International Pharmaceutical Excipients Council of the Americas

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Chair

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Cc: Catherine Sheehan
Hong Wang
John Giannone

Re: Glucose, Liquid PF 47(1)

Dear Dr. Saladi,

Members of the International Pharmaceutical Excipients Council of the Americas (IPEC-Americas) have reviewed revision to the Glucose, Liquid monograph as published in PF 47(1). IPEC-Americas appreciates the opportunity to provide comments for the proposed revision.

IPEC-Americas Background

IPEC-Americas represents more than 50 excipient manufacturers, distributors and pharmaceutical/biopharma companies to support the safe production and use of excipients. This letter represents the IPEC-Americas membership. A complete list of IPEC-Americas member companies can be found at: https://ipecamericas.org/what-ipec-americas/member-companies. IPEC-Americas is dedicated to working closely with regulatory authorities, industry organizations and scientific bodies (globally) to advance public health on matters relating to the quality, safety, manufacture, distribution, use and functionality of excipients. IPEC is the sole association representing excipients.

IPEC-Americas Comments

IPEC-Americas supports USP monograph modernization to implement more specific assay test methods (e.g. replacing titration-based methods with chromatographic methods). However, transferring the current titration-based assay method to the identification section creates an unnecessary redundancy and wastes stakeholder resources. The proposed chromatographic assay method provides more specific means of identification and eliminates the redundancy. Therefore, the proposed chromatographic assay procedure should be utilized for Identification Test A.

> **Identification Test A.** It meets the requirements in the Assay for Dextrose Equivalent.

Further, several inconsistencies in terminology were noted and should be corrected as shown below in red text.

- Assay Methodology – The degree of polymerization DP_9, DP_{10} and DP_{11} are not defined in the table footnote and there is no explanation as to why or how a flexible system suitability requirement is being provided. Further information should be provided to clarify intent.

  Suitability requirements

  Resolution: NLT 2.0 between dextrose and maltose peaks; NLT 0.5 between DP_9 and DP_{10} (or DP_{10} and DP_{11})

- Assay Acceptance Criteria – The documentation of the acceptance criteria should be consistent between the Assay and Definition. Since the dextrose equivalent is not defined with specific units, the range should be clearly described.

  DEFINITION

  Liquid Glucose is a product obtained by the incomplete hydrolysis of starch. It consists chiefly of dextrose, dextrins, maltose, and water. The dextrose equivalent (DE) of Liquid Glucose is NLT 20 and NMT 100, and 90.0%–110.0% of the labeled value on the anhydrous basis.

  ASSAY

  Acceptance criteria: The dextrose equivalent (DE) of Liquid Glucose is NLT 20 and NMT 100 ~~20–100~~, and 90.0%–110.0% of the labeled value on the anhydrous basis

IPEC-Americas recognizes the efforts of the USP and other pharmacopeias, to continually improve, harmonize, and modernize excipient monographs. Please consider the IPEC-Americas recommendations before implementation. We look forward to continued collaboration on the development of global standards which ensure the quality and safety of excipients.

Respectfully yours,

Janeen Skutnik-Wilkinson
Chair, IPEC-Americas