Monocyte activation test

Commonly used acronym: MAT


Contact person
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Organisation

Name of the organisation Sciensano
Department Chemical and physical health risks
Specific Research Group or Service Medicines and health products
Country Belgium
Geographical Area Brussels Region

SCOPE OF THE METHOD

<table>
<thead>
<tr>
<th>The Method relates to</th>
<th>Human health</th>
</tr>
</thead>
<tbody>
<tr>
<td>The Method is situated in</td>
<td>Regulatory use - Routine production</td>
</tr>
<tr>
<td>Type of method</td>
<td>In vitro - Ex vivo</td>
</tr>
<tr>
<td>Specify the type of cells/tissues/organs</td>
<td>Whole human blood cells</td>
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</table>

DESCRIPTION

Method keywords
Pyrogen test
alternative to rabbit pyrogen test
european pharmacopoeia
dotoxins and non-endotoxin pyrogens
Scientific area keywords
quality control of injectable medicines

Method description
The monocyte-activation test (MAT) is used to detect or quantify substances that activate human monocytes or monocytic cells to release endogenous mediators such as pro-inflammatory cytokines, for example tumour necrosis factor alpha (TNFα), interleukin-1 beta (IL-1β) and interleukin-6 (IL-6). These cytokines have a role in fever pathogenesis. Consequently, the MAT will detect the presence of pyrogens (endotoxins on non-endotoxin pyrogens) in the test sample. The MAT is suitable, after a product-specific validation, as a replacement for the rabbit pyrogen test (see European pharmacopoeia chapter 2.6.30). Although 3 methods (quantitative test, semi-quantitative test or reference lot comparison test) are described in the Ph. Eur.

Lab equipment
Biosafety cabinet;
CO2-incubator;
ELISA plate reader.

Method status
Still in development
History of use

PROS, CONS & FUTURE POTENTIAL

Advantages
No rabbits;
ex-vivo test.

Challenges
Proper storage of whole human blood (store only in nitrogen tank, not at minus 80°C).
REFERENCES, ASSOCIATED DOCUMENTS AND OTHER INFORMATION

References

User Manual of the PyroDetect System Monocyte-Activation Test (MAT) from Merck; Monocyte Activation Test guideline from European Pharmacopoeia.