

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

March 2024

Page 1 of 24

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

March 2024

Page 2 of 24

ABACAVIR SULFATE

TABLET;ORAL
 ABACAVIR SULFATE
 RX HETERO LABS LTD EQ 300MG BASE A091560 001 Sep 13, 2013 RLD: N020977
 III

ABACAVIR SULFATE; LAMIVUDINE

TABLET;ORAL
 ABACAVIR SULFATE AND LAMIVUDINE
 RX CIPLA EQ 600MG BASE;300MG A091144 001 Mar 28, 2017 RLD: N021652

ABACAVIR SULFATE; LAMIVUDINE; ZIDOVUDINE

TABLET;ORAL
 ABACAVIR SULFATE, LAMIVUDINE AND ZIDOVUDINE
 RX LUPIN LTD EQ 300MG BASE;150MG;300MG A202912 001 Dec 05, 2013 RLD: N021205

ACETAMINOPHEN

SOLUTION;INTRAVENOUS
 ACETAMINOPHEN
 RX SANDOZ 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 DR REDDYS LABS SA 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

ACETAZOLAMIDE

CAPSULE, EXTENDED RELEASE;ORAL
 ACETAZOLAMIDE
 RX CADILA 500MG A205301 001 Jan 16, 2019 RLD: N012945

ACYCLOVIR

CREAM;TOPICAL
 ACYCLOVIR
 RX PADAGIS ISRAEL 5% A208702 001 Feb 04, 2019 RLD: N021478
 SUSPENSION;ORAL
 ACYCLOVIR
 RX NOVITIUM PHARMA 200MG/5ML A212252 001 Jul 10, 2020 RLD: N019909

ALBENDAZOLE

TABLET;ORAL
 ALBENDAZOLE
 RX DR REDDYS 200MG A211034 001 Jan 26, 2021 RLD: N020666

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

March 2024

Page 3 of 24

ALBUTEROL SULFATE

SOLUTION; INHALATION
 ALBUTEROL SULFATE
 RX RITEDOSE CORP EQ 0.021% BASE A214531 001 Dec 28, 2021 RLD: N020949

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

ALLOPURINOL

TABLET; ORAL
 ALLOPURINOL
 RX UNICHEM 300MG A211820 002 Mar 12, 2019 RLD: N016084

ALMOTRIPTAN MALATE

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

ALVIMOPAN

CAPSULE; ORAL
 ALVIMOPAN
 RX WATSON LABS TEVA 12MG A208295 001 Dec 19, 2019 RLD: N021775

AMINOCAPROIC ACID

SOLUTION; ORAL
 AMINOCAPROIC ACID
 RX TULEX PHARMS INC 0.25GM/ML A212494 001 Aug 11, 2020 RLD: N015230
 TABLET; ORAL
 AMINOCAPROIC ACID
 RX SUNNY 1GM A209060 002 Nov 27, 2018 RLD: N015197

AMLODIPINE BESYLATE; TELMISARTAN

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

AMMONIUM LACTATE

CREAM; TOPICAL
 AMMONIUM LACTATE
 RX PADAGIS ISRAEL EQ 12% BASE A075774 001 May 01, 2002 RLD: N020508

AMOXICILLIN

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

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 AZURITY 10MG A200166 002 Aug 09, 2012 RLD: A083901

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

March 2024

Page 4 of 24

AMPICILLIN/AMPICILLIN TRIHYDRATE

CAPSULE; ORAL
 AMPICILLIN TRIHYDRATE
 RX SANDOZ EQ 500MG BASE A064082 002 Aug 29, 1995 RLD: N050056

ARGATROBAN

INJECTABLE; INJECTION
 ARGATROBAN
 RX HOSPIRA 250MG/2.5ML (100MG/ML) A204120 001 Sep 21, 2016 RLD: N020833

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

ASPIRIN; DIPYRIDAMOLE

CAPSULE, EXTENDED RELEASE; ORAL
 ASPIRIN AND DIPYRIDAMOLE
 RX GLENMARK PHARMS SA 25MG; 200MG A210318 001 May 24, 2019 RLD: N020884

ATORVASTATIN CALCIUM; EZETIMIBE

TABLET; ORAL
 LYPQOZET
 RX ALTHERA PHARMS EQ 80MG BASE; 10MG A206084 004 Apr 26, 2017 RLD: N200153

ATROPINE SULFATE

SOLUTION/DROPS; OPHTHALMIC
 ATROPINE SULFATE
 RX AMNEAL 1% A214752 001 Jul 14, 2022 RLD: N206289

AZELASTINE HYDROCHLORIDE; FLUTICASONE PROPIONATE

SPRAY, METERED; NASAL
 AZELASTINE HYDROCHLORIDE AND FLUTICASONE PROPIONATE
 RX APOTEX 0.137MG/SPRAY; 0.05MG/SPRAY A207712 001 Apr 28, 2017 RLD: N202236

BACLOFEN

TABLET; ORAL
 BACLOFEN
 RX RUBICON 5MG A209102 001 Nov 28, 2017 RLD: N017851

BENZONATATE

CAPSULE; ORAL
 BENZONATATE
 RX PURACAP PHARM LLC 100MG A206948 001 Dec 19, 2018 RLD: N011210
 RX 200MG A206948 002 Dec 19, 2018 RLD: N011210

BENZOYL PEROXIDE; CLINDAMYCIN PHOSPHATE

GEL; TOPICAL
 CLINDAMYCIN PHOSPHATE AND BENZOYL PEROXIDE
 RX GLENMARK PHARMS 5%; EQ 1% BASE A209252 001 Mar 14, 2019 RLD: N050756

BETAMETHASONE VALERATE

AEROSOL, FOAM; TOPICAL
 BETAMETHASONE VALERATE
 RX TARO 0.12% A208204 001 May 24, 2017 RLD: N020934

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

March 2024

Page 5 of 24

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 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 NOSTRUM LABS INC 262.4MG, N/A, N/A;N/A, 250MG, A202584 001 Nov 30, 2018 RLD: N050719
N/A;N/A, N/A, 500MG

BROMFENAC SODIUM

SOLUTION/DROPS;OPHTHALMIC
BROMFENAC SODIUM
RX ALEMBIC EQ 0.09% ACID A210560 001 Jun 21, 2019 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 PADAGIS US EQ 2.5MG BASE A077646 001 Oct 01, 2008 RLD: N017962

BROMPHENIRAMINE MALEATE; DEXTROMETHORPHAN HYDROBROMIDE; PSEUDOEPHEDRINE HYDROCHLORIDE

SYRUP;ORAL
BROMPHENIRAMINE MALEATE, PSEUDOEPHEDRINE HYDROCHLORIDE AND DEXTROMETHORPHAN HYDROBROMIDE
RX PADAGIS US 2MG/5ML;10MG/5ML;30MG/5ML A205292 001 Jul 15, 2014 RLD: A088811

BUPRENORPHINE HYDROCHLORIDE

INJECTABLE;INJECTION
BUPRENORPHINE HYDROCHLORIDE
RX PAR STERILE EQ 0.3MG BASE/ML A206586 001 Jul 28, 2015 RLD: N018401
PRODUCTS

BUPRENORPHINE HYDROCHLORIDE; NALOXONE HYDROCHLORIDE

TABLET;SUBLINGUAL
BUPRENORPHINE HYDROCHLORIDE AND NALOXONE HYDROCHLORIDE
RX HIKMA EQ 8MG BASE;EQ 2MG BASE A203326 002 Jun 27, 2014 RLD: N020733

BUPROPION HYDROCHLORIDE

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

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

CALCIPOTRIENE

OINTMENT;TOPICAL
CALCIPOTRIENE
RX GLENMARK PHARMS 0.005% A090633 001 Mar 24, 2010 RLD: N020273
INC

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

March 2024

Page 6 of 24

CALCITONIN SALMON

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

CARBIDOPA; LEVODOPA

TABLET, EXTENDED RELEASE;ORAL
 CARBIDOPA AND LEVODOPA
 RX SCIEGEN PHARMS INC 50MG;200MG A214091 002 Oct 05, 2021 RLD: N019856

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

CEFEPIME HYDROCHLORIDE

INJECTABLE;INJECTION
 CEFEPIME HYDROCHLORIDE
 RX QILU EQ 500MG BASE/VIAL A203704 001 Feb 01, 2016 RLD: N050679
 RX EQ 1GM BASE/VIAL A203704 002 Feb 01, 2016 RLD: N050679
 RX EQ 2GM BASE/VIAL A203704 003 Feb 01, 2016 RLD: N050679

CEFOTETAN DISODIUM

INJECTABLE;INJECTION
 CEFOTETAN
 RX FRESENIUS KABI USA EQ 1GM BASE/VIAL A065374 001 Aug 09, 2007 RLD: N050588
 RX EQ 2GM BASE/VIAL A065374 002 Aug 09, 2007 RLD: N050588

CEFUROXIME SODIUM

INJECTABLE;INJECTION
 CEFUROXIME SODIUM
 RX HIKMA EQ 1.5GM BASE/VIAL A065048 002 Jan 09, 2004 RLD: N050558
 INJECTABLE;INTRAMUSCULAR, INTRAVENOUS
 CEFUROXIME SODIUM
 RX HIKMA EQ 750MG BASE/VIAL A065048 001 Jan 09, 2004 RLD: N050558

CHLOROQUINE PHOSPHATE

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

CHLOROTHIAZIDE SODIUM

INJECTABLE;INJECTION
 CHLOROTHIAZIDE SODIUM
 RX SAGENT PHARMS INC EQ 500MG BASE/VIAL A202462 001 May 29, 2015 RLD: N011145

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

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

March 2024

Page 7 of 24

CIPROFLOXACIN

INJECTABLE; INJECTION						
CIPROFLOXACIN						
RX	BAXTER HLTHCARE CORP	200MG/20ML (10MG/ML)	A078062	001	Apr 29, 2008	RLD: N019847
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

CITRIC ACID; MAGNESIUM OXIDE; SODIUM PICOSULFATE

FOR SOLUTION; ORAL						
SODIUM PICOSULFATE, MAGNESIUM OXIDE AND ANHYDROUS CITRIC ACID						
RX	HETERO LABS LTD V	12GM/PACKET; 3.5GM/PACKET; 10MG/PACKET	A212789	001	Jul 18, 2022	RLD: N202535

CLINDAMYCIN PHOSPHATE

AEROSOL, FOAM; TOPICAL						
CLINDAMYCIN PHOSPHATE						
RX	PADAGIS ISRAEL	1%	A090785	001	Mar 31, 2010	RLD: N050801
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

CLOBETASOL PROPIONATE

AEROSOL, FOAM; TOPICAL						
CLOBETASOL PROPIONATE						
RX	PADAGIS ISRAEL	0.05%	A201402	001	Aug 14, 2012	RLD: N022013
RX	TARO	0.05%	A208779	001	Oct 04, 2018	RLD: N021142
CREAM; TOPICAL						
CLOBETASOL PROPIONATE						
RX	ENCUBE	0.05%	A212982	001	Aug 28, 2020	RLD: N019322
OINTMENT; TOPICAL						
CLOBETASOL PROPIONATE						
RX	FOUGERA PHARMS	0.05%	A074407	001	Feb 23, 1996	RLD: N019323

CLONIDINE HYDROCHLORIDE

TABLET, EXTENDED RELEASE; ORAL						
CLONIDINE HYDROCHLORIDE						
RX	AJANTA PHARMA LTD	0.1MG	A209686	001	Nov 20, 2017	RLD: N022331

CUPRIC SULFATE

INJECTABLE; INJECTION						
CUPRIC SULFATE						
RX	AM REGENT	EQ 0.4MG COPPER/ML	A216324	001	Dec 16, 2022	RLD: N019350

CYCLOBENZAPRINE HYDROCHLORIDE

TABLET; ORAL						
CYCLOBENZAPRINE HYDROCHLORIDE						
RX	RUBICON	10MG	A208170	003	May 31, 2017	RLD: N017821

CYPROHEPTADINE HYDROCHLORIDE

TABLET; ORAL						
CYPROHEPTADINE HYDROCHLORIDE						
RX	ZYDUS PHARMS	4MG	A208938	001	May 19, 2017	RLD: N012649

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
RX	WEST-WARD PHARMS	2GM/VIAL	A074245	002	Aug 31, 1994	RLD: N016793
INT						

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

March 2024

Page 8 of 24

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

DACTINOMYCIN

INJECTABLE; INJECTION
 DACTINOMYCIN
 RX EUGIA PHARMA 0.5MG/VIAL A203385 001 Nov 09, 2017 RLD: N050682

DAPSONE

TABLET; ORAL
 DAPSONE
 RX NOVITIUM PHARMA 100MG A206505 002 Dec 01, 2016 RLD: A086842

DAPTOMYCIN

POWDER; INTRAVENOUS
 DAPTOMYCIN
 RX QILU PHARM HAINAN 500MG/VIAL A215316 001 Aug 24, 2021 RLD: N021572

DARIFENACIN HYDROBROMIDE

TABLET, EXTENDED RELEASE; ORAL
 DARIFENACIN
 RX MACLEODS PHARMS EQ 15MG BASE A207302 002 Jul 28, 2017 RLD: N021513
 LTD

DECITABINE

INJECTABLE; INTRAVENOUS
 DECITABINE
 RX ACCORD HLTHCARE 50MG/VIAL A203475 001 Feb 27, 2017 RLD: N021790

DEFERIPRONE

TABLET; ORAL
 DEFERIPRONE
 RX HIKMA 1GM A213239 002 Feb 08, 2022 RLD: N021825

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

DESONIDE

GEL; TOPICAL
 DESONIDE
 RX CINTEX SVCS 0.05% A202470 001 May 11, 2020 RLD: N021844

DEXAMETHASONE SODIUM PHOSPHATE

INJECTABLE; INJECTION
 DEXAMETHASONE SODIUM PHOSPHATE PRESERVATIVE FREE
 RX FRESENIUS KABI USA EQ 10MG PHOSPHATE/ML A040491 001 Apr 11, 2003 RLD: N014694

DIAZEPAM

INJECTABLE; INJECTION
 DIAZEPAM
 RX BELOTECA 10MG/2ML (5MG/ML) A210363 001 Mar 18, 2019 RLD: N016087

DICLOFENAC POTASSIUM

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

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

March 2024

Page 9 of 24

DICLOFENAC SODIUM

GEL;TOPICAL					
DICLOFENAC SODIUM					
RX	TARO	3%	A206298	001	Apr 28, 2016 RLD: N021005
SOLUTION;TOPICAL					
DICLOFENAC SODIUM					
RX	LUPIN PHARMS	2%	A208021	001	Sep 20, 2022 RLD: N204623
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

DIHYDROERGOTAMINE MESYLATE

INJECTABLE;INJECTION					
DIHYDROERGOTAMINE MESYLATE					
RX	HIKMA PHARMS	1MG/ML	A206621	001	Sep 15, 2017 RLD: N005929

DIMENHYDRINATE

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

DORZOLAMIDE HYDROCHLORIDE

SOLUTION/DROPS;OPHTHALMIC					
DORZOLAMIDE HYDROCHLORIDE					
RX	MICRO LABS	EQ 2% BASE	A204778	001	Nov 08, 2019 RLD: N020408

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

DOXYCYCLINE HYCLATE

INJECTABLE;INJECTION					
DOXYCYCLINE					
RX	ZYDUS PHARMS	EQ 100MG BASE/VIAL	A207757	001	Sep 28, 2017 RLD: N050442
TABLET, DELAYED RELEASE;ORAL					
DOXYCYCLINE HYCLATE					
RX	HERITAGE PHARMS	EQ 200MG BASE	A200856	004	Nov 13, 2018 RLD: N050795

DROPERIDOL

INJECTABLE;INJECTION					
DROPERIDOL					
RX	AM REGENT	2.5MG/ML	A072123	001	Oct 24, 1988 RLD: N016796

DYCLONINE HYDROCHLORIDE

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

EDETATE CALCIUM DISODIUM

INJECTABLE;INJECTION					
EDETATE CALCIUM DISODIUM					
RX	CASPER PHARMA LLC	200MG/ML	A216435	001	May 03, 2023 RLD: N008922

EFAVIRENZ

CAPSULE;ORAL					
EFAVIRENZ					
RX	AUROBINDO PHARMA	200MG	A078064	003	Dec 15, 2017 RLD: N020972

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

March 2024

Page 10 of 24

TABLET; ORAL					
EFAVIRENZ					
RX	HETERO LABS LTD	600MG	A078886	001	Apr 27, 2018 RLD: N021360
III					
<u>EPOPROSTENOL SODIUM</u>					
INJECTABLE; INJECTION					
EPOPROSTENOL SODIUM					
RX	SUN PHARM	EQ 0.5MG BASE/VIAL	A210473	001	Jan 15, 2021 RLD: N022260
<u>EPTIFIBATIDE</u>					
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
<u>ERGOCALCIFEROL</u>					
CAPSULE; ORAL					
ERGOCALCIFEROL					
RX	STRIDES PHARMA	50,000 IU	A090455	001	Aug 03, 2010 RLD: N003444
<u>ERLOTINIB HYDROCHLORIDE</u>					
TABLET; ORAL					
ERLOTINIB HYDROCHLORIDE					
RX	ZYDUS PHARMS	EQ 150MG BASE	A213065	003	Apr 16, 2020 RLD: N021743
<u>ESOMEPRAZOLE MAGNESIUM; NAPROXEN</u>					
TABLET, DELAYED RELEASE; ORAL					
NAPROXEN AND ESOMEPRAZOLE MAGNESIUM					
RX	DR REDDYS	EQ 20MG BASE; 500MG	A204206	002	Feb 18, 2020 RLD: N022511
<u>ESTRADIOL</u>					
TABLET; ORAL					
ESTRADIOL					
RX	BARR LABS INC	2MG	A040197	003	Oct 22, 1997 RLD: A084500
<u>ETHINYL ESTRADIOL; NORETHINDRONE</u>					
TABLET; ORAL-28					
BALZIVA-28					
RX	BARR	0.035MG; 0.4MG	A076238	001	Apr 22, 2004 RLD: N017716
<u>ETHINYL ESTRADIOL; NORETHINDRONE ACETATE</u>					
TABLET; ORAL					
HAILEY 24 FE					
RX	GLENMARK PHARMS LTD	0.02MG; 1MG	A204847	001	Nov 17, 2017 RLD: N021871
NORETHINDRONE ACETATE AND ETHINYL ESTRADIOL AND FERROUS FUMARATE					
RX	GLENMARK PHARMS LTD	0.02MG; 1MG	A210369	001	Dec 26, 2017 RLD: N203667
TABLET; ORAL-28					
CHABELINA FE					
RX	NOVAST LABS	0.02MG, 0.03MG, 0.035MG; 1MG, 1MG, 1MG	A202962	001	Apr 15, 2020 RLD: N020130
<u>ETHINYL ESTRADIOL; NORGESTIMATE</u>					
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
<u>FAMCICLOVIR</u>					
TABLET; ORAL					
FAMCICLOVIR					
RX	TEVA PHARMS	500MG	A077487	003	Aug 24, 2007 RLD: N020363

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

March 2024

Page 11 of 24

FAMOTIDINE

	FOR SUSPENSION;ORAL						
	FAMOTIDINE						
RX	NOVITIUM PHARMA	40MG/5ML	A215043	001	Apr 20, 2021	RLD: N019527	
	TABLET;ORAL						
	FAMOTIDINE						
RX	AUROBINDO PHARMA LTD	40MG	A206530	002	Dec 22, 2015	RLD: N019462	

FAMOTIDINE; IBUPROFEN

	TABLET;ORAL						
	IBUPROFEN AND FAMOTIDINE						
RX	ALKEM LABS LTD	26.6MG;800MG	A211890	001	Aug 03, 2021	RLD: N022519	

FENOFIBRATE

	CAPSULE;ORAL						
	FENOFIBRATE (MICRONIZED)						
RX	AJANTA PHARMA LTD	200MG	A210705	003	Sep 10, 2018	RLD: N019304	
	TABLET;ORAL						
	FENOFIBRATE						
RX	AUROBINDO PHARMA	145MG	A205118	002	May 05, 2016	RLD: N021656	

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	

FLUNISOLIDE

	SPRAY, METERED;NASAL						
	FLUNISOLIDE						
RX	BAUSCH	0.025MG/SPRAY	A074805	001	Feb 20, 2002	RLD: N018148	

FLUOCINONIDE

	CREAM;TOPICAL						
	FLUOCINONIDE						
RX	AMNEAL	0.05%	A210554	001	Aug 21, 2018	RLD: N019117	

FLUOROURACIL

	SOLUTION;TOPICAL						
	FLUOROURACIL						
RX	TARO	5%	A076526	002	Nov 05, 2003	RLD: N016831	

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	

FLURANDRENOLIDE

	LOTION;TOPICAL						
	FLURANDRENOLIDE						
RX	PADAGIS ISRAEL	0.05%	A207133	001	Aug 30, 2016	RLD: N013790	
	OINTMENT;TOPICAL						
	FLURANDRENOLIDE						
RX	TELIGENT	0.05%	A207851	001	Dec 30, 2016	RLD: N012806	

FLURBIPROFEN

	TABLET;ORAL						
	FLURBIPROFEN						
RX	TEVA	100MG	A074431	001	May 31, 1995	RLD: N018766	

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

March 2024

Page 12 of 24

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	

FOSAMPRENAVIR CALCIUM

TABLET;ORAL		FOSAMPRENAVIR CALCIUM					
RX	MYLAN	EQ 700MG BASE	A204060	001	Apr 15, 2016	RLD: N021548	

GALANTAMINE HYDROBROMIDE

CAPSULE, EXTENDED RELEASE;ORAL		GALANTAMINE HYDROBROMIDE					
RX	AUROBINDO PHARMA	EQ 8MG BASE	A204895	001	Aug 05, 2016	RLD: N021615	

GANCICLOVIR SODIUM

INJECTABLE;INJECTION		GANCICLOVIR SODIUM					
RX	PHARMASCIENCE INC	EQ 500MG BASE/VIAL	A207645	001	Dec 08, 2017	RLD: N019661	

GLUCAGON

INJECTABLE;INJECTION		GLUCAGON					
RX	AMPHASTAR PHARMS INC	1MG/VIAL	A208086	001	Dec 28, 2020	RLD: N020928	

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	

GRANISETRON HYDROCHLORIDE

TABLET;ORAL		GRANISETRON HYDROCHLORIDE					
RX	ORBION PHARMS	EQ 1MG BASE	A078678	001	Feb 13, 2008	RLD: N020305	

HOMATROPINE METHYLBROMIDE; HYDROCODONE BITARTRATE

SYRUP;ORAL		HYDROCODONE BITARTRATE AND HOMATROPINE METHYLBROMIDE					
RX	ABHAI LLC	1.5MG/5ML;5MG/5ML	A207487	001	Feb 21, 2017	RLD: N005213	

TABLET;ORAL		HOMATROPINE METHYLBROMIDE AND HYDROCODONE BITARTRATE					
RX	AVANTHI INC	1.5MG;5MG	A207176	001	Aug 07, 2017	RLD: N005213	

HYDRALAZINE HYDROCHLORIDE; HYDROCHLOROTHIAZIDE

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

HYDROCHLOROTHIAZIDE; LISINAPRIL

TABLET;ORAL		LISINAPRIL AND HYDROCHLOROTHIAZIDE					
RX	INVAGEN PHARMS	12.5MG;20MG	A204058	002	May 23, 2017	RLD: N019888	
RX		25MG;20MG	A204058	003	May 23, 2017	RLD: N019888	

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

March 2024

Page 13 of 24

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

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

IMIQUIMOD

CREAM;TOPICAL
 IMIQUIMOD
 RX GLENMARK PHARMS INC 5% A201994 001 Mar 06, 2012 RLD: N020723

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

ISOPROTERENOL HYDROCHLORIDE

INJECTABLE;INJECTION
 ISOPROTERENOL HYDROCHLORIDE
 RX NEXUS 0.2MG/ML A206961 001 Aug 02, 2017 RLD: N010515

ISOSORBIDE MONONITRATE

TABLET, EXTENDED RELEASE;ORAL
 ISOSORBIDE MONONITRATE
 RX RICONPHARMA LLC 120MG A210918 003 Nov 05, 2018 RLD: N020225

ISOSULFAN BLUE

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

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

March 2024

Page 14 of 24

ISRADIPINE

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

KETOCONAZOLE

AEROSOL, FOAM; TOPICAL
 KETOCONAZOLE
 RX XIROMED 2% A213601 001 May 21, 2021 RLD: N021738

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

LAMIVUDINE; ZIDOVUDINE

TABLET; ORAL
 LAMIVUDINE AND ZIDOVUDINE
 RX HETERO LABS LTD 150MG; 300MG A079124 001 Sep 17, 2015 RLD: N020857
 III

LEUCOVORIN CALCIUM

INJECTABLE; INJECTION
 LEUCOVORIN CALCIUM
 RX FRESENIUS KABI USA EQ 10MG BASE/ML A207226 001 Jul 27, 2018 RLD: N008107
 RX EQ 10MG BASE/ML A207241 001 Mar 14, 2018 RLD: N008107

LEVOCETIRIZINE DIHYDROCHLORIDE

TABLET; ORAL
 LEVOCETIRIZINE DIHYDROCHLORIDE
 RX GLENMARK PHARMS LTD 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 NOVITIUM PHARMA 250MG/10ML A091678 001 Jun 20, 2011 RLD: N021721

LEVOLEUCOVORIN CALCIUM

SOLUTION; INTRAVENOUS
 LEVOLEUCOVORIN CALCIUM
 RX GLAND PHARMA LTD EQ 250MG BASE/25ML (EQ 10MG BASE/ML) A210892 002 Sep 14, 2018 RLD: N020140
 RX MEITHEAL EQ 175MG BASE/17.5ML (EQ 10MG BASE/ML) A211002 001 Aug 16, 2019 RLD: N020140

LEVORPHANOL TARTRATE

TABLET; ORAL
 LEVORPHANOL TARTRATE
 RX NOVITIUM PHARMA 3MG A213479 002 Jan 12, 2021 RLD: N008720

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

March 2024

Page 15 of 24

LIDOCAINE HYDROCHLORIDE

SOLUTION; ORAL
 LIDOCAINE HYDROCHLORIDE
 RX RUBICON 2% A216780 001 Mar 28, 2023 RLD: N009470
 SOLUTION; TOPICAL
 LIDOCAINE HYDROCHLORIDE
 RX HIKMA 4% A088803 001 Apr 03, 1985 RLD: N010417

LIDOCAINE; PRILOCAINE

CREAM; TOPICAL
 LIDOCAINE AND PRILOCAINE
 RX FOUGERA PHARMS 2.5%; 2.5% A076453 001 Aug 18, 2003 RLD: N019941

LITHIUM CITRATE

SYRUP; ORAL
 LITHIUM CITRATE
 RX RUBICON EQ 300MG CARBONATE/5ML A218036 001 Aug 14, 2023 RLD: N018421

LOPERAMIDE HYDROCHLORIDE

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

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
 TABLET; ORAL
 MEPERIDINE HYDROCHLORIDE
 RX EPIC PHARMA LLC 50MG A040331 001 May 28, 1999 RLD: N005010

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

MESALAMINE

TABLET, DELAYED RELEASE; ORAL
 MESALAMINE
 RX ZYDUS PHARMS 800MG A203286 001 Jul 21, 2017 RLD: N021830

METAXALONE

TABLET; ORAL
 METAXALONE
 RX AMNEAL PHARMS 800MG A203399 001 Jun 21, 2013 RLD: N013217

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

March 2024

Page 16 of 24

METFORMIN HYDROCHLORIDE

SOLUTION;ORAL				
METFORMIN HYDROCHLORIDE				
RX	SAPTALIS PHARMS	500MG/5ML	A211309 001	Mar 03, 2020 RLD: N021591
TABLET, EXTENDED RELEASE;ORAL				
METFORMIN HYDROCHLORIDE				
RX	ALKEM LABS LTD	750MG	A206145 002	Oct 22, 2018 RLD: N021202

METFORMIN HYDROCHLORIDE; SAXAGLIPTIN HYDROCHLORIDE

TABLET, EXTENDED RELEASE;ORAL				
METFORMIN HYDROCHLORIDE; SAXAGLIPTIN HYDROCHLORIDE				
RX	DR REDDYS LABS SA	1GM;EQ 5MG BASE	A207678 003	Aug 09, 2023 RLD: N200678

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 LTD	1GM	A205661 001	Jul 05, 2016 RLD: N017681

METHOCARBAMOL

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

METHOTREXATE SODIUM

INJECTABLE;INJECTION				
METHOTREXATE SODIUM PRESERVATIVE FREE				
RX	ACCORD HLTHCARE	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	CHARTWELL RX	0.2MG	A091577 001	May 02, 2011 RLD: N006035

METHYLPHENIDATE HYDROCHLORIDE

CAPSULE, EXTENDED RELEASE;ORAL				
METHYLPHENIDATE HYDROCHLORIDE				
RX	DR REDDYS LABS SA	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 PHARM US	72MG	A205327 005	Jul 28, 2017 RLD: N021121

METHYLPREDNISOLONE ACETATE

INJECTABLE;INJECTION				
METHYLPREDNISOLONE ACETATE				
RX	AMNEAL	40MG/ML	A210043 001	May 20, 2019 RLD: N011757
RX		80MG/ML	A210043 002	May 20, 2019 RLD: N011757
RX	SAGENT PHARMS INC	40MG/ML	A201835 002	Jun 27, 2018 RLD: N011757
RX		80MG/ML	A201835 003	Jun 27, 2018 RLD: N011757

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

March 2024

Page 17 of 24

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

METRONIDAZOLE

TABLET; ORAL
METRONIDAZOLE
RX AUROBINDO PHARMA LTD 500MG A203974 002 May 29, 2015 RLD: N012623

MOMETASONE FUROATE

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

MORPHINE SULFATE

CAPSULE, EXTENDED RELEASE; ORAL
MORPHINE SULFATE
RX UPSHER SMITH LABS 10MG A202104 001 Jun 03, 2013 RLD: N020616
RX 100MG A202104 007 Jun 03, 2013 RLD: N020616

MOXIFLOXACIN HYDROCHLORIDE

SOLUTION/DROPS; OPHTHALMIC
MOXIFLOXACIN HYDROCHLORIDE
RX LUPIN LTD EQ 0.5% BASE A204079 001 May 28, 2015 RLD: N022428
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 1% A205975 001 Sep 08, 2016 RLD: N019599

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

NARATRIPTAN HYDROCHLORIDE

TABLET; ORAL
NARATRIPTAN
RX HERITAGE PHARMS EQ 2.5MG BASE A200502 002 Feb 28, 2011 RLD: N020763

NATEGLINIDE

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

NEVIRAPINE

TABLET; ORAL
NEVIRAPINE
RX MACLEODS PHARMS LTD 200MG A090688 001 Jan 14, 2019 RLD: N020636

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

March 2024

Page 18 of 24

NIACIN

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

NICARDIPINE HYDROCHLORIDE

CAPSULE;ORAL
 NICARDIPINE HYDROCHLORIDE
 RX EPIC PHARMA LLC 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

NORTRIPTYLINE HYDROCHLORIDE

SOLUTION;ORAL
 NORTRIPTYLINE HYDROCHLORIDE
 RX PHARM ASSOC EQ 10MG BASE/5ML A075606 001 Aug 23, 2000 RLD: N014685

OFLOXACIN

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

OLOPATADINE HYDROCHLORIDE

SPRAY, METERED;NASAL
 OLOPATADINE HYDROCHLORIDE
 RX AMNEAL 0.665MG/SPRAY A210901 001 Jan 28, 2020 RLD: N021861

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

OMEPRAZOLE; SODIUM BICARBONATE

CAPSULE;ORAL
 OMEPRAZOLE AND SODIUM BICARBONATE
 RX AJANTA PHARMA LTD 40MG;1.1GM A204228 002 Jul 15, 2016 RLD: N021849
 FOR SUSPENSION;ORAL
 OMEPRAZOLE AND SODIUM BICARBONATE
 RX AJANTA PHARMA LTD 40MG/PACKET;1.68GM/PACKET A205545 002 Jul 27, 2016 RLD: N021636

ONDANSETRON

TABLET, ORALLY DISINTEGRATING;ORAL
 ONDANSETRON
 RX CHARTWELL 16MG A077406 001 Dec 26, 2006 RLD: N020781
 MOLECULES
 RX 24MG A077406 002 Dec 26, 2006 RLD: N020781

ONDANSETRON HYDROCHLORIDE

SOLUTION;ORAL
 ONDANSETRON HYDROCHLORIDE
 RX HIKMA EQ 4MG BASE/5ML A076960 001 Dec 26, 2006 RLD: N020605

OXALIPLATIN

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

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

March 2024

Page 19 of 24

OXYBUTYNIN CHLORIDE

TABLET, EXTENDED RELEASE;ORAL		OXYBUTYNIN CHLORIDE					
RX	ACCORD HLTHCARE	15MG		A207138	003	Feb 29, 2016	RLD: N020897
TABLET;ORAL		OXYBUTYNIN CHLORIDE					
RX	RISING	2.5MG		A209025	002	Feb 07, 2023	RLD: N017577

PALONOSETRON HYDROCHLORIDE

INJECTABLE;INTRAVENOUS		PALONOSETRON HYDROCHLORIDE					
RX	AVET LIFESCIENCES	EQ 0.075MG BASE/1.5ML (EQ 0.05MG BASE/ML)		A202951	001	Jun 29, 2021	RLD: N021372
RX	DR REDDYS	EQ 0.25MG BASE/5ML (EQ 0.05MG BASE/ML)		A201533	002	Apr 21, 2016	RLD: N021372

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

PEMETREXED DISODIUM

POWDER;INTRAVENOUS		PEMETREXED DISODIUM					
RX	FRESENIUS KABI USA	EQ 750MG BASE/VIAL		A090384	003	May 25, 2022	RLD: N021462
RX		EQ 1GM BASE/VIAL		A090384	004	May 25, 2022	RLD: N021462

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

CAPSULE;ORAL		PHENTERMINE HYDROCHLORIDE					
RX	NUVO PHARM	37.5MG		A205017	001	Sep 25, 2014	RLD: A088023
TABLET;ORAL		LOMAIRA					
RX	AVANTHI INC	8MG		A203495	001	Sep 12, 2016	RLD: N012737

PHENYLEPHRINE HYDROCHLORIDE

SOLUTION/DROPS;OPHTHALMIC		PHENYLEPHRINE HYDROCHLORIDE					
RX	MANKIND PHARMA	2.5%		A216859	001	Sep 29, 2022	RLD: N207926
RX		10%		A216496	001	Jan 11, 2023	RLD: N207926

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

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

March 2024

Page 20 of 24

PHYTONADIONE

INJECTABLE; INJECTION							
PHYTONADIONE							
RX	CIPLA	1MG/0.5ML	A214596	001	Apr 22, 2022	RLD: N012223	
RX		10MG/ML	A214596	002	Apr 22, 2022	RLD: N012223	
TABLET; ORAL							
PHYTONADIONE							
RX	ZYDUS	5MG	A210189	001	Feb 20, 2019	RLD: N010104	

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	
POTASSIUM CHLORIDE							
RX	TWI PHARMS	20MEQ	A209688	002	Jan 12, 2018	RLD: N018279	

PREDNISOLONE SODIUM PHOSPHATE

SOLUTION/DROPS; OPHTHALMIC							
PREDNISOLONE SODIUM PHOSPHATE							
RX	BAUSCH AND LOMB	EQ 0.9% PHOSPHATE	A040070	001	Jul 29, 1994	RLD: A080751	
SOLUTION; ORAL							
PREDNISOLONE SODIUM PHOSPHATE							
RX	PHARM ASSOC	EQ 15MG BASE/5ML	A076913	001	Apr 25, 2005	RLD: N019157	

PRILOCAINE HYDROCHLORIDE

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

PROGESTERONE

INJECTABLE; INJECTION							
PROGESTERONE							
RX	EUGIA PHARMA	50MG/ML	A210965	001	Dec 06, 2018	RLD: N017362	

PROPAFENONE HYDROCHLORIDE

CAPSULE, EXTENDED RELEASE; ORAL							
PROPAFENONE HYDROCHLORIDE							
RX	STRIDES PHARMA	425MG	A078540	003	Oct 18, 2010	RLD: N021416	

PROPARACAINE HYDROCHLORIDE

SOLUTION/DROPS; OPHTHALMIC							
PROPARACAINE HYDROCHLORIDE							
RX	BAUSCH AND LOMB	0.5%	A040074	001	Sep 29, 1995	RLD: N008883	

PYRAZINAMIDE

TABLET; ORAL							
PYRAZINAMIDE							
RX	HIKMA	500MG	A081319	001	Jun 30, 1992	RLD: A080157	

QUINAPRIL HYDROCHLORIDE

TABLET; ORAL							
QUINAPRIL HYDROCHLORIDE							
RX	LUPIN	EQ 40MG BASE	A077690	004	Jun 20, 2006	RLD: N019885	

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

March 2024

Page 21 of 24

RANOLAZINE

TABLET, EXTENDED RELEASE;ORAL
RANOLAZINE
RX SUN PHARM 1GM A211707 002 May 28, 2019 RLD: N021526

SAXAGLIPTIN HYDROCHLORIDE

TABLET;ORAL
SAXAGLIPTIN
RX MYLAN EQ 5MG BASE A205980 002 Jul 31, 2023 RLD: N022350

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 CHLORIDE

SOLUTION;INJECTION
SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER
RX TARO 45MG/5ML (9MG/ML) A077407 001 Aug 11, 2006 RLD: N019217
RX 90MG/10ML (9MG/ML) A077407 002 Aug 11, 2006 RLD: N019217

SODIUM PHOSPHATE, DIBASIC, HEPTAHYDRATE; SODIUM PHOSPHATE, MONOBASIC, ANHYDROUS

INJECTABLE;INJECTION
SODIUM PHOSPHATES
RX FRESENIUS KABI USA 142MG/ML;276MG/ML A209997 001 Mar 30, 2022 RLD: N018892

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 LLC 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

TAVABOROLE

SOLUTION;TOPICAL
TAVABOROLE
RX ENCUBE 5% A211297 001 Oct 13, 2020 RLD: N204427

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

March 2024

Page 22 of 24

TEMOZOLOMIDE

CAPSULE; ORAL
 TEMOZOLOMIDE
 RX ACCORD HLTHCARE 250MG A201528 006 Feb 27, 2017 RLD: N021029

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 10MG/0.5GM ACTUATION A204571 001 Aug 05, 2015 RLD: N021463
 INC

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

TETRACYCLINE HYDROCHLORIDE

CAPSULE; ORAL
 TETRACYCLINE HYDROCHLORIDE
 RX AMNEAL PHARMS NY 500MG A210674 002 Sep 18, 2018 RLD: N050278

THEOPHYLLINE

SOLUTION; ORAL
 THEOPHYLLINE
 RX CHARTWELL 80MG/15ML A091156 001 Apr 13, 2011 RLD: A087449
 MOLECULAR

TABLET, EXTENDED RELEASE; ORAL
 THEOPHYLLINE
 RX ALEMBIC 450MG A090430 002 Oct 27, 2010 RLD: A085328

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 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 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 CHARTWELL RX 0.004% A091340 001 Mar 01, 2013 RLD: N021257

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

March 2024

Page 23 of 24

TRIAMCINOLONE ACETONIDE

OINTMENT; TOPICAL
 TRIAMCINOLONE ACETONIDE
 RX ENCUBE 0.05% A212384 001 Nov 29, 2019 RLD: N011600
 SPRAY; TOPICAL
 TRIAMCINOLONE ACETONIDE
 RX PADAGIS ISRAEL 0.147MG/GM A205782 001 Apr 13, 2015 RLD: N012104

TRIMIPRAMINE MALEATE

CAPSULE; ORAL
 TRIMIPRAMINE MALEATE
 RX BRECKENRIDGE 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

VALSARTAN

SOLUTION; ORAL
 VALSARTAN
 RX NOVITIUM PHARMA 20MG/5ML A214102 001 Nov 02, 2021 RLD: N209139

VARDENAFIL HYDROCHLORIDE

TABLET, ORALLY DISINTEGRATING; ORAL
 VARDENAFIL HYDROCHLORIDE
 RX ALEMBIC 10MG A208324 001 Nov 16, 2018 RLD: N200179
 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 PHARMS 180MG A090700 002 Aug 03, 2011 RLD: N019152
 LTD
 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

ZILEUTON

TABLET, EXTENDED RELEASE; ORAL
 ZILEUTON
 RX RISING 600MG A204929 001 Mar 17, 2017 RLD: N022052

ZOLEDRONIC ACID

INJECTABLE; INTRAVENOUS
 ZOLEDRONIC
 RX GLAND PHARMA LTD EQ 4MG BASE/100ML A205749 001 Jun 29, 2018 RLD: N021223

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

March 2024

Page 24 of 24

ZOLMITRIPTAN

	SPRAY;NASAL								
	ZOLMITRIPTAN								
RX	PADAGIS ISRAEL	5MG/SPRAY	A212469	002	Sep 30, 2021	RLD: N021450			
	TABLET, ORALLY DISINTEGRATING;ORAL								
	ZOLMITRIPTAN								
RX	ZYDUS PHARMS USA	5MG	A202890	002	May 15, 2013	RLD: N021231			
	INC								
	TABLET;ORAL								
	ZOLMITRIPTAN								
RX	AJANTA PHARMA LTD	5MG	A204041	002	May 20, 2016	RLD: N020768			