

U.S. PHARMACOPEIA

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Polyoxyl 40 Hydrogenated Castor Oil

» Polyoxyl 40 Hydrogenated Castor Oil contains mainly the tri-hydroxystearate ester of ethoxylated glycerol, with smaller amounts of polyethylene glycol tri-hydroxystearate and of the corresponding free glycols. It results from the reaction of glycerol tri-hydroxystearate with about 40 to 45 moles of ethylene oxide.

Packaging and storage— Preserve in tight containers.

Identification—

A: Dissolve about 0.1 g in 1 mL of water, add 9 mL of sodium chloride solution (1 in 20), and heat in a water bath: the solution becomes turbid at a temperature between 70° and 85°.

B: Dissolve about 0.1 g in 10 mL of [alcoholic potassium hydroxide TS](#), boil for about 3 minutes, and evaporate to dryness. Mix the residue with 5 mL of water: it dissolves, yielding a clear solution. Add a few drops of glacial acetic acid: a white precipitate is formed.

Congealing temperature [〈 651 〉](#): between 16° and 26°.

Acid value [〈 401 〉](#): not more than 2.0.

Hydroxyl value [〈 401 〉](#): between 60 and 80.

Iodine value [〈 401 〉](#): not more than 2.0.

Saponification value [〈 401 〉](#): between 45 and 69.

Water, Method I [〈 921 〉](#): not more than 3.0%.

Residue on ignition [〈 281 〉](#): not more than 0.3%.

Heavy metals, Method II [〈 231 〉](#): 0.001%.

Organic volatile impurities, Method I [〈 467 〉](#): meets the requirements.

Residual solvents [〈 467 〉](#): meets the requirements.

(Official January 1, 2007)

Auxiliary Information— *Staff Liaison*: [Hong Wang, Ph.D., Senior Scientific Associate](#)

Expert Committee : (EM205) Excipient Monographs 2

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Phone Number : 1-301-816-8351