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Evaluation and Establishment of New Quality Specification to Immunoglobulin and Albumin

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***SUMMARY*. The limits of quality specification for the parameter alcohol content, using 50 industrial batches of immunoglobulin and albumin, were calculated employing Bowker's method to get the upper specification limits for three different conditions. All the measurements of the alcohol content as impurity were performed by an enzymatic method. In addition, the behaviour of the parameter alcohol content was evaluated after the quality specification limits were estimated. The results of the follow-up phase of the 30 industrial batches were processed statistically giving best performance for the immunoglobulin. Using the control charts as tool, showed that both process were under a state of statistical control, and tend to be a capable process for immunoglobulin when Q = 99 %.**

KEY WORDS: Albumin, Alcohol content, Bowker's method, Immunoglobulin, Quality specifications.

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