# ExMC Approach to Pharmaceutical Stability Research: An Overview

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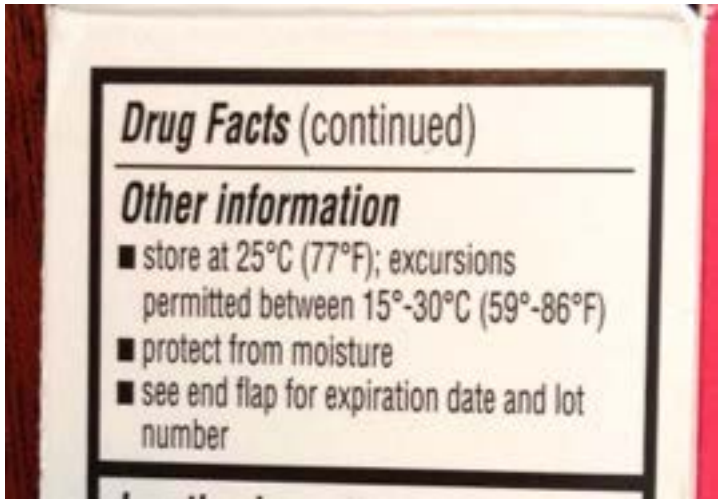
# Goals of Stability Studies

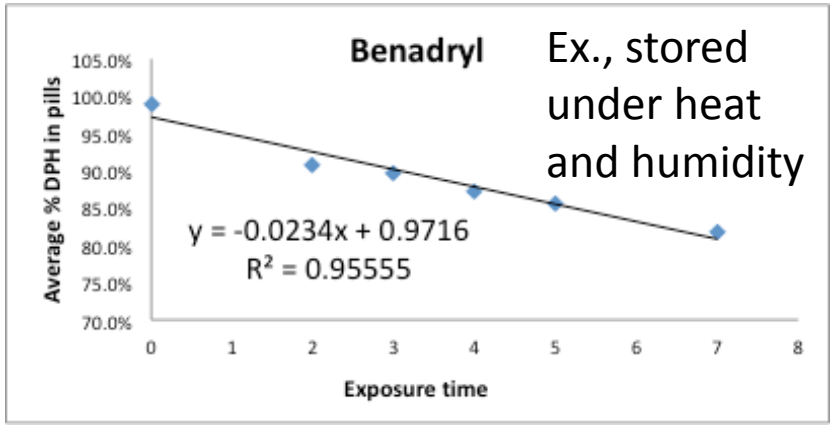
- Identify medications that are stable under real and simulated space conditions, especially deep space radiation
- Identify medications that are potent and safe after their expiration dates

- Ultimately provide a **safe and effective formulary for exploratory spaceflight missions**

# Pharmaceutical Stability




- Medication expiration dates are determined according to the protocol:
  - Exposure of medications under recommended storage conditions
  - Potency, purity, and other chemical testing at set timepoints
  - Comparison of results to specified acceptance limits set by the FDA and published in the US Pharmacopeia.




For example, typical acceptance limits for potency are 90.0 – 110.0% for many dosage forms.

# Challenges

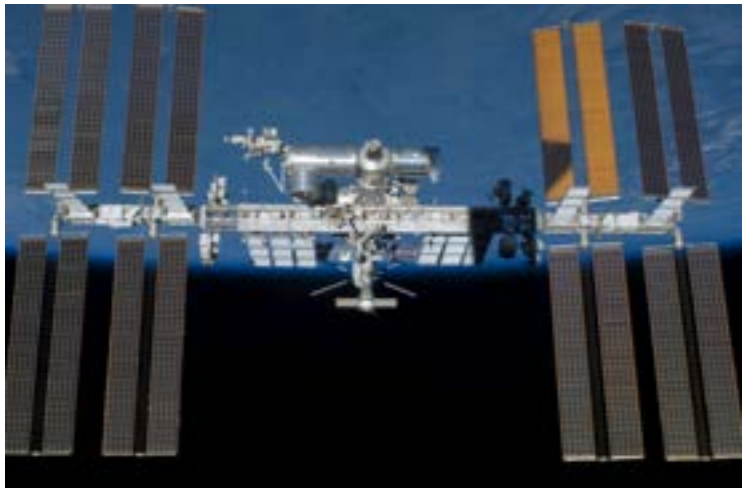
- Developing the laboratory capabilities for chemical testing of exposed medications
- Designing studies with exposure/storage conditions that closely mimic exploratory space mission conditions
- Mining reams of data from FDA report requests

# Examination of previous FDA stability data

- Data from FDA filings for medications will be requested according to current FDA/NASA Memo of Understanding.
- FDA data will include stability testing results from approval filings – up until the expiration date (shelf life)
- Can be used to predict longer term stability

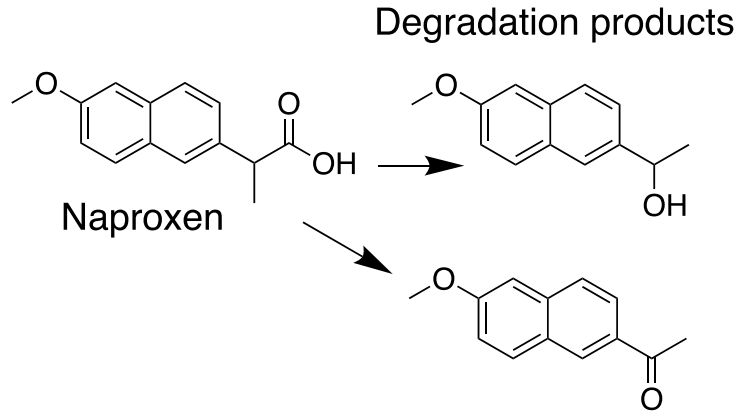
# ISS-Stored Medication Study

- Store medications on the ISS for return at specific timepoints:
  - At time of expiration
  - One year past expiration
  - Two years
  - Three years



https://www.nasa.gov/mission_pages/station/main/index.html

- Chemical analysis will provide results that can be compared to controls stored on Earth:
  - Potency
  - Purity (degradation products)
  - Dissolution (bioavailability)
  - Appearance



# Dribble Study

- Unused medications stored for use on the ISS are returned after they have expired.

- Controls are stored under controlled conditions at JSC for stability comparison, to assess effect of radiation.

https://www.nasa.gov/mission_pages/station/structure/launch/overview.html

# NSRL Beam Study

- Initial study of four medications done in 2018: Medications are exposed to simulated deep space radiation, doses of 0.5-1 Gy for short amounts of time.

- Data assessment underway to determine whether this radiation exposure is a good model for the exposure that has been observed on the ISS.

- This type of study would be a good “worst case scenario” for drugs that are expected to be stable.

# Gateway Spacecraft Study

- Store medications on the gateway spacecraft
- Exposure to radiation outside LEO

https://www.nasa.gov/feature/questions-nasas-new-spaceship

# Development of Analytical Testing Capabilities at JSC

- Needs:
  - Laboratory equipment for chemical analysis testing
  - Personnel

- Advantages over testing at contract labs:
  - Higher sample volume testing at lower cost
  - Ability to react immediately to test results

# Thank You