



5.0 Alcohol containing products in the Operating Room

The use of lower molecular weight alcohol(ethyl, isopropyl or n-propyl alcohol for example) based patient preoperative skin preparations in the operating room may pose safety concerns if not delivered by a well-designed system. Requiring a contraindication or warning is not an effective way to assure that products do not pose safety risks. Due to the specific safety concern with products containing alcohol, all alcohol based skin preps containing 40% by volume or greater alcohol should be supported by an NDA to establish the safety and effectiveness of the delivery system. This would require the applicant to report any adverse events or flammability issues to the FDA, and provide a means for the FDA to track this issue.