## TEST PARAMETER

<table>
<thead>
<tr>
<th>Characters</th>
<th>Requirements</th>
<th>Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance</td>
<td>Light yellow, viscous oil</td>
<td>Visual</td>
</tr>
</tbody>
</table>

### Identification

- Identification: Must comply Ph.Eur. 1)

### Tests

- **Optical rotation**
  - (2.50 g/25 ml ethanol)
  - Min. –0.01
  - Max. +0.01

- **Acidity**
  - Must comply USP/FCC

- **Lead**
  - Must comply PM0160 2)

### Related substances

- Impurity A
  - Max. 0.5 area %
- Impurity B
  - Max. 1.5 area %
- Impurity C
  - Max. 0.5 area %
- Impurities D + E in sum
  - Max. 1.0 area %
- Any other impurity
  - Max. 0.25 area % each
- Impurities in total
  - Max. 2.5 area %

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1) May also be guaranteed by other means / methods (General Monographs Ph.Eur./USP)

2) Tested every 100th batch.
**Vitamine -E-acetate (DL-alpha-Tocopheryl Acetate) /USP/EP/FCC**

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<th>TEST PARAMETER</th>
<th>REQUIREMENTS</th>
<th>METHOD</th>
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<tbody>
<tr>
<td><strong>Assay</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tocopheryl acetate vs. USP</td>
<td>Min. 96.0 %</td>
<td>PM0827</td>
</tr>
<tr>
<td>standard</td>
<td>Max. 102.0 %</td>
<td></td>
</tr>
<tr>
<td>Tocopheryl acetate (EP)</td>
<td>Min. 96.5 %</td>
<td>Ph. Eur.</td>
</tr>
<tr>
<td></td>
<td>Max. 102.0 %</td>
<td></td>
</tr>
<tr>
<td>Tocopheryl acetate (USP/FCC)</td>
<td>Min. 960 I.U./g</td>
<td>USP/FCC</td>
</tr>
<tr>
<td></td>
<td>Max. 1020 I.U./g</td>
<td></td>
</tr>
</tbody>
</table>

Residual solvents, class 1 (PhEur/USP) are not present due to synthesis.

Only class 2 solvent methanol and class 3 solvent heptane are likely to be present.

Residual class 2 solvents are below the limits given in PhEur/USP and class 3 solvents are below 0.5%.

Vitamin-E-Acetate meets the requirements of the current monographs of:

- Ph.Eur. “all-rac-alpha-Tocopheryl Acetate”
- USP/NF “Vitamin E”
- FCC “all-rac-alpha-Tocopheryl Acetate”

The aforementioned data shall constitute the agreed contractual quality of the product at the time of passing of risk. The data are controlled at regular intervals as part of our quality assurance program. Neither these data nor the properties of product specimens shall imply any legally binding guarantee of certain properties or of fitness for a specific purpose. No liability of ours can be derived therefrom.