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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.

Conventional Calibration vs prepFAST Autocalibration

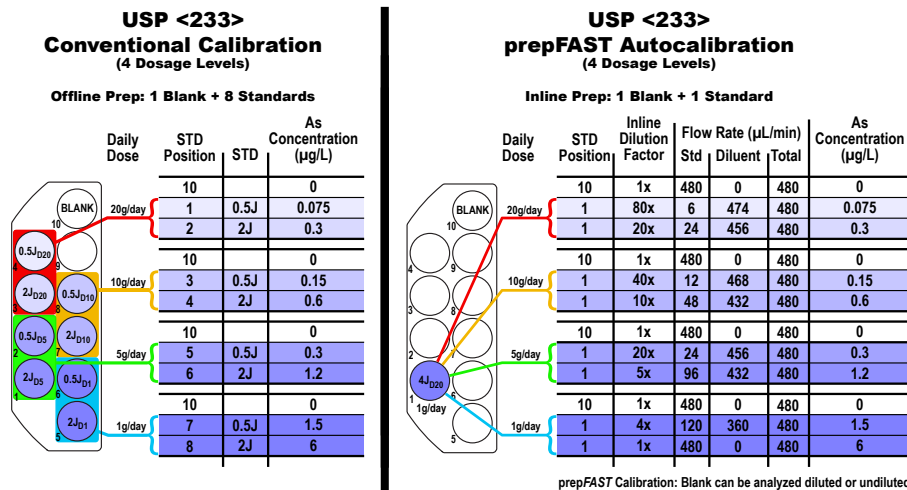


Figure 1. prepFAST autocalibration allows for calibrating for multiple products from the same stock standard. Performing autocalibration has the benefit of both reducing analyst work load by reducing standard production, as well as reducing a point of contamination from manually making low level standards.

ICH "J" Calibration Coefficients

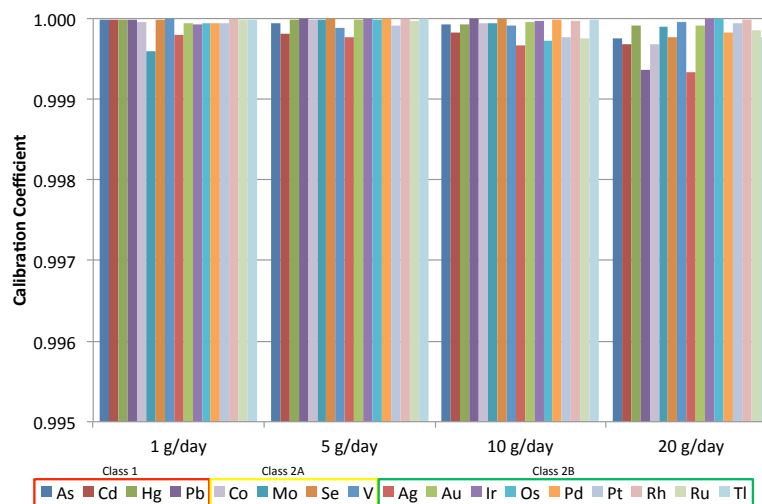
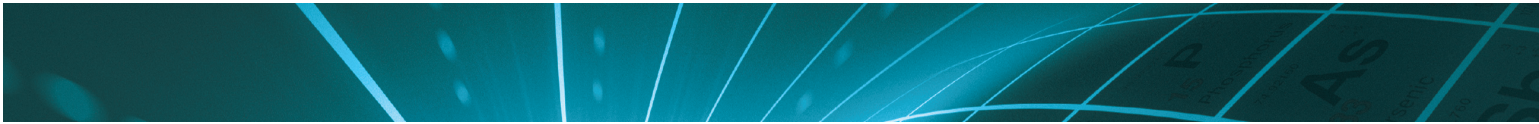


Figure 2. Calibrations were run for elements in new ICH regulations at a range of daily doses with ICP-MS. Calibration coefficients of >0.999 show excellent linearity for new PDE levels for all elements tested.

UPDATE



USP / ICH PDE Differences			
Element	Class	Oral PDE - USP (µg/day)	Oral PDE - ICH (µg/day)
As	1	15	15
Cd	1	5	5
Hg	1	15	30
Pb	1	30	5
Co	2A	50	50
Mo	2A	3000	3400
Se	2A	150	170
V	2A	100	120
Ag	2B	150	167
Au	2B	100	134
Ir	2B	100	100
Os	2B	100	100
Pd	2B	100	100
Pt	2B	100	108
Rh	2B	100	100
Ru	2B	100	100
Tl	2B	8	8
Ba	3	1400	1460
Cr	3	11000	10700
Cu	3	3000	3400
Li	3	550	560
Ni	3	200	220
Sb	3	1200	1200
Sn	3	6000	6400



2DX prepFAST



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