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*

Created on: 09-10-2023 - Last modified on: 19-12-2023

Contact person

Léa Hiéronimus

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

The Method relates to	Human health
The Method is situated in	Regulatory use - Routine production
Type of method	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
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

Coordinated by

Financed by