Pharmaceutical Failure Mode and Effects Analysis
Naropin ® (ropivacaine)

**Step 1:**

Describe how the intended product will be procured and used, from acquisition through administration.

Who will prescribe the drug and for what type of patient?
*Anesthesiologists will prescribe Naropin ® for a variety of patients for surgical anesthesia, labor pain management, and/or postoperative pain management.*

Where will the drug be stored?
*Naropin ® will be stored at in the pharmacy storeroom at room temperature.*

Who will prepare and dispense it?
*The pharmacy technician will prepare the dose and the pharmacist will check and dispense the dose.*

How will it be administered?
*Naropin ® will be administered via local infiltration, epidural block and epidural infusion, or intermittent bolus.*

**Step 2:**

Identify potential failure modes (how and where systems and processes may fail) while considering how the product will be used.

Could the drug be mistaken for another similarly packaged product?
*Naropin ampuls could be mistaken for cromolyn for inhalation or ipratropium bromide for inhalation.*

Does the label clearly express the strength or concentration?
*Yes, ampuls are clear with small black print of the name and strength on the vials. However, ISMP has a near miss report filed due to small illegible printing.*

Does the name sound or look like another drug on the formulary?
*Ropivacaine may be confused with Bupivacaine, ropinirole.*

Are dosing parameters complex?
*No*

Is the administration process error prone?
*Continuous infusion sets should be removed and discarded after 24 hours.*
Step 3:

Once failure modes have been identified, determine the likelihood of making a mistake and the potential consequences of an error.

What would happen to the patient if the drug were given in the wrong dose, at the wrong time, to the wrong patient, by the wrong route, at the wrong rate?

Wrong dose could lead to CNS toxicity or under-sedation. Chondrolysis has occurred with continuous intra-articular infusions of Naropin®. Local anesthetics can lead to respiratory arrest. Intravascular injections of Naropin® have caused seizures due to systemic toxicity.

Step 4:

Identify any preexisting processes in place that could help detect the error before it reaches the patient, and evaluate their effectiveness based upon knowledge of human factors.

Step 5:

If failure modes could cause errors with significant consequences, what actions could be taken to prevent the error, detect it before it reaches the patient, or minimize its consequences? (A few examples include: using an alternative product; preparing the drug in the pharmacy; standardizing drug concentrations, order communication and dosing methods; using auxiliary warning labels or computer alerts; and requiring entry of specific data into computer systems before processing orders).