



Hanson Policy on ASTM Certificates of Conformity (COC)

As an industry expert and ASTM member, Hanson Research Corp. participated in the formulation of ASTM Standard E2503-07, Standard Practice for Qualification of Basket and Paddle Apparatus, established in 2007. “This practice outlines a procedure for the mechanical calibration of paddle and basket dissolution units to ensure reproducibility of results” (section 2.1).

Hanson provides a Certificate of Conformity (COC) with its USP vessels, paddles, baskets and basket shafts. These COCs provide detailed dimensional verification of conformity to USP <711> dissolution apparatus specifications. Hanson COCs are suitable for use in the mechanical qualification of USP dissolution apparatus pursuant to ASTM E2503-07.

Background on the standard: ASTM E2503-07 section 3.1 stipulates that the analyst is responsible to “Verify the vessel, basket, and paddle dimensions on receipt through measurement or Certificate of Analysis (COA) or *Certificate of Conformity (COC)*.” Sections 4.3.1, 4.3.2 & 4.3.3 require the measurement of dissolution accessories only “*in the absence of a COA or COC*”. Hanson COCs are therefore compliant to the ASTM standard for mechanical qualification of dissolution vessels, paddles, baskets and basket shafts, and further measurement is not required. This compliance has been verified by the Director of USFDA Division of Pharmaceutical Analysis, whose office was instrumental in establishing the ASTM standard.

Hanson provides COCs at no cost to its customers purchasing USP accessories. Standard COCs provide groupings by serial number for each purchased set of accessories. Individual COCs are available upon request at a nominal charge. Range COCs are available on the Hanson website. Certificates of Analysis (COA), showing measurement data of relevant dimensions, are available and will be quoted upon request. Hanson HRCare™ also offers its customers complete ASTM qualification protocols to meet mechanical calibration requirements.

Royal Hanson, CEO

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