Fiscal Year:	FY 2010	**Task Last Updated:**	FY 01/26/2010
PI Name:	Putcha, Lakshmi Ph.D.		
Project Title:	Stability of Pharmacotherapeutics and Nutrition Compounds-Pharma		
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		
PI Email:	lakshmi.putcha-1@nasa.gov, jason.boyd-1@nasa.gov	**Fax:**	FY 281-244-5734
PI Organization Type:	NASA CENTER	**Phone:**	281-483-7760
Organization Name:	NASA Johnson Space Center		
PI Address 1:	2101 NASA Parkway		
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PI Web Page:			
City:	Houston	**State:**	TX
Zip Code:	77058	**Congressional District:**	22
Comments:	Deceased as of September 2015.		
Project Type:	FLIGHT	**Solicitation / Funding Source:**	2004 Space Life Sciences 04-OBPR-01: ILSRA 2004
Start Date:	10/01/2005	**End Date:**	12/31/2009
No. of Post Docs:	0	**No. of PhD Degrees:**	1
No. of PhD Candidates:	1	**No. of Master' Degrees:**	0
No. of Master's Candidates:	0	**No. of Bachelor's Degrees:**	0
No. of Bachelor's Candidates:	0	**Monitoring Center:**	NASA JSC
Contact Monitor:	Goodwin, Thomas	**Contact Phone:**	
Contact Email:	thomas.j.goodwin@nasa.gov		
Flight Program:	Shuttle/ISS		
Flight Assignment:	ISS STS-121, STS-117, STS-122, STS-126		
Key Personnel Changes/Previous PI:	NOTE: previously combined in project entitled Stability of Pharmacotherapeutics and Nutrition Compounds, with Scott Smith as PI and Lakshmi Putcha as Co-PI; split into two Task Book projects in January 2010 for the entire project period, per JSC direction, with each CoPI listed as PI (ed.)		
COI Name (Institution):	Du, Brian (Wyle Life Sciences) Boyd, Jason (Universities Space Research Association)		
Grant/Contract No.:			
Performance Goal No.:			
Performance Goal Text:			

Task Description:	Data gathered from past Space Shuttle missions suggest that some of the medications packed in the Shuttle's medical pack degrade even after relatively brief periods (less than 20 days) of space flight. The observed degradation included both physical and chemical characteristics of medicine formulations. The degradation was sufficient to influence FDA stipulated shelf-life for these formulations and may result in a loss of potency. Physical and chemical instability of medications could render treatments with degraded drugs ineffective for assurance of optimal crew health during long duration space exploration missions. An evaluation of subjective data on medications used by crewmembers during space flight indicated that eight percent of all treatments administered in the Space Shuttle program were reported ineffective. Pharmaceutical instability may modify effectiveness and safety, and is one possible cause of the ineffectiveness of treatments. Degradation of food products will also render them ineffective in providing health and energy sustenance. The stability of medications and foods used by the crew, therefore, must be adequate to facilitate safe exploration of space in the future. The Stability of Pharmaceuticals, constituent Stability payload investigation, evaluated mission critical medications understand issues relating to loss of potency and resultant impact on shelf-life of medications in space. See also http://www.nasa.gov/
Rationale for HRP Directed Research:	
Research Impact/Earth Benefits:	The results of this investigation will help understand the effects of adverse environments on stability and shelf-life of medications, this information will be useful for long-range military operations and Earth based explorers make choices for efficacious treatments in remote and adverse habitats like the Antarctic, arctic and multiple world terrains. With the advent of emerging global pharmaceutical supply industry and adverse environment war-zone activities, understanding shelf-life characteristics of medications will assure safe and effective therapeutics in the future.
Task Progress:	Sixteen medication kits were designed containing identical sets of 35 medications from various dosage forms and therapeutic classes exposed to flight and ground-control environment paradigms. The flight paradigm involved 4 medication kits flown aboard a Shuttle to the International Space Station (ISS). Three flight kits were stored on the ISS and returned to Earth incrementally; while one kit remained on the Shuttle for immediate return 13 days later. Content-indicating assays produced by Ultra and High Performance Liquid Chromatography and physical stability assessments for each medication were performed using methods and testing procedures obtained from the most current version available of the United States Pharmacopoeia or scientific literature. Simultaneous analysis was performed on flight and ground-control kit medications. After 28 month of space exposure, 17 percent of flight kit and 5 percent of ground-control kit medications had changes in appearance; which included discoloration, and phase separation for semi-solid formulations. Nine medications in the flight kits met content acceptance criteria following 28 months of space exposure; which included one aqueous formulation, ciprofloxacin ophthalmic solution, a semi-solid, triamcinolone ointment, and seven solids, acyclovir tablet, atorvastatin tablet, azithromycin tablet, cefadroxil capsule, ibuprofen tablet, imipenem / cilastatin injection powder, and metronidazole tablet. After 28 months of spaceflight, there were medications that failed content requirement in flight, but met it in the control kits; which suggests altered physiochemical stability due to the spaceflight environment.
Bibliography Type:	Description: (Last Updated: 11/12/2020)
Abstracts for Journals and Proceedings	Du B, Daniels V, Crady C, Boyd J, Putcha L. "Pharmaceutical stability in Space - content analysis." Presented at the Annual meeting and Exposition of the AAPS, Sept. 8-12, 2009. AAPS Journal 2009(S2). , Nov-2009
Abstracts for Journals and Proceedings	Chuong MC, Prasad D, LeDuc B, Du B, Putcha L. "Pharmaceutical Stability of Vitamin B Complex in the Outer Space Bioenvironments Retrieved Multivitamin and Multimineral Supplements." Presented at the Annual Meeting and Exposition of the AAPS, November 8-12, 2009. AAPS Journal 2009;11(S2): abstract #1021. http://www.aapsj.org/abstracts/AM_2009/AAPS2009-001021.PDF , Nov-2009
Articles in Peer-reviewed Journals	Du B, Daniels VR, Vaksman Z, Boyd JL, Crady C, Putcha L. "Evaluation of physical and chemical changes in pharmaceuticals flown on space missions." AAPS J. 2011 Jun;13(2):299-308. Epub 2011 Apr 9. PMID: 21479701 , Jun-2011
Articles in Peer-reviewed Journals	Chuong MC, Prasad D, Leduc B, Du B, Putcha L. "Stability of vitamin B complex in multivitamin and multimineral supplement tablets after space flight." J Pharm Biomed Anal. 2011 Jul 15;55(5):1197-200. Epub 2011 Mar 29. PubMed PMID: 21515013 , Jul-2011