Explanatory Note – USP Statement on Prednisone Tablets: Notice of Change in Performance

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Based on reports from stakeholders, USP has confirmed that the release rate of Prednisone Tablets RS, Lot P0E203, in Apparatus 2 is slowing over time. In consequence, USP has adjusted the acceptance criteria for Lot POE203 from 37%–70% to 30%–57% for Apparatus 2. Adjustment was based on statistical analysis of the collaborative study data relative to the more recent information. Performance in Apparatus 1 is unchanged and in consequence the acceptance criteria remain unchanged. USP staff are working with a Subcommittee of the Biopharmaceutics Expert Committee of the Council of Experts and the manufacturer of Lot P0E203, to understand that change in performance of Lot P0E203. These findings will be used to formulate the next lot (Lot Q) of Prednisone Tablets RS. USP will also monitor the continuing performance of Lot P0E203 and adjust the acceptance criteria again if necessary. USP does not believe the change in acceptance criteria alter the value of Lot P0E203 in the conduct of a Performance Verification Test as described in USP General Chapters Dissolution <711>. The primary quality attributes of Lot P0E203, except for release, are unchanged. As USP's investigation of the Prednisone RS Tablet evolves, further information will be forthcoming.