

**4th PQRI Workshop on ICH Q3D
Elemental Impurities Requirements
November 9-10, 2020**

**PQRI Phase 2 Elemental Impurities Collaborative Study
Results Review and Publication**

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Product Quality Research Institute

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Communication of Data/Results

Study Report

Participant Meeting

Individual Lab Reports

Peer Reviewed Publications

Data Visualization for Tablet Analysis



Study Report

PQRI Interlaboratory Study on the Determination of Elemental Impurities in Drug Products

FINAL REPORT

October 10, 2019

- Contains all methods, data, statistical analysis, and data visualizations
- Distributed to participant labs in early September
- Available on workshop website for attendee use

Participant Meeting and Individual Lab Results

Participant Meeting

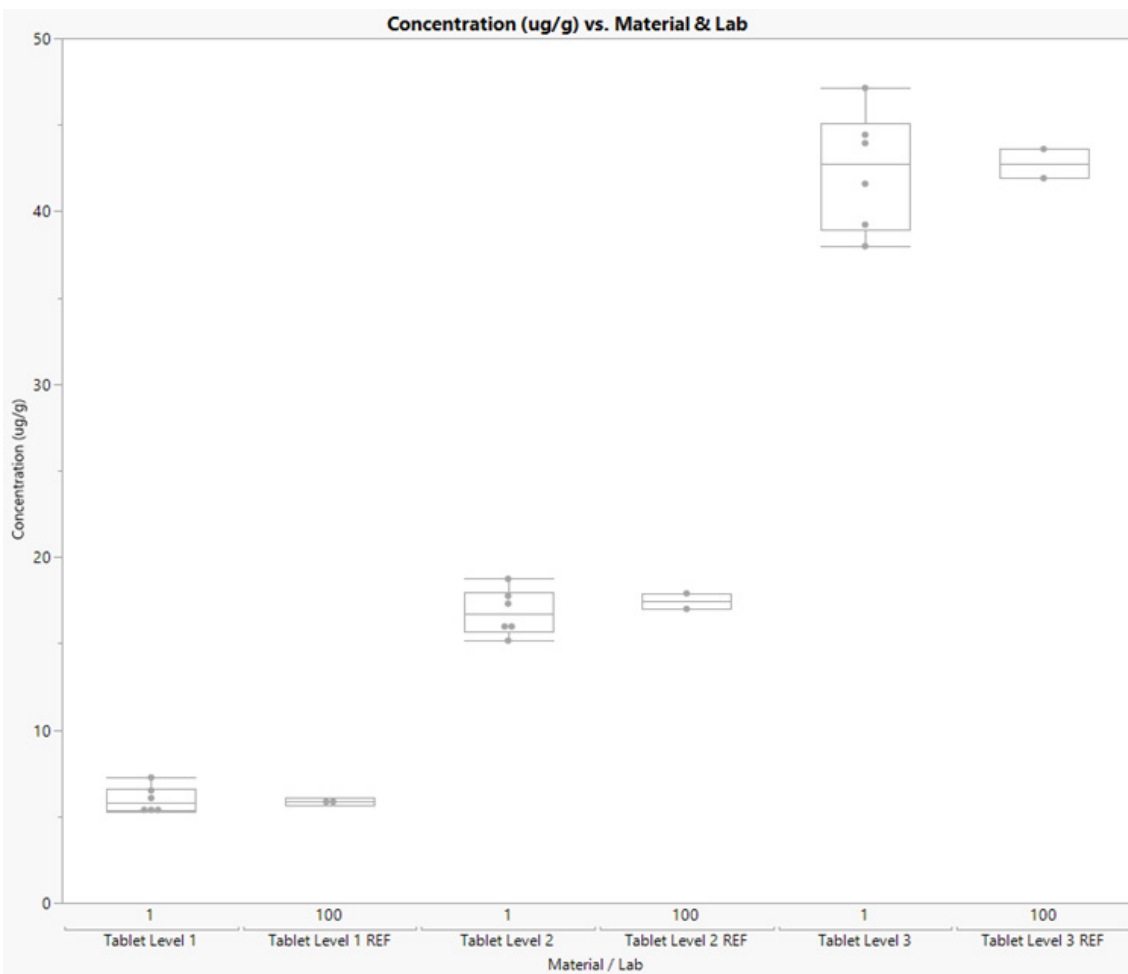
- Held in October
- Shared high level results with participating labs

Individual Lab Reports

- Are currently being sent
- Blinded distribution



Individual Lab Reports for Participant Labs



33

As

Arsenic
74.922

ICP/MS measurements for each element with comparison to reference lab at each tablet level

Individual Lab Reports for Participant Labs

Analyte	Material	WorkSheet	Ref.log10. Concentration	Mean.log10. Concentration	SD.log10. Concentration	CI95.log10. Concentration	P.value*
As	Lactose	Exhaustive	NA	NA	NA	(NaN, NaN)	NA
As	Magnesium Aluminum Silicate	Exhaustive	0.240549	0.45117	0.011681	(0.438, 0.464)	0.001024
As	Red Ferric Oxide	Exhaustive	-0.35458	NA	NA	(NaN, NaN)	NA
As	Silicon Dioxide Material 1	Exhaustive	3.037426	3.009318	0.063651	(2.958, 3.060)	0.32877
As	Silicon Dioxide Material 2	Exhaustive	NA	NA	NA	(NaN, NaN)	NA
As	Starch	Exhaustive	NA	NA	NA	(NaN, NaN)	NA
As	Tablet Level 1	Exhaustive	0.752199	0.730521	0.007715	(0.722, 0.739)	0.039722
As	Tablet Level 2	Exhaustive	1.230507	1.196132	0.013369	(1.181, 1.211)	0.046898
As	Tablet Level 3	Exhaustive	1.622347	1.59735	0.019996	(1.575, 1.620)	0.162769
As	Tablet Level 1	Total Dig.	0.781755	0.814975	0.040366	(0.769, 0.861)	0.290113
As	Tablet Level 2	Total Dig.	1.252853	1.253422	0.01762	(1.233, 1.273)	0.960505
As	Tablet Level 3	Total Dig.	1.639486	1.654579	0.016382	(1.636, 1.673)	0.251614

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As

Arsenic
74.922

Tabular summary for each element with statistical comparison to reference lab for each raw material and at each tablet level for each type of digestion



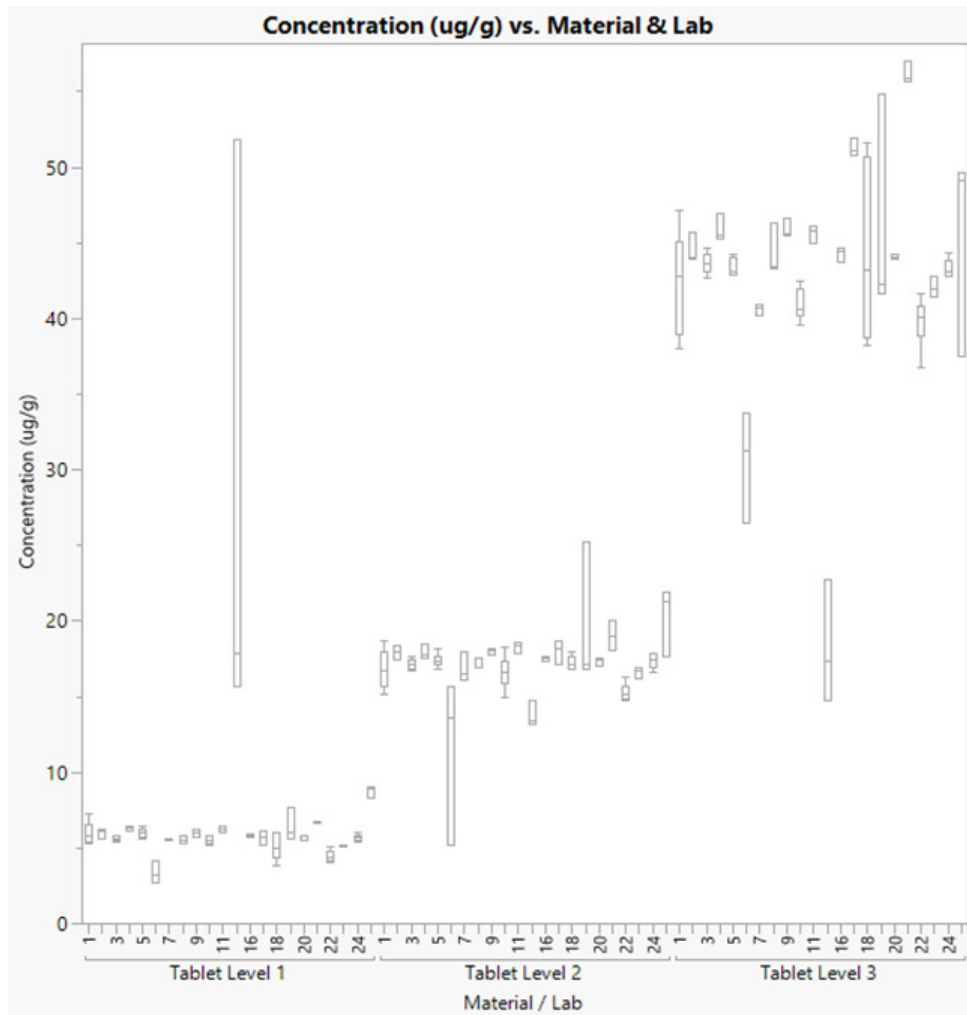
Peer Reviewed Publications

Topic	Target Journal
Study Summary	J Pharm Sci
Formulation Challenges and Method Development	J Pharm Sci
XRF results and loss of Hg	TBD



Visualizations

33
As
Arsenic
74.922

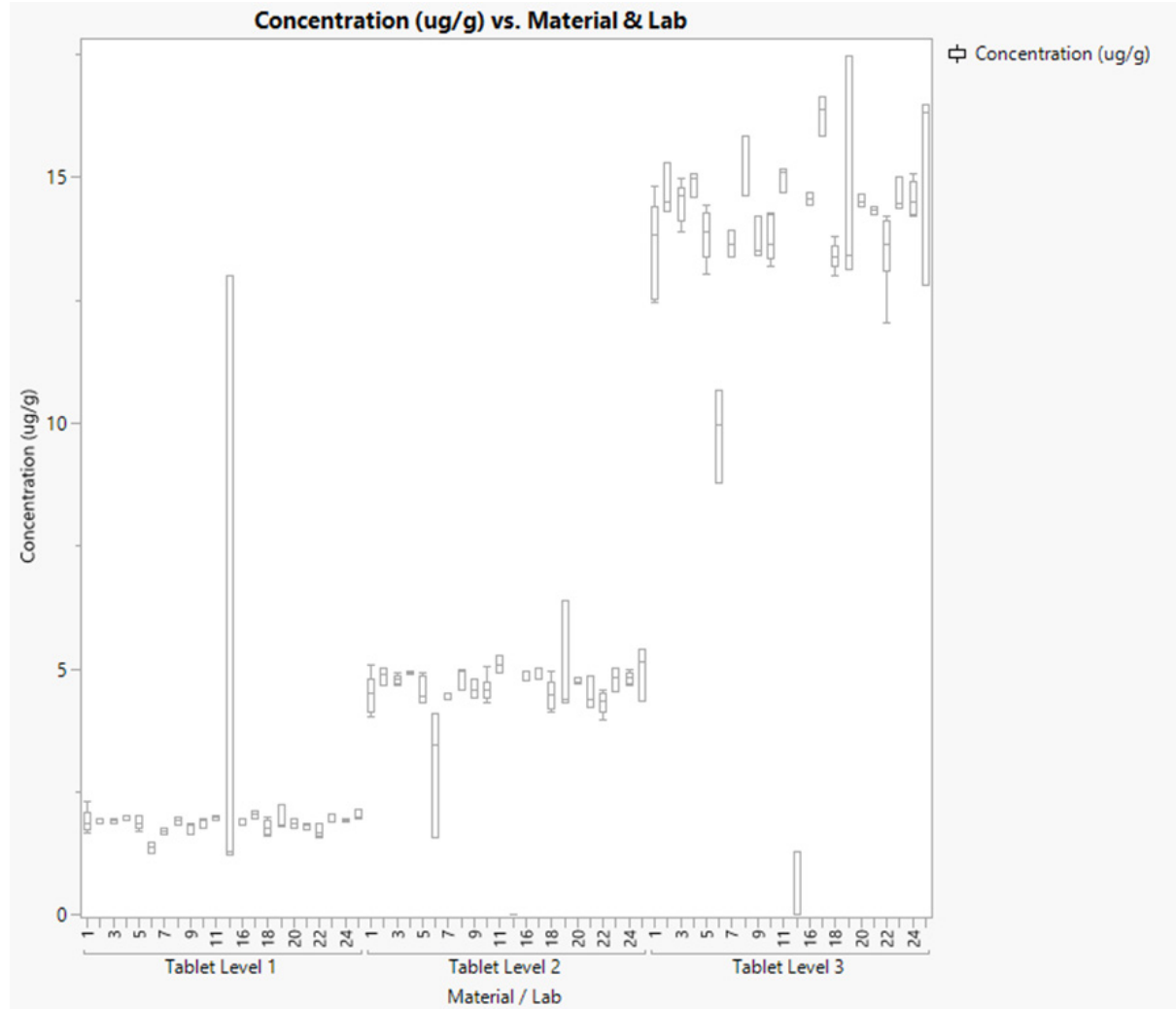


Visualizations

48

Cd

Cadmium
112.414



Visualizations

