RLD: N019439
----	-------------------	-------	---------	-----	--------------	--------------

PREDNISOLONE SODIUM PHOSPHATE

SOLUTION/DROPS; OPHTHALMIC

PREDNISOLONE SODIUM PHOSPHATE

RX	BAUSCH AND LOMB	EQ 0.9% PHOSPHATE	A040070	001	Jul 29, 1994	RLD: A080751
----	-----------------	-------------------	---------	-----	--------------	--------------

PRILOCAINE HYDROCHLORIDE

INJECTABLE; INJECTION

PRILOCAINE HYDROCHLORIDE

RX	SEPTODONT INC	4%	A079235	001	Sep 29, 2010	RLD: N021382
----	---------------	----	---------	-----	--------------	--------------

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

April 2022

Page 14 of 15

PYRAZINAMIDE

TABLET; ORAL

PYRAZINAMIDE

RX	AKORN	500MG	A081319	001	Jun 30, 1992	RLD: A080157
----	-------	-------	---------	-----	--------------	--------------

SELEGILINE HYDROCHLORIDE

CAPSULE; ORAL

SELEGILINE HYDROCHLORIDE

RX	APOTEX	5MG	A075321	001	Dec 04, 1998	RLD: N020647
----	--------	-----	---------	-----	--------------	--------------

SODIUM BICARBONATE

INJECTABLE; INJECTION

SODIUM BICARBONATE

RX	EXELA PHARMA	0.5MEQ/ML	A211091	001	Jun 20, 2019	RLD: N019443
RX		0.9MEQ/ML	A211091	002	Jun 20, 2019	RLD: N019443
RX		1MEQ/ML	A211091	003	Jun 20, 2019	RLD: N019443

SODIUM POLYSTYRENE SULFONATE

POWDER; ORAL, RECTAL

KALEXATE

RX	KVK TECH	454GM/BOT	A040905	001	Mar 30, 2009	RLD: N011287
----	----------	-----------	---------	-----	--------------	--------------

STERILE WATER FOR INJECTION

LIQUID; N/A

STERILE WATER FOR INJECTION

RX	MEDEFIL INC	100% (2.5ML)	A211188	002	Dec 02, 2019	RLD: N018801
RX		100% (3ML)	A211188	003	Dec 02, 2019	RLD: N018801
RX		100% (5ML)	A211188	004	Dec 02, 2019	RLD: N018801

SUCCINYLCHOLINE CHLORIDE

INJECTABLE; INJECTION

SUCCINYLCHOLINE CHLORIDE

RX	ZYDUS PHARMS	20MG/ML	A209467	001	May 04, 2018	RLD: N008845
----	--------------	---------	---------	-----	--------------	--------------

SULFADIAZINE

TABLET; ORAL

SULFADIAZINE

RX	EPIC PHARMA	500MG	A040091	001	Jul 29, 1994	RLD: N004122
----	-------------	-------	---------	-----	--------------	--------------

SULFAMETHOXAZOLE; TRIMETHOPRIM

INJECTABLE; INJECTION

SULFAMETHOXAZOLE AND TRIMETHOPRIM

RX	MYLAN LABS LTD	80MG/ML; 16MG/ML	A206607	001	Aug 30, 2017	RLD: N018374
----	----------------	------------------	---------	-----	--------------	--------------

TERBUTALINE SULFATE

TABLET; ORAL

TERBUTALINE SULFATE

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

TERCONAZOLE

CREAM; VAGINAL

TERCONAZOLE

RX	TARO	0.8%	A075953	001	Apr 06, 2004	RLD: N019964
----	------	------	---------	-----	--------------	--------------

TESTOSTERONE

GEL, METERED; TRANSDERMAL

TESTOSTERONE

RX	ACTAVIS LABS UT INC	12.5MG/1.25GM ACTUATION	A076737	003	Mar 09, 2015	RLD: N021015
----	---------------------	-------------------------	---------	-----	--------------	--------------

GEL; TRANSDERMAL

TESTOSTERONE

RX	PADAGIS ISRAEL	1.62% (40.5MG/2.5GM PACKET)	A205781	002	Jul 12, 2017	RLD: N022309
----	----------------	-----------------------------	---------	-----	--------------	--------------

SOLUTION, METERED; TRANSDERMAL

TESTOSTERONE

RX	PADAGIS ISRAEL	30MG/1.5ML ACTUATION	A204255	001	Feb 28, 2017	RLD: N022504
----	----------------	----------------------	---------	-----	--------------	--------------

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

April 2022

Page 15 of 15

THEOPHYLLINE

SOLUTION; ORAL
 THEOPHYLLINE
 RX LANNETT CO INC 80MG/15ML A091156 001 Apr 13, 2011 RLD: A087449

THIOTHIXENE

CAPSULE; ORAL
 THIOTHIXENE
 RX NOVITIUM PHARMA 5MG A211642 003 Apr 05, 2019 RLD: N016584

TIMOLOL MALEATE

SOLUTION, GEL FORMING/DROPS; OPHTHALMIC
 TIMOLOL MALEATE
 RX ALEMBIC PHARMS LTD EQ 0.25% BASE A212942 001 Oct 22, 2020 RLD: N020330
 RX EQ 0.5% BASE A212942 002 Oct 22, 2020 RLD: N020330

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

TABLET; ORAL
 TIMOLOL MALEATE
 RX MYLAN 20MG A072668 001 Jun 08, 1990 RLD: N018017

TRAVOPROST

SOLUTION/DROPS; OPHTHALMIC
 TRAVOPROST
 RX STRIDES PHARMA 0.004% A091340 001 Mar 01, 2013 RLD: N021257

TRIMIPRAMINE MALEATE

CAPSULE; ORAL
 TRIMIPRAMINE MALEATE
 RX CROSSMEDIKA SA EQ 50MG BASE A208127 002 Apr 15, 2016 RLD: N016792

URSODIOL

CAPSULE; ORAL
 URSODIOL
 RX LGM PHARMA 400MG A205789 002 May 08, 2020 RLD: N019594

VARDENAFIL HYDROCHLORIDE

TABLET; ORAL
 VARDENAFIL HYDROCHLORIDE
 RX ZYDUS PHARMS EQ 20MG BASE A208960 004 Oct 31, 2018 RLD: N021400

VARENICLINE TARTRATE

TABLET; ORAL
 VARENICLINE TARTRATE
 RX PAR PHARM INC EQ 1MG BASE A201785 002 Aug 11, 2021 RLD: N021928

VERAPAMIL HYDROCHLORIDE

INJECTABLE; INJECTION
 VERAPAMIL HYDROCHLORIDE
 RX EUGIA PHARMA 2.5MG/ML A212965 001 Jul 06, 2020 RLD: N018485

TABLET, EXTENDED RELEASE; ORAL
 VERAPAMIL HYDROCHLORIDE
 RX GLENMARK GENERICS 180MG A090700 002 Aug 03, 2011 RLD: N019152

TABLET; ORAL
 VERAPAMIL HYDROCHLORIDE
 RX HERITAGE PHARMS 120MG A071881 001 Apr 05, 1988 RLD: N018593

VINBLASTINE SULFATE

INJECTABLE; INJECTION
 VINBLASTINE SULFATE
 RX HIKMA 10MG/VIAL A089395 001 Apr 09, 1987 RLD: N012665