




BPA Study Report Card – Pharmacokinetic Criteria

The criteria identified in this Report Card have been established by the U.S. Food and Drug Administration in critical aspects of Pharmacokinetics studies for evaluation of BPA studies as it relates to human exposures.*



<http://www.fda.gov/downloads/Food/IngredientsPackagingLabeling/FoodAdditivesIngredients/UCM424071.pdf>

 Study Meets Criteria	 Study Criteria Unknown or not applicable	 Study fails criteria
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Study: Bisphenol A Exposure in Children With Autism Spectrum Disorders

Authors: T. Peter Stein, Margaret D. Schluter, Robert A. Steer, Lining Guo, and Xue Ming

Journal: Autism Research (2015)

CRITERIA	SCORE	COMMENTS
Analytical methodology sufficiently validated and reported		Poor design with no control over contamination
Measurement of both the conjugated and unconjugated (aglycone or "free") forms of BPA		Although measured, the data is so inconsistent with any previous reported BPA metabolism, the study is clearly fraught with contamination issues
Preferred dosing with isotopically labeled BPA		Did not use isotopically labeled BPA
Quality of methods used, with the highest weight given to mass spectrometric methods, particularly liquid-chromatography–tandem mass spectrometry (LC/MS/MS)		Little details about methods of analysis
Use of isotope dilution quantification (i.e., use of isotopically-labeled internal standards) of at least 3 atomic mass units is preferred because of higher performance		
Adequate demonstration of quality control in sample preparation and analysis (i.e., laboratory reagent and sample collection blanks, matrix spikes at relevant concentrations, authentic standards)		Levels of reported Free BPA fall outside of published norms. Clear case of contamination
For determination of pharmacokinetic parameters, samples obtained from individual animals (and humans) were considered more powerful statistically than those derived from pooled/averaged determinations		

Note: Previous studies (Teeguarden, NIEHS) study confirmed >99% glucuronidation from human oral exposure; this study suggests ~90%. The Free BPA numbers are independent of total BPA. This suggests a constant level of contamination. Based on report, study did not include control for contamination, no measured dose, no description of the population, and no diet information. The study is not suitable for characterizing differences in metabolism, or exposure. A single spot urine sample is uninformative with regards to long term exposure, and even daily exposure. The study did not consider reverse causation, that ASD children consume more canned goods versus control subjects.