

ExMC Approach to Pharmaceutical Stability Research: An Overview

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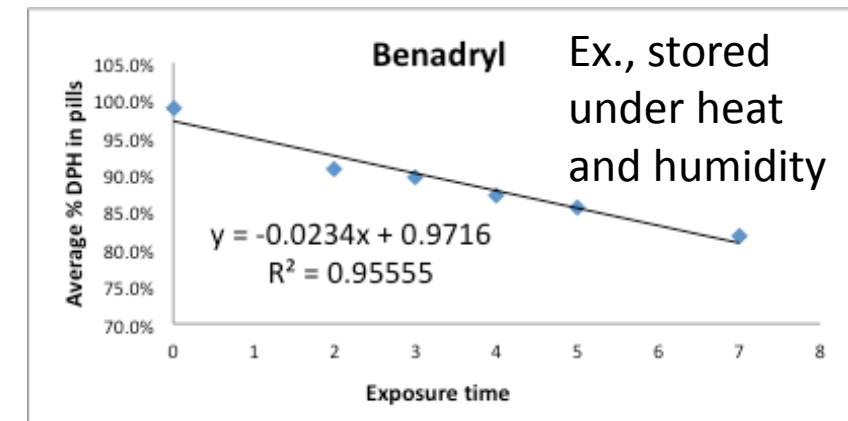
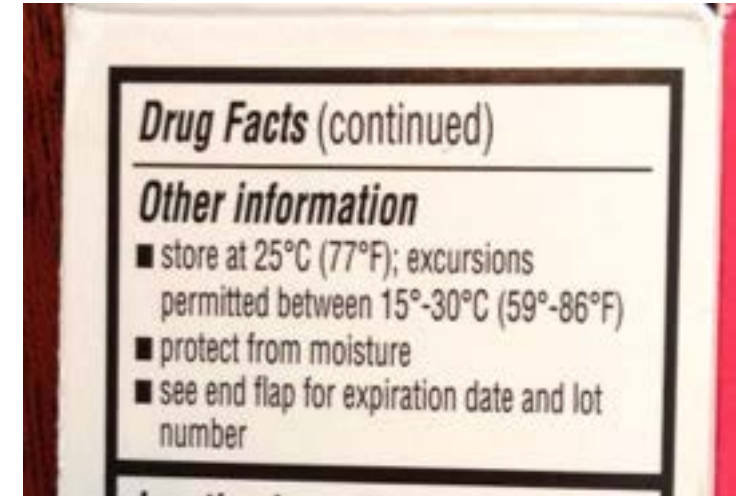
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Goals of Stability Studies

- 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

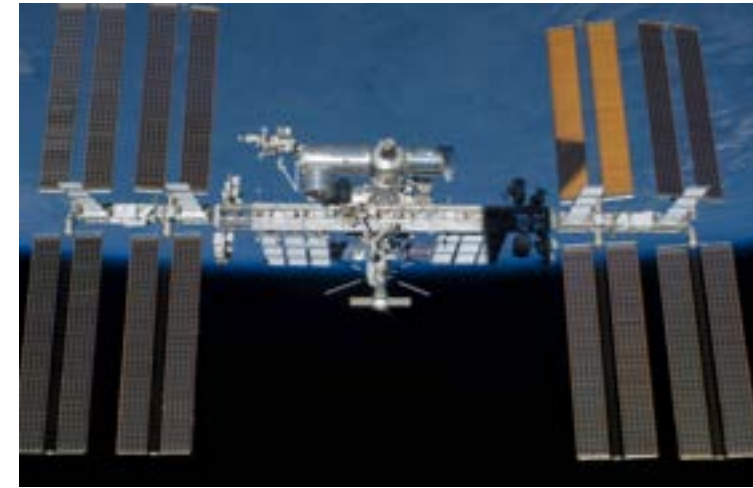
Examination of previous FDA stability data

- 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

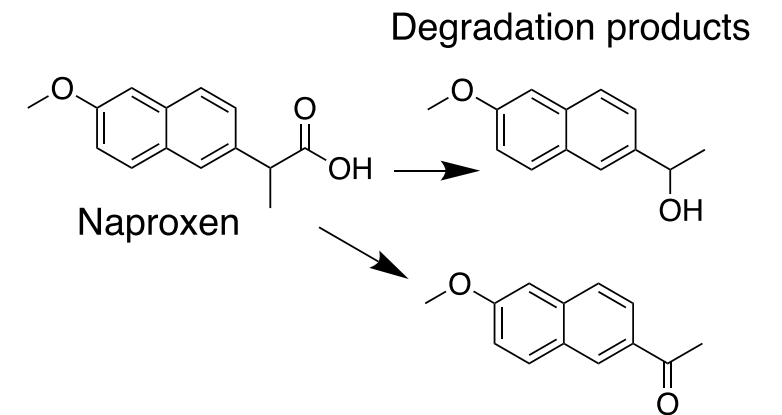


ISS-Stored Medication Study

- Store medications on the ISS for return at specific timepoints:
 - At time of expiration
 - One year past expiration
 - Two years
 - Three years
- Chemical analysis will provide results that can be compared to controls stored on Earth:
 - Potency
 - Purity (degradation products)
 - Dissolution (bioavailability)
 - Appearance



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



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