

# ASTM Program

## Mechanical Qualification & Certification for Dissolution Lab Equipment & Accessories

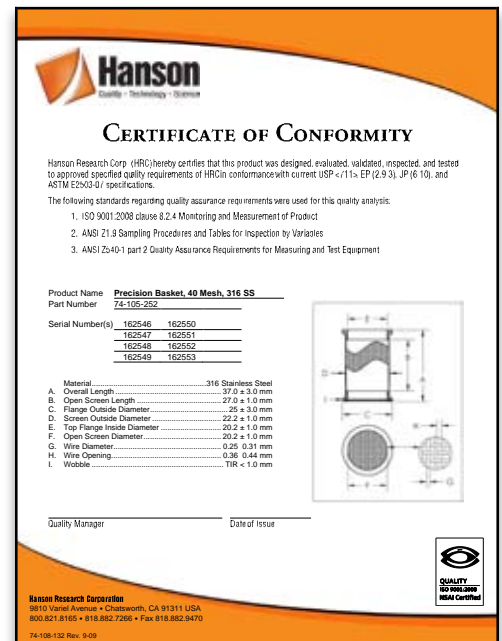
Hanson HRCare provides ASTM E2503-07 mechanical qualification in addition to our comprehensive IQOQPQ, service, and extended warranty programs. While we continue to recommend and provide instrument performance qualification (PQ) with the USP Performance Verification Test (PVT), a rigorous mechanical calibration also carries benefit. To support laboratories that desire to comply with the new ASTM standard, we provide a complete ASTM mechanical qualification and certification program for our equipment and accessories.

Hanson HRCare ASTM mechanical qualification is available for Hanson SR8-Plus™ and Vision® dissolution testers, including units already installed and in use. See “Ordering Information” for more information.



*The Hanson HRCare team is factory-trained and certified on all aspects of instrument qualification, service, and preventive maintenance.*

*USP/ASTM Certificates of Conformity (COC) are available for USP accessories (vessels, paddles, baskets, and shafts), detailing all relevant USP/ASTM dimensions and tolerances. These quality accessories, with corresponding COCs, are required for ASTM.*



## Super Precision Vessels

Recommended for labs requiring ASTM mechanical qualification, Hanson Super Precision vessels are manufactured with a unique proprietary method providing a “super” precision inside diameter and spherical radius. Super Precision vessels come with USP/ASTM Certificates of Conformity (COC) and are available for Hanson SR8-Plus™ and Vision® dissolution testers.

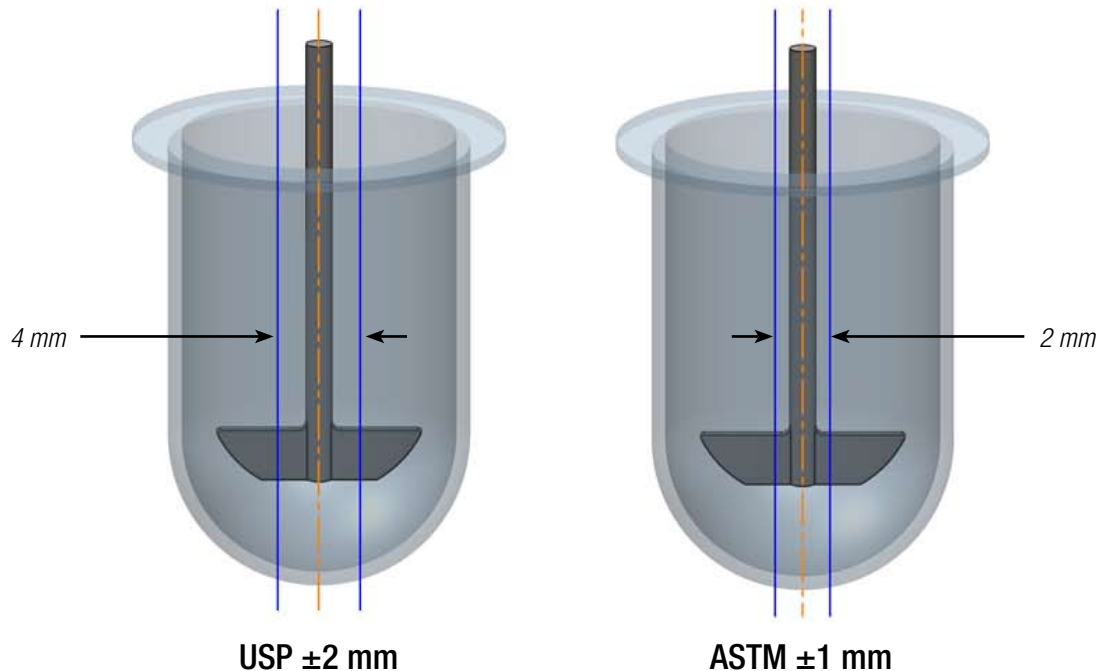


QUALITY  
ISO 9001:2008  
NSAI Certified

Hanson HRCare  
is internationally  
certified to strict  
ISO 9001 standards

## Vessel Center Line Alignment

Generally, ASTM E2503-07 prescribes USP <711> specifications, dimensions, and tolerances. One significant difference is vessel center line alignment of the drive shaft. USP prescribes a mechanical tolerance of  $\pm 2$  mm. ASTM prescribes  $\pm 1$  mm, requiring much tighter mechanical alignment.



## Ordering Information

ASTM mechanical qualification is available for Hanson SR8-Plus™ and Vision® dissolution testers. A suitable preventive maintenance (PM) program is recommended for older equipment, and a convenient “pre-scan” to evaluate previously installed equipment is available prior to full ASTM mechanical qualification. HRCare programs are available to all U.S. customers. Similar programs are available worldwide. *Please consult Hanson for details.*

### ASTM Certificates of Conformity (COC)

Hanson USP accessories (vessels, paddles, baskets, and shafts) are available with ASTM Certificates of Conformity (COC) at time of order. COCs for individual accessories are available on special order. “Range” COCs are available on the Hanson Web site.

p/n	Description
7-909	Individual COC for USP Accessory ( <i>Special Order</i> )
7-910	Document Replacement Service for COC ( <i>Special Order</i> )