Pharmaceutical Failure Mode and Effects Analysis
Sitagliptin (Januvia™)

· 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 on the general medicine floors and in clinics, for patients who have uncontrolled diabetes, as monotherapy or in combination with metformin or a thiazolidinedione.

Where will the drug be stored?
Drug will be stored in inpatient and outpatient pharmacies, on the regular shelf, at room temperature.

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 orally, 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. Januvia™ is packaged in a yellow container

Does the label clearly express the strength or concentration?
The label on the bottle expresses the strength of the tablets, however, the individual tablets do not.

Does the name sound or look like another drug on the formulary?
Januvia™ may sound like Janimine® (imipramine) or Jantoven® (warfarin).

Are dosing parameters complex?
No. Dosing is 100 mg daily for CrCl > 50 mL/min, 50 mg daily for CrCl 30-50 mL/min and 25 mg daily for CrCl < 30 mL/min.

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?

If the patient is not a diabetic with poor glucose control, he/she may suffer from hypoglycemia and require dextrose solution infusions. Serious adverse effects are rare.

· **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 verification after physician order entry and double-check at the service coordinator station provide a number of checks before the drug reaches the floor. Nurse’s check prior to administration of drug and dual sign-off system for high alert medications such as hypoglycemic agents, also allows the verification of the order. Most of the time, these checks are effective.

· **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 dual sign-off system, described above, and the use of patient identifiers, such as UH number and date of birth, allow the prevention of medication errors such as administration to wrong patient.