Pharmaceutical Failure Mode and Effects Analysis
Collagenase (Santyl®)

· 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?
Drug will be prescribed by physicians to debride chronic dermal ulcers and severely burned areas.

Where will the drug be stored?
Drug will be refrigerated in the inpatient pharmacy.

Who will prepare and dispense it?
The drug will be prepared by the pharmacy technician and dispensed to the patient by the pharmacist.

How will it be administered?
The drug will be administered topically once daily.

· 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?
No. Santyl® is packaged in a white rectangular box with blue lettering.

Does the label clearly express the strength or concentration?
Yes.

Does the name sound or look like another drug on the formulary?
No.

Are dosing parameters complex?
No. Daily application.

Is the administration process error prone?
Since no dosage calculation or measurements have to be made, administration errors are less likely.

· 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?

- The optimal pH range for Collagenase Santyl® Ointment is 6 to 8. Higher or lower pH conditions will decrease the enzyme’s activity and appropriate precautions should be taken.
- The enzymatic activity is also adversely affected by certain detergents, and heavy metal ions such as mercury or silver, which are used in some antiseptics. When it is suspected that such materials have been used, the site should be carefully cleansed by repeated washings with normal saline before Collagenase Santyl® Ointment is applied. Soaks containing metal ions or acidic solutions should be avoided because of the metal ion and low pH. Cleansing materials such as hydrogen peroxide, Dakin’s solution, and normal saline are compatible with Collagenase Santyl® Ointment.
- Debilitated patients should be closely monitored for systemic bacterial infections because of the theoretical possibility that debriding enzymes may increase the risk of bacteremia.
- A slight transient erythema has been noted occasionally in the surrounding tissue, particularly when Collagenase Santyl® Ointment was not confined to the wound. Therefore, the ointment should be applied carefully within the area of the wound. Safety and effectiveness in pediatric patients have not been established.

**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.

A pharmacist verifies the order after a physician places the order and a pharmacist-check is performed prior to the drug leaving the pharmacy. A nurse checks the medication prior to administration of drug.

**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).

The use of patient identifiers prevents administration to wrong patient.