Medicines do not seem to degrade faster in space

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The results of an opportunistic, pilot-scale study led by Virginia Wotring of the Center for Space Medicine and Department of Pharmacology at Baylor College of Medicine in the US suggest that medication degradation on the International Space Station (ISS) does not differ from what is typically seen on Earth. The study, which used medicine samples sent back to Earth from the ISS, appears in *The AAPS Journal*.

While the ISS is regularly resupplied with medicines to replace those which have passed their expiry date, this may not be possible on exploration missions that travel to more distant points. On Earth, medicines degrade over time, particularly when exposed to light, oxygen or humidity. Although temperature and humidity conditions on board the ISS are generally within ideal ranges for medicine storage on Earth, until now, there has been little evidence of how medicines might react to factors unique to spaceflight, such as microgravity and constant exposure to elevated radiation levels.

Wotring analysed nine medications which had been stocked on the ISS and returned to Earth unused after 550 days of storage in spaceflight. The medications included sleeping aids, pain relievers, antihistamines/decongestants, an antidiarrhoeal, and an alertness drug. The medicines were returned to Earth and, upon arrival, they were kept under controlled conditions until analysis 3-5 months later.

The researchers measured the quantity of active ingredients and degradation products present in the medicines. They then used 2012

United States Pharmacopeia (USP) guidelines (which provide clear requirements of the quantity of active ingredients and limits of degradation products allowed in viable medicines) to determine whether or not the ISS medicines were still viable after being stored in space.

According to the 2012 USP guidelines, one medication met USP requirements five months after its expiration date. Four of the nine drugs were still viable up to eight months after officially expiring. Another three medications met USP guidelines when they were tested three months before their expiry date. A dietary supplement/sleeping aid did not meet USP requirements eleven months after it had expired. No unusual degradation products could be identified in any of the tests.

The authors note that the opportunistic nature of the study means that the results are based only on measurements made at a single point in time, for a handful of medications. The findings cannot, therefore, be applied to gauge the safety and effectiveness of other medicines, or extrapolated to other storage times.

The findings suggest that further research is necessary before planning long-term space flights - such as missions to Mars - because missions like this won't have the opportunity to restock medicines in the way that the ISS can. The next step is to conduct rigorous stability studies with appropriate ground control and multiple time points, extended to include additional medicines, and to cover longer periods of time, and see whether they support the initial findings outlined in the present study.

More information: Virginia E. Wotring. Chemical Potency and Degradation Products of Medications Stored Over 550 Earth Days at the International Space Station, *The AAPS Journal* (2015). DOI: 10.1208/s12248-015-9834-5

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