IV Compatibility Product

Trissel's Drugs and Solutions Data
oxyCODONE hydrochloride

pH Range [99607]

pH of solution is not cited.

Formulation [99607]

Provided as a liquid injection containing oxycodone hydrochloride 10 mg/mL (equivalent to 9 mg of oxycodone base). Also present in the formulation are citric acid monohydrate, sodium citrate, sodium chloride, hydrochloric acid, and sodium hydroxide in water for injection.

Reconstitution [99607]

Oxycodone hydrochloride injection may be administered undiluted by subcutaneous injection. Oxycodone hydrochloride injection may also be diluted to 1 mg/mL with sodium chloride 0.9%, dextrose 5%, or sterile water for injection for intravenous injection or infusion and for subcutaneous infusion.

Dilutions prepared with sterile water for injection require consideration of the osmolality of the dilution and the potential for adverse clinical effects including death from excessively large volumes.

Storage [99607]

Intact ampules of oxycodone hydrochloride should be stored at controlled room temperature for long-term storage.

Maximum Stability [96484]

Maximum reported stability periods:
In D5W- 35 days at room temperature and refrigerated

In NS- 35 days at room temperature and refrigerated

Stability (Detailed) [67353] [71005] [96484] [99607]

Oxycodone hydrochloride injection in intact containers stored as directed by the manufacturer is stable until the labeled expiration date.

Once the ampules are opened, the drug solution should be used immediately, and any remaining solution should be discarded.

Infusion Solutions:
The manufacturer indicates that oxycodone hydrochloride injection diluted to a concentration of 1 mg/mL in sodium chloride 0.9%, dextrose 5%, and sterile water for injection is stable for 24 hours at room temperature.

Turnbull et al. found that oxycodone hydrochloride 5 and 50 mg/mL in dextrose 5% and sodium chloride 0.9% in polyvinyl chloride (PVC) bags was physically stable and HPLC analysis found little or no drug loss in 35 days when stored at 24 °C exposed to fluorescent light and refrigerated at 4 °C protected from exposure to light.

Gardiner reported that oxycodone hydrochloride diluted to 1 mg/mL in sodium chloride 0.9%, dextrose 5%, and sterile water for injection in glass containers was physically and chemically stable for at least 14 days at room temperature near 25 °C and refrigerated at 4 °C. Less than 4% change in drug concentration by HPLC analysis occurred within the study period.

Oxycodone hydrochloride 10 mg/mL undiluted and also diluted to 1 mg/mL in these same solutions were also found to be physically and chemically stable for at least 7 days at room temperature when packaged in polyvinyl chloride (PVC) bags and ethylene vinyl acetate (EVA) bags.

Packaged in Syringes:

Turnbull, et al. reported on the stability of oxycodone hydrochloride 100 mg/mL in sterile water for injection for use as a stock solution. The high-concentration solution was packaged in polypropylene syringes and sealed with tip caps. The

solution was physically stable and HPLC analysis found little or no drug loss in 35 days when stored at 24 °C exposed to fluorescent light and refrigerated at 4 °C protected from exposure to light.

Gardiner reported that oxycodone hydrochloride 10 mg/mL undiluted and also diluted to 1 mg/mL in sodium chloride 0.9%, dextrose 5%, and sterile water for injection in polypropylene syringes and polycarbonate syringes was found to be physically and chemically stable for at least 7 days at room temperature.

Amri et al. reported on the physical and chemical stability of oxycodone hydrochloride (Mundipharma) undiluted at 10 mg/mL and diluted in dextrose 5%, sterile water for injection, or sodium chloride 0.9% to 1 mg/mL. The test solutions were packaged in (1) Pharmacia-Deltec CADD pump reservoirs composed of polyvinyl chloride (PVC) with an inner layer of phthalate ester inside of light-protecting polycarbonate and (2) Arcomed A.G. Medical Systems Rythmic pump reservoirs composed of PVC but no light protection. Samples were stored at room temperature of 15 to 25 °C for 28 days. Half of the Rythmic pumps were protected from exposure to light while the other half was exposed to light. The samples were evaluated by visual observations, pH and osmolality measurements, solution in container weight determinations, and stability-indicating HPLC analysis of drug concentrations.

All samples were found to be physically stable. No visible haze, precipitation, or color change was observed. Small changes (less than 4%) in osmolality were determined. pH increases up to 7.3% were also determined but considered acceptable. Approximately 1% loss of weight per month occurred, but the authors stated that this small amount of evaporation can be considered negligible. The samples were also chemically stable throughout the test period. Only small changes in oxycodone concentration not exceeding 3.9% were found over 28 days of storage in any of the pump reservoirs. No degradation products were found to have formed during the study period.

The samples were also tested for sterility and found to have remained sterile over the 28-day study. These sterility results apply to the sterile compounding that yielded these test samples but cannot be logically applied to other sterile compounding operations having differing equipment, facilities, and personnel.

Interaction with Plastics [67353] [20651] [71005] [96484] [99607]

Oxycodone hydrochloride has not been found to undergo substantial sorption to glass containers, polyvinyl chloride (PVC), polyolefin, and ethylene vinyl acetate (EVA) bags, PVC and polyethylene tubing, and polypropylene syringes.

Gardiner reported that oxycodone hydrochloride 10 mg/mL was stable and compatible in polycarbonate syringes for up to 14 days at 4 and 25 °C. Hines and Pleasance also found oxycodone hydrochloride 50 mg/mL was stable and compatible in polycarbonate syringes for 24 hours at room temperature of 25 °C. However, an increase in "related substances" occurred after storage for 7 days. Hines and Pleasance did not recommend storing oxycodone hydrochloride in polycarbonate syringes for longer than 24 hours.

LightEffects [67353] [96484] [99607]

The manufacturer indicates oxycodone hydrochloride solutions need not be protected from exposure to light.

Turnbull et al. reported no adverse effect on oxycodone hydrochloride stability in dextrose 5% and in sodium chloride 0.9% from exposure to fluorescent light for 35 days at room temperature.

Amri et al. found no effect of light exposure on oxycodone hydrochloride 10 mg/mL or diluted to 1 mg/mL in dextrose 5%, sterile water for injection, or sodium chloride 0.9% during 28 days of storage at room temperature.

Reference Section