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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SCOPE OF THE METHOD

The Method relates to	Human health
The Method is situated in	Regulatory use - Routine production
Type of method	In vitro - Ex vivo
This method makes use of	Other (e.g. bacteria): fluid in a acellular model

DESCRIPTION

Method keywords

MMVF

In vitro acellular dissolution

US pharmacopeia apparatus 4 (USP-4)

Dissolution profile

fluid

Scientific area keywords

glass wool
stone wool
biopersistency
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. Additionnally, the USP-4 system, in a closed loop configuration, allows for a clear differenciation between low- and high-solubility glass and stone wool fibres, with good reproducility 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

PARTNERS AND COLLABORATIONS

Organisation

Name of the organisation Eurima is the European Insulation Manufacturers Association

Department Health and Safety

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Coordinated by

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