

〈Regular Article〉

## Determination of Ethylene Glycol and Diethylene Glycol as the Adulterant in Concentrated Glycerin, Glycerin and Propylene Glycol

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### Abstract

Due to a fatal accident that occurred in 2006 for diethylene glycol (DEG) adulterated in glycerin, the Pharmaceutical and Food Safety Bureau in the Ministry of Health, Labour and Welfare (MHLW) has notified the partial revision of the purity test of Glycerin in the Japanese Standards of Quasi-Drug Ingredients (JSQI) 2006 at the Notification No. 1221004 on February 21, 2008. Since the fatal accidents caused by the contamination of syrup with DEG also occurred in 2009, USP proposed the purity test of concentrated glycerin, glycerin and propylene glycol about ethylene glycol (EG) and DEG as the adulterant instead of the purity test of concentrated glycerin and glycerin about DEG on May 21, 2009 to the Pharmacopoeial Discussion Group. In response to this, the Expert Committee on Excipients on JP made the decision to establish the new modified method. This paper proposes the new modified method of DEG including EG for the purity test in concentrated glycerin, glycerin and propylene glycol in JSQI 2006. This analytical method was the gas chromatographic method by using the fused-silica column 0.32 mm × 30 m coated with 14% cyanopropylphenyl/86% methylsilicon polymer and the column temperature for injecting at a constant temperature of about 100°C and raising at the ratio of 7.5°C per minute to 220°C. The retention times of EG, propylene glycol, DEG and glycerin were 2.45, 2.78, 6.02 and 7.66 minutes, respectively. The working curves of EG and DEG were the good correlation between their concentrations of 2.5 to 80 μg/ml and the peak areas. The resolutions between EG and DEG, and between DEG and glycerin were not less than 70 and not less than 20, respectively. Also those between EG and propylene glycol, and between propylene glycol and DEG were not less than 6 and not less than 60, respectively. The quantitation limits of EG and DEG in glycerin were 0.005% and 0.01%.

**Key words:** ethylene glycol, diethylene glycol, glycerin, propylene glycol, adulterant.