Pharmaceutical Failure Mode and Effects Analysis
Dexrazoxane (Totect®)

· 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?
Physicians will prescribe dexrazoxane for patients experiencing an anthracycline induced extravasation. It can also be used in patients experiencing doxorubicin induced cardiomyopathy.

Where will the drug be stored?
Dexrazoxane can be stored at room temperature prior to reconstitution. Following reconstitution, Totect can be stored 2-4 hours at room temperature and Zinecard can be stored at room temperature or refrigerator for 6 hours.

Who will prepare and dispense it?
Pharmacists should prepare and dispense Dexrazoxane

How will it be administered?
Dexrazoxane will be administered as an intravenous infusion.

· 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?
Dexrazoxane can be mistaken for any drug that is in 50 mL vial that has a red top.

Does the label clearly express the strength or concentration?
Yes, each vial is clearly labeled with the strength.

Does the name sound or look like another drug on the formulary?
It can sound like Dexamethasone, Dexmedetomidine, Dexpanthenol possibly.

Are dosing parameters complex?
Dosing is based on BSA (m²). Creatinine clearance should also be calculated (50% dose reduction in patients with CrCl < 40 mm/min).

Is the administration process error prone?
Yes, the patient MUST receive dexrazoxane within 6 hours of extravasation.
· **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? If maximum dose is exceeded, the main effect to a patient would be myelosuppression. Alopecia, tissue necrosis (even without extravasation), changes in blood mineral content can occur if patient received a wrong dose or if the wrong patient received dexrazoxane.

· **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.

Pharmacist/Nursing/Physician second checks will minimize possible dosing errors. The use of two patient identifiers will reduce the risk of administration to the wrong patient.

· **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).

Prepare the drug in the pharmacy and have all calculations done by a pharmacist. These calculations should be checked by a second individual to assure accuracy. Education concerning the use of dexrazoxane should be given to all chemotherapy trained nurses, physicians, and pharmacists.