Pharmaceutical Failure Mode and Effects Analysis
Nucynta® (tapentadol)

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?
Nucynta® will be prescribed by Pain Service physicians as part of multimodal analgesia, to treat breakthrough pain, and transition from IV or epidural analgesia to oral analgesia.

Where will the drug be stored?
Nucynta® will be stored at room temperature and protected from moisture in the pharmacy narcotic vault.

Who will prepare and dispense it?
Pharmacy technicians will prepare the dose and pharmacists will check and dispense the dose.

How will it be administered?
Nucynta® will be administered orally, without regards to food.

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?
All tablets are round with OM imprint on one side and the strength imprint on the other side. 50 mg are light yellow, 75 mg are yellow-orange, and 100 mg are bright orange. They could be confused with any other tablets of the same size, shape, and color.

Does the label clearly express the strength or concentration?
Yes- 50, 75, 100 mg

Does the name sound or look like another drug on the formulary?
Tapentadol may be confused with Tramadol.

Are dosing parameters complex?
Yes-It is also recommended to taper the dose when discontinuing therapy.
Acute moderate-severe pain: Oral: U.S. labeling (immediate release): Day 1: 50-100 mg every 4-6 hours as needed; may administer a second dose ≥1 hour after the initial dose (maximum dose on first day: 700 mg/day); Day 2 and subsequent dosing: 50-100 mg every 4-6 hours as needed (maximum: 600 mg/day)

Is the administration process error prone?
No
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?

Nucynta® may cause CNS depression. Serotonin syndrome may occur if given with SSRIs, SNRIs, TCAs, triptans, or tramadol. Use of alcohol or alcohol-containing medications may increase risk of fatal overdose.

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.

Nurses check two patient identifiers prior to administering medications. A pharmacist will verify the physician’s order in Epic and serve as a double check prior to the nurse withdrawing the medication from Pyxis.

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).

Nucynta® is restricted to the Pain Service which limits the number of physicians able to prescribe the medication. Nucynta® will not be available from the Pyxis machines until an order is verified which prevents accessing the wrong medication on a wrong patient.

Administration Information:

What are the most common side effects that Nursing should be aware of to ensure proper monitoring?

Respiratory depression, nausea, vomiting, headache. Contraindicated in patients with asthma, paralytic ileus, those on MAO inhibitors, with sensitivity or allergic reaction to Nucynta®, hypercapnia, hepatic and renal impairment.

Is there any associated laboratory monitoring that Nursing should be aware of to ensure proper patient care? If yes, please list.

Respiratory rate.