



APPROVED DRUG PRODUCTS

WITH

THERAPEUTIC
EQUIVALENCE
EVALUATIONS

38th EDITION

THE PRODUCTS IN THIS LIST HAVE BEEN APPROVED UNDER
SECTION 505 OF THE FEDERAL FOOD, DRUG, AND COSMETIC ACT.

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION
OFFICE OF MEDICAL PRODUCTS AND TOBACCO
CENTER FOR DRUG EVALUATION AND RESEARCH
OFFICE OF GENERIC DRUGS
OFFICE OF GENERIC DRUG POLICY

2018

APPROVED DRUG PRODUCTS with THERAPEUTIC EQUIVALENCE EVALUATIONS

The products in this list have been approved under section 505 of the Federal Food, Drug, and Cosmetic Act. This volume is current through December 31, 2017.

38th EDITION



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**FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH**

**APPROVED DRUG PRODUCTS
With
Therapeutic Equivalence Evaluations**

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PRESCRIPTION DRUG PRODUCT LIST

MORPHINE SULFATE

TABLET, EXTENDED RELEASE;ORAL

MORPHINE SULFATE

<u>AB</u>		<u>100MG</u>	<u>A077855 001</u>	Sep 27, 2007
<u>AB</u>		<u>200MG</u>	<u>A077855 002</u>	Sep 27, 2007
<u>AB</u>	NOVEL LABS INC	<u>15MG</u>	<u>A203602 001</u>	Dec 16, 2015
<u>AB</u>		<u>30MG</u>	<u>A203602 002</u>	Dec 16, 2015
<u>AB</u>		<u>60MG</u>	<u>A203602 003</u>	Dec 16, 2015
<u>AB</u>		<u>100MG</u>	<u>A203602 004</u>	Dec 16, 2015
<u>AB</u>		<u>200MG</u>	<u>A203602 005</u>	Dec 16, 2015
<u>AB</u>	RHODES PHARMS	<u>15MG</u>	<u>A074862 001</u>	Jul 07, 1998
<u>AB</u>		<u>30MG</u>	<u>A074862 002</u>	Jul 07, 1998
<u>AB</u>		<u>60MG</u>	<u>A074862 003</u>	Jul 07, 1998
<u>AB</u>		<u>100MG</u>	<u>A074769 001</u>	Jul 02, 1998
<u>AB</u>		<u>200MG</u>	<u>A074769 002</u>	Jul 02, 1998
<u>AB</u>	SPECGX LLC	<u>15MG</u>	<u>A076412 001</u>	Jul 31, 2003
<u>AB</u>		<u>30MG</u>	<u>A076412 002</u>	Jul 31, 2003
<u>AB</u>		<u>60MG</u>	<u>A076412 003</u>	Jul 31, 2003
<u>AB</u>		<u>100MG</u>	<u>A076438 001</u>	Jul 03, 2003
<u>AB</u>		<u>200MG</u>	<u>A076438 002</u>	Jul 03, 2003
<u>AB</u>	SUN PHARM INDS LTD	<u>15MG</u>	<u>A078761 001</u>	May 11, 2012
<u>AB</u>		<u>30MG</u>	<u>A078761 002</u>	May 11, 2012
<u>AB</u>		<u>60MG</u>	<u>A078761 003</u>	May 11, 2012
<u>AB</u>		<u>100MG</u>	<u>A078761 004</u>	May 11, 2012
<u>AB</u>		<u>200MG</u>	<u>A078761 005</u>	May 11, 2012
<u>AB</u>	SUN PHARM INDUSTRIES	<u>15MG</u>	<u>A205634 001</u>	Aug 25, 2016
<u>AB</u>		<u>30MG</u>	<u>A205634 002</u>	Aug 25, 2016
<u>AB</u>		<u>60MG</u>	<u>A205634 003</u>	Aug 25, 2016
<u>AB</u>		<u>100MG</u>	<u>A205634 004</u>	Aug 25, 2016
<u>AB</u>		<u>200MG</u>	<u>A205634 005</u>	Aug 25, 2016
<u>AB</u>	VINTAGE PHARMS LLC	<u>15MG</u>	<u>A075295 001</u>	Oct 28, 1998
<u>AB</u>		<u>30MG</u>	<u>A075295 002</u>	Oct 28, 1998
<u>AB</u>		<u>60MG</u>	<u>A075295 003</u>	Oct 28, 1998
<u>AB</u>		<u>100MG</u>	<u>A075295 004</u>	Sep 15, 2000
<u>AB</u>		<u>200MG</u>	<u>A075295 005</u>	Sep 15, 2000

MS CONTIN

<u>AB</u>	+	PURDUE PHARMA LP	<u>15MG</u>	<u>N019516 003</u>	Sep 12, 1989
<u>AB</u>	+		<u>30MG</u>	<u>N019516 001</u>	May 29, 1987
<u>AB</u>	+		<u>60MG</u>	<u>N019516 002</u>	Apr 08, 1988
<u>AB</u>	+		<u>100MG</u>	<u>N019516 004</u>	Jan 16, 1990
<u>AB</u>	+		<u>200MG</u>	<u>N019516 005</u>	Nov 08, 1993
		ARYMO ER			
	+	EGALET	15MG	N208603 001	Jan 09, 2017
	+		30MG	N208603 002	Jan 09, 2017
	+		60MG	N208603 003	Jan 09, 2017
		MORPHABOND ER			
	+	DAIICHI SANKYO INC	15MG	N206544 001	Oct 02, 2015
	+		30MG	N206544 002	Oct 02, 2015
	+		60MG	N206544 003	Oct 02, 2015
	+		100MG	N206544 004	Oct 02, 2015

MORPHINE SULFATE; NALTREXONE HYDROCHLORIDE

CAPSULE, EXTENDED RELEASE;ORAL

EMBEDA

+	ALPHARMA PHARMS	20MG; 0.8MG	N022321 001	Aug 13, 2009
+		30MG; 1.2MG	N022321 002	Aug 13, 2009
+		50MG; 2MG	N022321 003	Aug 13, 2009
+		60MG; 2.4MG	N022321 004	Aug 13, 2009
+		80MG; 3.2MG	N022321 005	Aug 13, 2009
+		100MG; 4MG	N022321 006	Aug 13, 2009

MOXIFLOXACIN HYDROCHLORIDE

SOLUTION; IV (INFUSION)

MOXIFLOXACIN HYDROCHLORIDE

+	FRESENIUS KABI USA	EQ 400MG BASE/250ML (EQ 1.6MG BASE/ML)	N205572 001	Apr 03, 2015
!	MYLAN LABS LTD	MOXIFLOXACIN HYDROCHLORIDE IN SODIUM CHLORIDE 0.8% IN PLASTIC CONTAINER	A205833 001	May 05, 2017

SOLUTION/DROPS; OPHTHALMIC

MOXIFLOXACIN HYDROCHLORIDE

<u>AT1</u>	AKORN	<u>EQ 0.5% BASE</u>	<u>A202916 001</u>	Nov 09, 2017
<u>AT1</u>	APOTEX INC	<u>EQ 0.5% BASE</u>	<u>A090080 001</u>	Jun 30, 2017