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

<table>
<thead>
<tr>
<th>The Method relates to</th>
<th>Human health</th>
</tr>
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<tbody>
<tr>
<td>The Method is situated in</td>
<td>Regulatory use - Routine production</td>
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<tr>
<td>Type of method</td>
<td>In vitro - Ex vivo</td>
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<tr>
<td>This method makes use of</td>
<td>Other (e.g. bacteria): fluid in a acellular model</td>
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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 diferenciacion 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


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

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