Drugs@FDA
FDA Approved Drug Products

Drug Details

Drug Name(s)	**HYDROMORPHONE HYDROCHLORIDE**
FDA Application No.	**(ANDA) 205629**
Active Ingredient(s)	**HYDROMORPHONE HYDROCHLORIDE**
Company	**OSMOTICA**
Original Approval or Tentative Approval Date	**July 7, 2016**

- **Therapeutic Equivalents**
- **Approval History, Letters, Reviews, and Related Documents**
- **Labels are not available**

Products on Application (ANDA) #205629
Click on a column header to re-sort the table:

Drug Name	Active Ingredients	Strength	Dosage Form/Route	Marketing Status	RLD	TE Code
HYDROMORPHONE HYDROCHLORIDE	HYDROMORPHONE HYDROCHLORIDE	8MG	TABLET, EXTENDED RELEASE;ORAL	Prescription	No	AB
HYDROMORPHONE HYDROCHLORIDE	HYDROMORPHONE HYDROCHLORIDE	12MG	TABLET, EXTENDED RELEASE;ORAL	Prescription	No	AB
HYDROMORPHONE HYDROCHLORIDE	HYDROMORPHONE HYDROCHLORIDE	16MG	TABLET, EXTENDED RELEASE;ORAL	Prescription	No	AB
HYDROMORPHONE HYDROCHLORIDE	HYDROMORPHONE HYDROCHLORIDE	32MG	TABLET, EXTENDED RELEASE;ORAL	Prescription	No	AB

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