

Fiscal Year:	FY 2014	Task Last Updated:	FY 09/04/2014
PI Name:	Wotring, Virginia Ph.D.		
Project Title:	Development of Methods/Technologies for Medication Stability and Shelf-life		
Division Name:	Human Research		
Program/Discipline:	HUMAN RESEARCH		
Program/Discipline--Element/Subdiscipline:	HUMAN RESEARCH--Biomedical countermeasures		
Joint Agency Name:	TechPort:	No	
Human Research Program Elements:	(1) HHC: Human Health Countermeasures		
Human Research Program Risks:	(1) Pharm: Risk of Ineffective or Toxic Medications During Long-Duration Exploration Spaceflight		
Space Biology Element:	None		
Space Biology Cross-Element Discipline:	None		
Space Biology Special Category:	None		
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Zip Code:	77030	Congressional District:	9
Comments:	PI formerly with Universities Space Research Association until fall 2015.		
Project Type:	FLIGHT,GROUND	Solicitation / Funding Source:	Directed Research
Start Date:	01/31/2013	End Date:	12/31/2013
No. of Post Docs:	No. of PhD Degrees:		
No. of PhD Candidates:	No. of Master' Degrees:		
No. of Master's Candidates:	No. of Bachelor's Degrees:		
No. of Bachelor's Candidates:	Monitoring Center: NASA JSC		
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Flight Program:	ISS		
Flight Assignment:	ISS		
Key Personnel Changes/Previous PI:			
COI Name (Institution):			
Grant/Contract No.:	Directed Research		
Performance Goal No.:			
Performance Goal Text:			
Task Description:	<p>This study will analyze 9 expired medications that were returned from the ISS in numbers sufficient for analysis (at least 40 units each). These medications include several of the most heavily used by our crewmembers: 2 sleep aids, 2 antihistamines/decongestants, 3 pain relievers, an antidiarrheal, and an alertness medication. All of these medications expired between February and June 2012. The Clinical Pharmacy has records of their lot numbers, purchase dates, launch dates, and for those medications that were repackaged, repackaging dates. There are no control samples available, which is a significant drawback. Notwithstanding, we suggest that analysis should be conducted using the HPLC/MS methods described in the United States Pharmacopeia for each of these medications to measure the amount of intact active ingredient in each medication, identify degradation products, and measure their amounts as well. Without ground controls, we cannot answer the question of differences in flight-aging compared to ground-aging. However, determination of the safety and efficacy of these 9 heavily-used medications soon after storage on the ISS will</p>		

	provide useful information on the stability of these medications and may help determine the priority of future studies.
Rationale for HRP Directed Research:	Pharmacology has obtained some medications that expired on the ISS and were returned on the fall 2012 SpaceX flight. These medications have now been inventoried by the Clinical Pharmacy and transferred to a stability chamber in the research laboratory, pending approval to proceed. A rapid determination of the safety and efficacy of these 9 heavily-used medications soon after storage on the ISS will be very informative.
Research Impact/Earth Benefits:	
Task Progress:	Nine medications were chosen on the basis of their availability for study. Each medication was available at a single time point; analysis of the same medication at multiple time points was not possible. Because the samples examined in this study were obtained opportunistically from medical supplies, there were no control samples available (i.e. samples aged for a similar period of time on Earth); a significant limitation of this study. Medications were analyzed using the HPLC/MS methods described in the United States Pharmacopeia (USP) to measure the amount of intact active ingredient, identify degradation products and measure their amounts. Only more comprehensive analysis of flight-aged samples compared to appropriately matched ground controls will permit determination of spaceflight effects on medication stability.
Bibliography Type:	Description: (Last Updated: 12/24/2019)
Articles in Peer-reviewed Journals	Wotring VE. "Chemical potency and degradation products of medications stored over 550 Earth days at the International Space Station." AAPS J. 2016 Jan;18(1):210-6. Epub 2015 Nov 6. http://dx.doi.org/10.1208/s12248-015-9834-5 ; PubMed PMID: 26546565 ; PubMed Central PMCID: PMC4706284 , Jan-2016