



Informal Commentary

Limit of Ethylene Glycol (EG) and Diethylene Glycol (DEG) in Maltitol Solution April 2010

Monograph/Section(s): Maltitol Solution/Identification C: Limit of EG and DEG

Expert Committee(s): Excipient Monographs 1

No. of Commenters: 1

Comment Summary #1: In the *System suitability* section, the commenter indicated that if a relative retention time was included in the table outlining the Relative Retention Times (RRT) for the major components, then a qualifying statement that RRTs are provided for information only, and that the standards should be used to ensure appropriate peak identification, could also be included.

Response: Comment incorporated. The Expert Committee added a statement in the NOTE, "Relative retention times are provided for information only, and the standards should be used to ensure appropriate peak identification." The EC agrees that since RRTs are provided for information only, the qualifying statement will help to clarify concerns regarding slight variations in the Relative Retention Times depending on the chromatographic conditions of use.