Pharmaceutical Failure Mode and Effects Analysis
Magnesium Plus Protein

· 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 the drug for transplant patients.

Where will the drug be stored?
The drug will be stored in the pharmacy storeroom and in the central inpatient pharmacy.

Who will prepare and dispense it?
The medication will be prepared by pharmacy technicians and dispensed by pharmacists.

How will it be administered?
The medication will be administered orally.

· 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?
The product is available in 100 tablet bottles. Magnesium Plus Protein is not currently available in a prepacked unit dose container. If it is prepacked by UTMB pharmacy, it will look similar to other UTMB prepacked items.

Does the label clearly express the strength or concentration?
Unknown what the container looks like. The oval tablet is marked “MG Plus”.

Does the name sound or look like another drug on the formulary?
It is similar to the other magnesium products.

Are dosing parameters complex?
No – 1 tablet (133 mg) three times daily

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?

Magnesium Plus Protein contains 133 mg elemental magnesium; magnesium oxide 400 mg contains 242 mg elemental magnesium; magnesium gluconate 500 mg contains only 27 mg elemental magnesium. Confusion between the products could lead to a lower or higher dose than intended. The RDA of elemental magnesium in adults is >300 mg minimizing consequences in patients with normal renal function. Patients with creatinine clearance <30 ml/minute should be monitored for hypermagnesemia.

- 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.

There is a double check between the physician and the pharmacy and again between the pharmacy and nursing. Health care providers follow a two patient identifier policy prior to administration. Duplicate warnings are within Epic, the order entry system.

- 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).

Education could be rolled out to Pharmacy and Nursing comparing all oral magnesium products.

**Administration Information:**

What are the most common side effects that Nursing should be aware of to ensure proper monitoring?
Upset stomach, diarrhea.
Is there any associated laboratory monitoring that Nursing should be aware of to ensure proper patient care?

Serum magnesium levels
Basic metabolic panel
Serum calcium levels

Monitor for signs/symptoms of hypomagnesemia with serum magnesium <1.7 mmol/L (ie-leg cramping, tremors, seizures, arrhythmias, etc.)

Monitor for signs/symptoms of hypermagnesemia which are rare and usually occur with serum magnesium >5 mmol/L (ie-deep tendon reflex attenuation, facial paresthesias, muscle weakness, hypotension, bradycardia, hypocalcemia, N/V, cutaneous flushing)