

# Measuring the dissolution profiles of man-made vitreous fibres (MMVF) using an US Pharmacopeia Apparatus 4 (USP-4) system

**Commonly used acronym:** dissolution of MMVF using a USP-4 system

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## Organisation

**Name of the organisation** Eurima is the European Insulation Manufacturers Association

**Department** Health and Safety

**Country** Belgium

Brussels Region

**Geographical Area** Walloon

## SCOPE OF THE METHOD

<b>The Method relates to</b>	Human health
<b>The Method is situated in</b>	Regulatory use - Routine production
<b>Type of method</b>	In vitro - Ex vivo

## DESCRIPTION

## Method keywords

MMVF

In vitro acellular dissolution

US pharmacopeia apparatus 4 (USP-4)

Dissolution profile

fluid

## Scientific area keywords

glass wool

stone wool

biopersistence

durability

## Method description

Fiber biopersistence is a key factor in understanding the pathogenicity of man-made vitreous fibres (MMVF). Today, compliance to Note Q in Annex VI of Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures may only be demonstrated via *in vivo* biopersistence testing. Our method is taking advantage of a US Pharmacopeia Apparatus 4 (USP-4) system, a robust and regulatory accepted system for dissolution testing in pharmaceutical applications. We have found that the USP-4 system can be used for measuring the dissolution profiles of MMVF. Additionally, the USP-4 system, in a closed loop configuration, allows for a clear differentiation between low- and high-solubility glass and stone wool fibres, with good reproducibility between replicates. These findings support the continued development of a USP-4 protocol for MMVF *in vitro* acellular testing. The detailed method can be found under DOI: 10.1016/j.toxlet.2023.09.005

## Lab equipment

- US Pharmacopeia Apparatus 4 (USP-4) system (SOTAX CE7 Smart), equipped with 7 standard 22.6 mm diameter cells and piston pumps (SOTAX CP7–35) with automated sample collection,
- ICP-OES (Agilent Technologies, or equivalent) is used for dissolution measurement

## Method status

Still in development

Internally validated

Published in peer reviewed journal

## PROS, CONS & FUTURE POTENTIAL

### Advantages

Apparatus 4 is built in a standardized manner in order to generate consistent data to support the regulatory approval process of pharmaceutical products. We have found the USP-4 to be a valid tool to generate repeatable results on fibre dissolution. The USP-4 system can be installed on any benchtop. It is automated and performs MMVF dissolution and sampling over a set period of time.

### Modifications

Future investigations using the Apparatus 4 will be focused on studying effects of fluid composition, pH and fibre sample surface area-to-solution volume ratio on MMVF dissolution.

## REFERENCES, ASSOCIATED DOCUMENTS AND OTHER INFORMATION

### References

" Initial evaluation of USP apparatus 4 for measuring dissolution profile of man-made vitreous fibers",  
by J.W.Hoffmann et al. 2023 (DOI : 10.1016/j.toxlet.2023.09.005)

### Associated documents

[Initial-evaluation-of-USP-apparatus-4-for-measuring-dissolut\\_2023\\_Toxicology.pdf](#)

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