Drug Details

Drug Name(s)	**DEXMEDETOMIDINE HYDROCHLORIDE**
FDA Application No.	**(NDA) 206628**
Active Ingredient(s)	**DEXMEDETOMIDINE HYDROCHLORIDE**
Company	**HQ SPCLT PHARMA**
Original Approval or Tentative Approval Date	**October 21, 2015**
Chemical Type	**5 New formulation or new manufacturer**
Review Classification	**S Standard review drug**

- **There are no Therapeutic Equivalents**
- **Approval History, Letters, Reviews, and Related Documents**
- **Label Information**

Products on Application (NDA) #206628
Click on a column header to re-sort the table:

Drug Name	Active Ingredients	Strength	Dosage Form/Route	Marketing Status	RLD	TE Code
DEXMEDETOMIDINE HYDROCHLORIDE	DEXMEDETOMIDINE HYDROCHLORIDE	EQ 400MCG BASE/4ML (EQ 100MCG BASE/ML)	SOLUTION;IV (INFUSION)	Prescription	No	None
DEXMEDETOMIDINE HYDROCHLORIDE	DEXMEDETOMIDINE HYDROCHLORIDE	EQ 1MG BASE/10ML (EQ 100MCG BASE/ML)	SOLUTION;IV (INFUSION)	Prescription	Yes	None

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