

Diethylene Glycol Stearates

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Expert Committee	Complex Excipients

In accordance with the Rules and Procedures of the Council of Experts, the Complex Excipients Expert Committee has revised the Diethylene Glycol Stearates monograph. The purpose of this revision is to widen the *Acceptance criteria* in the test for *Fats and Fixed Oils (401)*, *Saponification value* from 150–170 to 150–180. The increase of the upper limit of the *Saponification value* is the result of lowering the content of free diethylene glycol, a toxic compound, in Diethylene Glycol Stearates. This change will make Diethylene Glycol Stearates with lower content of diethylene glycol available to drug product manufacturers as well as align the upper limit of *Saponification value* with that in the *European Pharmacopoeia 10.6* monograph for Diethylene Glycol Palmitostearate.

Additionally, in the monograph *Definition*, ethylene glycol was incorrectly listed as one of the compounds used in reaction of condensation to manufacture Diethylene Glycol Stearate. It is replaced with diethylene glycol.

Additionally, minor editorial changes have been made to update the monograph to current *USP* style.

The Diethylene Glycol Stearates Revision Bulletin supersedes the currently official monograph.

Should you have any questions, please contact Galina Holloway, Principal Scientist (301-816-8133 or gvh@usp.org).