Pharmaceutical Failure Mode and Effects Analysis
Emend® for Injection (fosaprepitant)

· 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?
Oncologists will prescribe Emend® for Injection to patients for the prevention of chemotherapy-induced nausea and vomiting.

Where will the drug be stored?
Emend® for Injection vials will be stored in the refrigerators of the pharmacy store room or IV room.

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

How will it be administered?
The medication will be administered by intravenous infusion over 20 to 30 minutes, approximately 30 minutes prior to chemotherapy

· 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?
Emend® for Injection could be mistaken for other 5 mL vials with a green and black cap.

Does the label clearly express the strength or concentration?
The vial clearly states Emend® for Injection 150 mg on the vial and outer packaging of the medication.

Does the name sound or look like another drug on the formulary?
Emend® for Injection could be mistaken for Emend® (aprepitant) oral capsules or Vfend® (voriconazole).
Are dosing parameters complex?
No-150 mg intravenous over 20 to 30 minutes is the only dosing recommended.

Is the administration process error prone?
Emend® for Injection must be reconstituted with 5 mL of sodium chloride 0.9% in the vial, mixed by gentle swirling (avoid shaking) and then added into a 145 mL sodium chloride 0.9% IV bag. This should be inverted several times to ensure complete mixing before administration. Emend® for Injection is stable in sodium chloride 0.9%. Emend® for injection is incompatible with any solution that contains calcium or magnesium, such as lactated ringers or Hartmann’s solution.

· **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?
Hypersensitivity reactions have been reported with intravenous injections of fosaprepitant. One case of Steven-Johnson syndrome has been reported with oral aprepitant.

· **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.**

Emend® for Injection is restricted for use in the UTMB Galveston Infusion Clinic and Dickinson Chemotherapy Clinics only.

· **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).

Emend® for Injection could be prepared in the pharmacy prior to administration to avoid preparation errors. Its use is also restricted, limiting who has access to prescribe this medication.
Dosage Forms:

Are there any specific dosage forms tailored towards the geriatric or pediatric populations that should be considered? (A few examples include: pediatric oral solutions with different concentrations; lower strength dosage forms intended for the geriatric population).

Emend® for Injection is not indicated for patients under 18 years of age. No geriatric dose adjustments or adjustments for renal or hepatic impairment are available from the manufacturer at this time.

Administration Information:

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

- **Gastrointestinal:** Burping (1%), Constipation (2.2%), Diarrhea (1.1%), Indigestion (1.5%), Loss of appetite (2%), Duodenal ulcer with perforation (less than 1%), Neutropenic colitis (less than 1%)
- **Hepatic:** ALT/SGPT level raised (2.8%), AST/SGOT level raised (1.1%)
- **Neurologic:** Asthenia, Headache (2.2%)
- **Respiratory:** Hiccoughs (4.6%)
- **Dermatologic:** Stevens-Johnson syndrome, Urticaria
- **Hematologic:** Febrile neutropenia (less than 1%), Thrombophlebitis after infusion (greater than 0.1%)
- **Immunologic:** Hypersensitivity reaction
- **Other:** Fatigue (1.4%), Angioedema

The coadministration of fosaprepitant or aprepitant may reduce the efficacy of hormonal contraceptives (these can include birth control pills, skin patches, implants, and certain IUDs) during and for 28 days after administration of the last dose of fosaprepitant or aprepitant. Alternative or back-up methods of contraception should be used during treatment with and for 1 month following the last dose of fosaprepitant or apreptant.

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

Evidence of reduced or absent emetic episodes/nausea in acute and delayed phases following chemotherapy