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# Fentanyl Citrate Injection

» Fentanyl Citrate Injection is a sterile solution of Fentanyl Citrate in Water for Injection. It contains the equivalent of not less than 90.0 percent and not more than 110.0 percent of the labeled amount of fentanyl ($C_{22}H_{28}N_2O$), present as the citrate.

**Packaging and storage**—Preserve in single-dose containers, preferably of Type I glass, protected from light.

**USP Reference standards** ⟨11⟩—
USP Fentanyl Citrate RS

**Identification**—The retention time of the major peak in the chromatogram of the *Assay preparation* corresponds to that in the chromatogram of the *Standard preparation,* as obtained in the *Assay*.

**Bacterial Endotoxins Test** ⟨85⟩ —It contains not more than 50.0 USP Endotoxin Units per mg.

**pH** ⟨791⟩: between 4.0 and 7.5.

**Other requirements**—It meets the requirements under *Injections and Implanted Drug Products* ⟨1⟩.

***Change to read:***

**Assay**—

*Mobile phase*—Prepare a filtered and degassed mixture containing 4 volumes of ammonium acetate solution (1 in 100) and 6 volumes of a mixture of methanol, acetonitrile, and glacial acetic acid (400:200:0.6). Adjust this solution to a pH of 6.6 ± 0.1 by the dropwise addition of glacial acetic acid, and make adjustments if necessary (see *System Suitability* under *Chromatography* ⟨621⟩), to obtain a retention time of about 5 minutes for the fentanyl peak.

*Standard preparation*—Dissolve an accurately weighed quantity of USP Fentanyl Citrate RS in water, and quantitatively dilute with water to obtain a solution having a known concentration of about 80 µg per mL.

*Assay preparation*—If necessary, dilute the Injection with water so that each mL contains the equivalent of about 50 µg of fentanyl.

*Chromatographic system* (see *Chromatography* ⟨621⟩)—The liquid chromatograph is equipped with a 230-nm detector and a 4.6-mm × 25-cm column that contains packing L1. The flow rate is about 2 mL per minute. Chromatograph the *Standard preparation*, and record the peak response as directed for *Procedure:* the tailing factor for the fentanyl peak is not more than 2.0, and the relative standard deviation for replicate injections is not more than 2.0%.

*Procedure*—Separately inject equal volumes (about 25 µL) of the *Standard preparation* and the *Assay preparation* into the chromatograph, record the chromatograms, and measure the responses for the major peaks. Calculate the quantity, in µg, of fentanyl ($C_{22}H_{28}N_3O$) in each mL of the Injection taken by the formula:

$$(336.48/{}^{\blacktriangle}528.60{}^{\blacktriangle}_{\text{(ERR 1-Jan-2021)}})CD(r_U/r_S)$$

in which 336.48 and ${}^{\blacktriangle}528.60{}^{\blacktriangle}_{\text{(ERR 1-Jan-2021)}}$ are the molecular weights of fentanyl and fentanyl citrate, respectively; $C$ is the concentration, in µg per mL, of USP Fentanyl Citrate RS in the *Standard preparation; D* is the dilution factor used to obtain the *Assay preparation;* and $r_U$ and $r_S$ are the peak responses for the fentanyl peak obtained from the *Assay preparation* and the *Standard preparation*, respectively.



**Auxiliary Information** - Please check for your question in the FAQs before contacting USP.

| Topic/Question | Contact | Expert Committee |
|---|---|---|
| FENTANYL CITRATE INJECTION | Documentary Standards Support | SM22020 Small Molecules 2 |

**Chromatographic Database Information:** Chromatographic Database

**Most Recently Appeared In:**
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