Investigating the Risk of Toxic Elements in Tampons

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Introduction

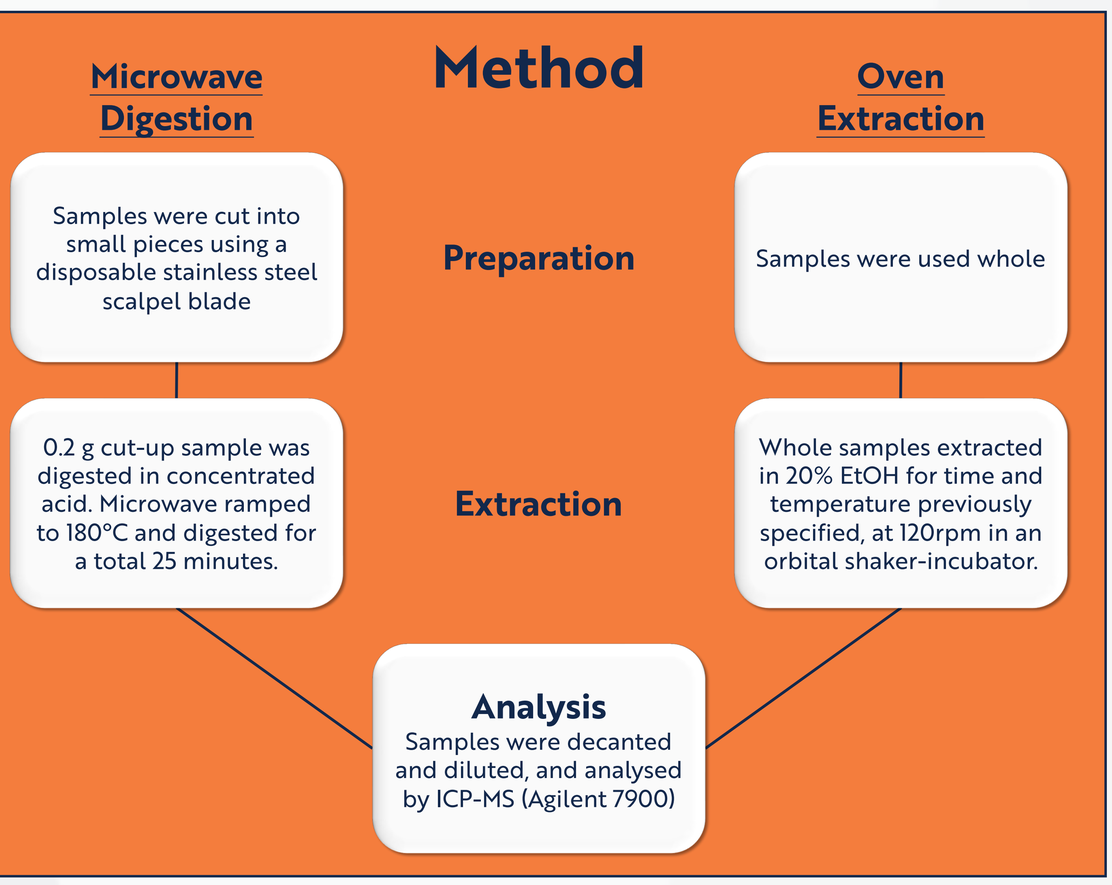
In the UK, tampons are not viewed as medical devices so are not regulated by the Medicines and Healthcare products Regulatory Agency (MHRA). Instead, they must follow The General Product Safety Regulations 2005, but metal testing is not part of these requirements. This poster investigates the safety of tampons, as well as the validity of a study in 2024 that found the presence of 16 metals (including Cd, Pb, As, and Hg) in tampons.[1]

In this project, 7 tampon products of varying brands, absorbency, applicator types, and composition were analysed for 28 elements using Inductively Coupled Plasma Mass Spectroscopy (ICP-MS). Three separate extractions were used:

- Microwave-assisted acid digestion, to obtain a worst-case scenario, full elemental composition of the product.
- 72h exaggerated extraction at 50°C in 20% EtOH (blood simulant) [2], to obtain a cautious estimate of potential extractables.
- 6h simulated extraction at 37°C in 20% EtOH, to represent a realistic use of the product.

ICH Q3D parenteral limits (option 1 – assuming 10g maximum daily dose (MDD)) were used to assess the 24 elements detailed in ICH Q3D(R2),[3] whilst Al, Fe, Mn, & Zn do not have published limits.

Method



Results and Discussion

The figure below shows the mean concentration of element detected for the three different extraction methods, compared with each element's limit.

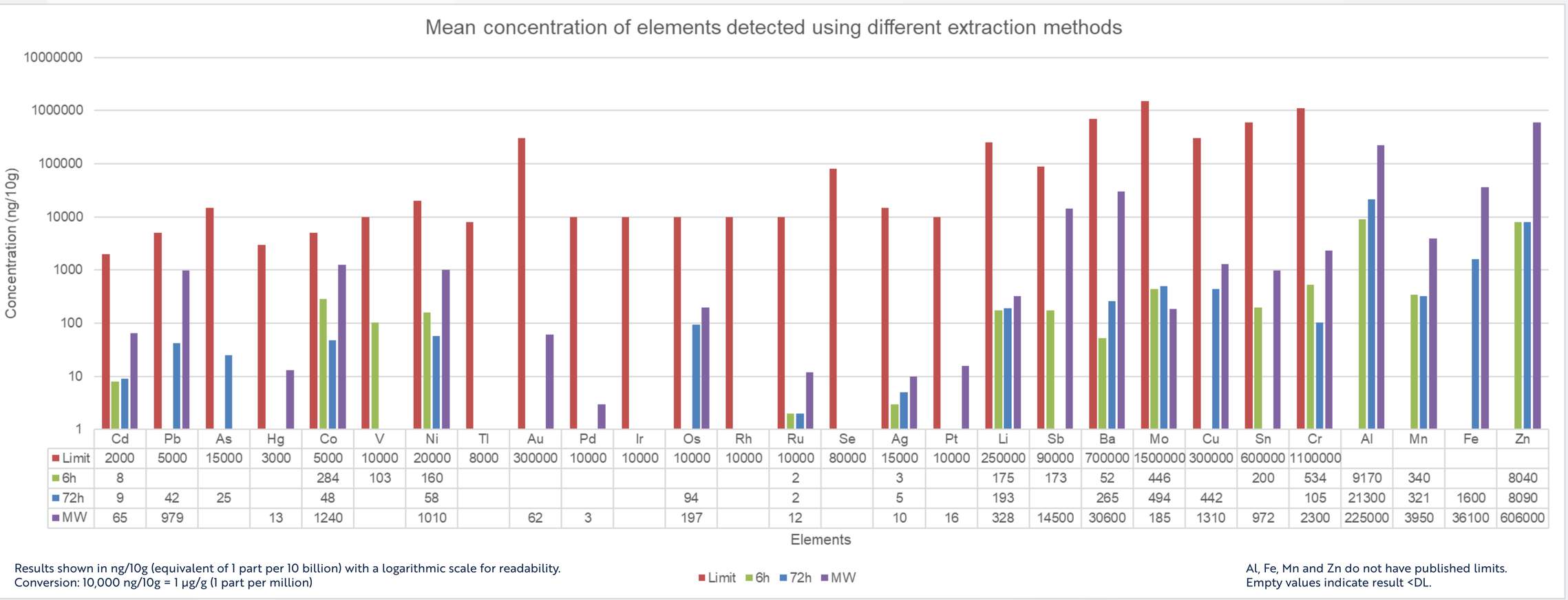
All 24 ICH Q3D elements were found at concentrations less than the limit for parenteral administration, even when fully digesting the sample in concentrated acid. Similar levels were also found in the 2024 study, giving further validity to their results.[1]

No trend was observed for the concentration found between the differing absorbencies of tampons, or by the type of applicator used. Concentrations did vary by brand, with the organic tampon containing higher concentrations of Al, Fe, Mn and Sb, but lower values of Cd, Pb, Li, Ba and Zn. The store own-brand tampon contained higher values of Al, Mn and Sn, whilst a market-leading brand had the lowest value of Sb from those tested. Importantly, all the products individually passed the limits for all elements.

Results vary drastically by extraction method, showing the importance of choosing the correct extraction for the testing required. Acid digestion resulted in concentrations frequently 10x or even 100x greater than simulated-use extractions, with the exaggerated 72h extraction and simulated-use 6h extraction not differing too much from each other.

Although total elemental composition data can be useful for the manufacturer, it does not accurately represent the risk towards the consumer when the product is not being destroyed. A simulated-use extraction is designed to represent the same conditions that the end-product would be used, therefore giving a more realistic representation of that risk.

The simulated-use results show that the risk towards consumers is very low, with all elements found at orders of magnitude less than the limit, with the highest percentage of limit being cobalt at under 6%.



	Cd	Pb	As	Hg	Co	V	Ni	Tl	Au	Pd	Ir	Os	Rh	Ru	Se	Ag	Pt	Li	Sb	Ba	Mo	Cu	Sn	Cr	Al	Mn	Fe	Zn
Limit	2000	5000	15000	3000	5000	10000	20000	8000	300000	10000	10000	10000	10000	10000	80000	15000	10000	250000	90000	700000	1500000	300000	600000	1100000				
6h	8				284	103	160							2		3		175	173	52	446		200	534	9170	340		8040
72h	9	42	25		48		58					94		2		5		193		265	494	442		105	21300	321	1600	8090
MW	65	979		13	1240		1010		62	3		197		12		10	16	328	14500	30600	185	1310	972	2300	225000	3950	36100	606000

Results shown in ng/10g (equivalent of 1 part per 10 billion) with a logarithmic scale for readability.
Conversion: 10,000 ng/10g = 1 µg/g (1 part per million)

Al, Fe, Mn and Zn do not have published limits.
Empty values indicate result <DL.

Conclusion

This poster shows that the extraction method chosen for analysis is very important to the results acquired. If a complete elemental composition is required, then acid digestion is very effective; but an accurate representation of the risk to the consumer for a lot of medical devices is better represented by simulating the conditions of use, or even by an exaggerated extraction.

Establishing limits is also important, not only for the elements currently not covered, but there are also several important routes of administration currently without limits. The body interacts differently with drugs depending on the administration route; so parenteral limits may not be entirely accurate for vaginal or rectal administration, and parenteral/oral limits may not be accurate for ocular administration. Topical/cutaneous limits were recently added to the ICH guidelines, but a wider variety of limits may be useful to better assess patient safety.

References

1. J. A. Shearston et al, *Environ. Int.*, 2024, **190**, 108849.
2. M. A. Jordi et al, *PDA J. Pharm. Sci. Technol.*, 2024, **78**, 560-571.
3. International Council for Harmonisation, 2022, *Guideline for Elemental Impurities Q3D(R2)*.

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