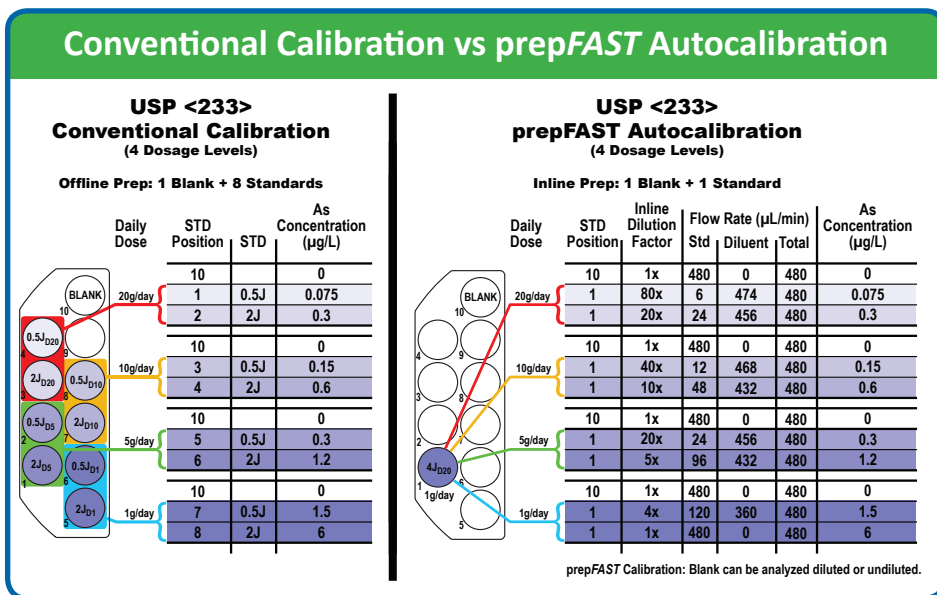


Authors: Kyle Uhlmeier (kyle.uhlmeier@icpms.com)

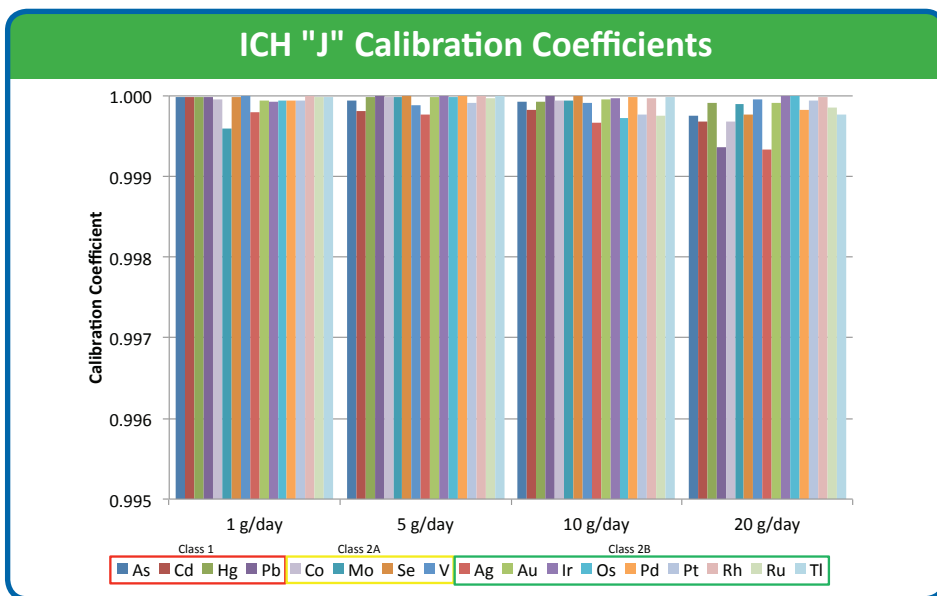
## Brief

The International Committee on Harmonization has released a Q3D document on elemental impurities in pharmaceutical products. This document contains updates to elements for analysis and Permissible Daily Dose (PDE) levels. Calibrations at 0.5J and 2J for the new elements and levels show excellent linearity (>0.999), demonstrating the robustness of the prepFAST and the ability to adapt to changing industry regulations.

UPDATE



**Figure 1.** prepFAST Autocalibration allows for calibrating for multiple products from the same stock standard. Performing autocalibration has the benefit of both reducing analyst work load by reducing standard production, as well as reducing a point of contamination from manually making low level standards.



**Figure 2.** Calibrations were run for elements in new ICH regulations at a range of daily doses with ICP-MS. Calibration coefficients of >0.999 show excellent linearity for new PDE levels for all elements tested.

USP / ICH PDE Differences

Element	Class	Oral PDE - USP (µg/day)	Oral PDE -ICH (µg/day)
As	1	1.5	15
Cd	1	25	5
Hg	1	15	40
Pb	1	5	5
Co	2A	NA	50
Mo	2A	100	180
Se	2A	NA	170
V	2A	100	120
Ag	2B	NA	170
Au	2B	NA	130
Ir	2B	100	1000
Os	2B	100	1000
Pd	2B	100	100
Pt	2B	100	1000
Rh	2B	100	1000
Ru	2B	100	1000
Tl	2B	NA	8
Ba	3	NA	13000
Cr	3	NA	11000
Cu	3	1000	1300
Li	3	NA	780
Ni	3	500	600
Sb	3	NA	1200
Sn	3	NA	6400

**Table 1.** An example of the differences from USP to ICH regulations. Despite changes in elements for analysis and the PDE levels, prepFAST is still capable of autocalibrating with excellent linearity.



SC-2 DX prepFAST System

7277 World Communications Drive | Omaha, NE 68122 USA

Phone: 1.402.991.7800 | Fax: 1.402.991.7799

Email: [prepFAST@icpms.com](mailto:prepFAST@icpms.com)

Web: [www.prepFAST.com](http://www.prepFAST.com) | [www.icpms.com](http://www.icpms.com)

