Vessel Measurement

- Vessel Centering
- Vessel Verticality (x and y axis)
- Shaft Wobble
- Vessel/paddle Depth

Basket Wobble and Vessel Plate Level Not Shown

Dissolution Mechanical Qualification Specifications and Tolerances

<table>
<thead>
<tr>
<th></th>
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</thead>
<tbody>
<tr>
<td>Basket and paddle depth</td>
<td>25 ± 2 mm</td>
<td>25 ± 2 mm</td>
<td>26 ± 2 mm (or &lt;8%)</td>
<td>23.27 mm</td>
</tr>
<tr>
<td>Rotational speed</td>
<td>± 4% of specified rate</td>
<td>± 2 rpm of target</td>
<td>± 2 rpm or within 2% of target</td>
<td>± 1 rpm of target</td>
</tr>
<tr>
<td>Shaft wobble</td>
<td>No significant wobble</td>
<td>≤ 1.0 mm total runout</td>
<td>≤ 1.0 mm total runout</td>
<td>≤ 1.0 mm total wobble</td>
</tr>
<tr>
<td>Shaft verticality</td>
<td>Not measured</td>
<td>≤ 0.5° from vertical</td>
<td>Within bubble</td>
<td>Not measured</td>
</tr>
<tr>
<td>Basket wobble</td>
<td>± 1 mm</td>
<td>≤ 1.0 mm total runout</td>
<td>≤ 1.0 mm total runout</td>
<td>≤ 1.0 mm total wobble</td>
</tr>
<tr>
<td>Vessel/ shaft centering</td>
<td>NMT 2 mm from center axis</td>
<td>≤ 1.0 mm from center line</td>
<td>≤ 1.0 mm from center line</td>
<td>NMT 2.0 mm difference (4-90° positions)</td>
</tr>
<tr>
<td>Vessel verticality</td>
<td>Not measured</td>
<td>≤ 1.0° from vertical (2-90° positions)</td>
<td>≤ 1.0° from vertical (2-90° positions)</td>
<td>NOM 0.5° from vertical</td>
</tr>
<tr>
<td>Vessel plate level</td>
<td>Not measured</td>
<td>Not measured</td>
<td>Not measured</td>
<td>NOM 0.5° from horizontal</td>
</tr>
<tr>
<td>Performance Verification</td>
<td>USP Prednisone Tablets RS</td>
<td>Not measured</td>
<td>Not measured</td>
<td>USP Prednisone Tablets RS</td>
</tr>
</tbody>
</table>

Accessory Inspection

Accessories can change in form with use. Thus, a critical element of MQ is inspecting the integrity of the dissolution instrument and its accessories prior to starting a test.

Acceptable Accessory Photos

- New stainless paddle
- New PTFE-coated paddle
- New stainless steel basket
- New stainless steel basket shaft

Unacceptable Accessory Photos

- Rusted stainless steel paddle
- Slightly worn PTFE paddle
- Bent stainless steel basket
- Basket shaft with bent prongs
- Badly damaged PTFE-coated paddle
- Damaged PTFE-coated basket
- Damaged stainless steel basket seam
- O-ring stainless steel basket shaft

Pre-run Checklist

- Vessel examination/orientation
- Paddle examination
- Basket/basket shaft examination
- Measurement of initial vessel temperatures
- Evaluation of vibration
- Ensure water bath is clean

Preventive Maintenance Recommendation

Preventative Maintenance should be performed every 6 months. The appropriate internal components should be lubricated, belts checked for wear, and all electrical connections inspected.

Dissolution Hotline

Questions? Contact us for complete method development, regulatory guidance and instrument-related support at dissolution.hotline@agilent.com

Mechanical Qualification Guide

Agilent Technologies

The Measure of Confidence