Application Of A Dissolution Test Using Crescent-Shaped Spindle (CSS) To Evaluate Assay And Uniformity Of Dosage Units Parameters

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ABSTRACT
To evaluate the use of the CSS to assess the quality parameters from a dissolution test.

METHOD
The dissolution tests were conducted using a Hansen system (SR8-Plus) which met the mechanical and operational specifications. Two stirring approaches were used: (1) USP Paddle spindles and; (2) the Crescent-shape spindle (CSS).

RESULTS
No further tests were conducted for Assays and UDU which were derived from the dissolution test results. Assays and UDU were evaluated as per respective USP approach and CSS approach. The values obtained from the last sampling point to represent Assay and UDU using CSS are presented in Figure 2. Table 1 and Table 2 provide comparison of quality within and between products.

CONCLUSION
Both approaches, using USP Paddle and CSS, provide consistent dissolution results within the acceptable limits.

REFERENCES