Kap 27.12 ON-Q - USP-NF 27 <797>

Relationship between the ON-Q® Pain Relief System and the USP-NF 27 <797> Pharmaceutical Compounding – Sterile Preparations

Introduction
The ON-Q PainBuster® and C-bloc® systems are intended to provide continuous infusions of a local anesthetic directly into an intra-operative site or near a nerve for postoperative pain relief. ON-Q helps to break the circle of pain by providing non-narcotic pain relief for up to five days. The system requires little management by either the caregiver or the patient and encourages the patient's return to normal function. The ON-Q Pain Relief System is provided as a sterile, non-pyrogenic, single use medical device intended for filling in either the pharmacy or surgical suite. When the ON-Q elastomeric pump is filled at the healthcare facility, by USP-NF definition, it becomes a Compounded Sterile Preparation (CSP). Recent changes to the United States Pharmacopoeia (USP-NF 27, effective January 1, 2004) have altered the scope for producing CSPs and now require healthcare facilities to follow certain guidelines when filling, storing and dispensing CSPs.

This technical bulletin provided to you by I-Flow Corporation, is intended to provide the reader with a summary of the technical information regarding the microbial contamination risk level of the ON-Q pump, storage and beyond use dating of the pump and filling/media fill qualification studies.

Microbial Contamination Risk Levels/Compounding Conditions
The USP-NF classification into low-, medium- and high-risk CSPs is based upon the probability of microbial and chemical contamination and the potential risk to the patient. These risk classifications are based upon the environment in which the CSP is filled. Depending upon the location where the ON-Q Pump is filled, the device is classified as either a medium-risk or a high-risk CSP.

- When the ON-Q pump is aseptically filled in the pharmacy in an ISO Class 5 or better (formerly classification known as Class 100) laminar flow bench, USP-NF 27 <797> classifies the device as a medium-risk CSP.
- When the ON-Q pump is aseptically filled in the surgical suite, USP classifies the device as a high-risk CSP.

Storage and Beyond Use Dating
I-Flow Corporation has generated numerous chemical and microbiological stability studies to support storage conditions prior to and during administration. I-Flow's recommendations for storage and beyond use dating comply fully with the requirements of USP-NF 27 <797>. Pumps filled in the surgical suite (high-risk classification) should be stored at room temperature for no longer than 24 hours prior to the pump being connected to the patient. Pumps filled in the pharmacy (medium-risk classification) should be stored at room temperature for no longer than 30 hours or refrigerated at 2-8°C for no longer than 9 days prior to use. These recommendations are supported by microbiological stability studies.

Chemical stability of the pump has been verified with the following drugs:

The chemical stability studies performed by I-Flow Corporation exceed the USP storage requirements and support the storage conditions and beyond use dating recommendations of I-Flow Corporation.

Drug Description	Concentration	Storage Time at RT
Bupivacaine	0.25 – 0.5%	30 days
Lidocaine	1%	30 days
Ropivacaine	0.2%	30 days
Ropivacaine	0.2 – 0.75%	14 days

Filling/Media Fill Qualification
USP-NF 27 <797> contains extensive information on processing CSPs and performance evaluation of personnel preparing CSPs. The USP requires "Each person assigned to the aseptic area in the preparation of sterile products must successfully complete specialized training in aseptic techniques and aseptic area practices prior to preparing CSPs." To assist the healthcare facility with this requirement, I-Flow Corporation has developed specific training and performance evaluation programs for healthcare facilities to use. These programs provide the facility with instructions for filling the ON-Q pump and protocols for performing the required media fill qualification studies.

When these protocols are used as part of the established training program of the healthcare facility they provide an effective method of complying with the requirements of USP-NF 27 <797> as it pertains to filling and use of the ON-Q Pain Relief System.

Summary
I-Flow Corporation is committed providing information and training to ensure compliance with these regulations as they apply to the use of the ON-Q Pain Relief System. When the system is used as recommended in the labeled instructions and with support of the other available technical documents, the device can be used in a manner that fully complies with the specific requirements of USP 27 <797>.
For additional information contact your I-Flow representative

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

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