Drugs@FDA
FDA Approved Drug Products



## Drug Details

| | |
|---|---|
| **Drug Name(s)** | **GEMCITABINE HYDROCHLORIDE** |
| **FDA Application No.** | **(ANDA) 204549** |
| **Active Ingredient(s)** | **GEMCITABINE HYDROCHLORIDE** |
| **Company** | **ACTAVIS INC** |
| **Original Approval or Tentative Approval Date** | **April 11, 2016** |

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

**Products on Application (ANDA) #204549**
**Click on a column header to re-sort the table:**

| Drug Name | Active Ingredients | Strength | Dosage Form/Route | Marketing Status | RLD | TE Code |
|---|---|---|---|---|---|---|
| GEMCITABINE HYDROCHLORIDE | GEMCITABINE HYDROCHLORIDE | 200MG/5.26ML (38MG/ML) | INJECTABLE;INJECTION | Prescription | No | AP |
| GEMCITABINE HYDROCHLORIDE | GEMCITABINE HYDROCHLORIDE | 1GM/26.3ML (38MG/ML) | INJECTABLE;INJECTION | Prescription | No | AP |
| GEMCITABINE HYDROCHLORIDE | GEMCITABINE HYDROCHLORIDE | 2GM/52.6ML (38MG/ML) | INJECTABLE;INJECTION | Prescription | No | AP |

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