

Title : Verification of Benzethonium Chloride Titrant Standardization for the Assay of Sodium Lauryl Sulfate in accordance with EP Version 11

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ABSTRACT

As part of the revision of the analytical documentation for the raw material Sodium Lauryl Sulfate, a key ingredient in toothpaste formulations, in accordance with the European Pharmacopoeia Version 11, the procedure for standardizing the benzethonium chloride solution used in the Assay section has been modified. Therefore, a method verification study was conducted to ensure the accuracy, reliability, and practical applicability of the new procedure. The objective was to validate the preparation and standardization method of 0.004 M benzethonium chloride solution and to update the assay documentation for Sodium Lauryl Sulfate to align with the revised pharmacopoeial standard. The benzethonium chloride solution was prepared and standardized, resulting in an actual concentration of 0.0038 M. It was then applied in the assay testing of Sodium Lauryl Sulfate raw materials A and B. For raw material A, the average %Assay from three replicates was 94.04%, meeting the acceptance criterion of $\geq 85\%$. For raw material B, the average %Assay from three replicates was 95.60%, meeting the acceptance criterion of $\geq 92\%$. These results confirm that the new standardization method for 0.004 M benzethonium chloride solution is accurate and suitable for use, and the assay documentation for Sodium Lauryl Sulfate has been updated accordingly to comply with the European Pharmacopoeia Version 11.

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