

Stability Data for Pain Management Medications in the I-Flow Elastomeric Pump

I-Flow® is responsible for the stability data provided herein. These data are not intended to endorse any specific drug product or dosage for medical use. Always refer to the drug manufacturer's prescribing information when administering any drug with the I-Flow elastomeric pump.

Stability testing was performed by independent laboratories. Drug test samples were collected from the pump and either HPLC chromatography or UV Spectroscopy was used to analyze the test samples. Acceptance criteria for stability is based on USP Monograph Potency Concentration Limits specified for each medication tested.

The stability data provided relates to chemical stability of the drugs tested, and not to sterility. The pharmacist dispensing the drug is responsible for ensuring proper preparation using validated aseptic techniques to prevent microbiological contamination. For practice and quality standards, refer to USP<797> Pharmaceutical Compounding – Sterile Preparations.

This information should be used as a reference only; it is not to replace specific instructions from physicians or pharmacists with experience and additional information about administering these drugs.

Note: Filled pumps stored beyond 8 hours before use may result in reduction in flow rate below the nominal rate. For additional information, a Technical Bulletin - *Effect of Storage Times on Flow Rate of Pre-filled Elastomeric Pumps* - is available at www.myON-Q.com.

Please refer to the following page for stability data.

The drugs listed below have been tested by independent laboratories to verify chemical stability in the I-Flow elastomeric pump. Unless otherwise specified, all local anesthetics are preservative free.

Local Anesthetics

MEDICATION	CONCENTRATION	DILUENT	STORAGE
			Room Temp (~22°C)
Bupivacaine HCL	0.25-0.5%	---	30 days
	0.0625-0.125%	NS	30 days
Bupivacaine HCL (with preservative)	0.25-0.5%	---	30 days
Lidocaine HCL	1%	---	30 days
Ropivacaine HCL	0.2%	---	30 days
Ropivacaine HCL	0.1%	NS	30 days

Local Anesthetic Mixtures

MEDICATION	CONC	DILUENT	STORAGE		
			Room Temp (~22°C)	Refrig (~4°C)	Room Temp (~22°C) Simulated Infusion
Bupivacaine HCL & Ketorolac Tromethamine*	0.5% 1 mg/ml	---	---	7 days	7 days
Ropivacaine HCL & Ketorolac Tromethamine*	0.5% 1 mg/ml	----	---	7 days	7 days
Bupivacaine HCL & Ketorolac Tromethamine & Morphine Sulfate*	0.5% 0.24 mg/ml .032 mg/ml	----	---	9 days	5 days
Bupivacaine HCL & Ceftriaxone NA	0.5% 3.7 mg/ml	---	---	---	2 days
Bupivacaine HCL & Cefazolin NA	0.5% 3.7 mg/ml	---	---	----	3 days
Bupivacaine & Dexamethasone Phosphate*	0.5% 0.4 mg/ml	---	---	7 days	5 days
Ropivacaine HCL & Hydromorphone HCL	0.1% 20 µg/ml	NS	30 days	---	---
Bupivacaine HCL & Fentanyl	0.0625% 2-5 µg/ml	NS	7 days	---	---

*Stability testing at room temperature storage followed by simulated infusion for times specified
NS = Normal Saline (0.9% NaCl)

Please contact the Clinical Services Department @ 800-448-3569 or 949-206-2700 if you have any questions regarding this information.