

U.S. PHARMACOPEIA

Amorphous Core
Amorphous C-Co

Amorphous core,
Nanocrystalline core C-co
(cuts) E-core, Block Core

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Sorbitan Trioleate

» Sorbitan Trioleate is the triester of Oleic Acid and Sorbitol and its mono- and dianhydrides. It yields, upon saponification, not less than 85.5 percent and not more than 90.0 percent of fatty acids, and not less than 13.0 percent and not more than 19.0 percent of polyols (w/w).

Packaging and storage— Preserve in tight containers.

USP Reference standards 〈 11 〉 — [USP Isosorbide RS](#). [USP 1,4-Sorbitan RS](#).

Identification— It responds to *Identification* tests *A* and *B* under [Sorbitan Monooleate](#).

Acid value 〈 401 〉 : not more than 17.

Hydroxyl value 〈 401 〉 : between 50 and 75.

Iodine value 〈 401 〉 : between 77 and 85.

Saponification value 〈 401 〉 : between 169 and 183.

Water, Method I 〈 921 〉 : not more than 0.7%.

Residue on ignition 〈 281 〉 : not more than 0.25%.

Heavy metals, Method II 〈 231 〉 : 0.001%.

Residual solvents 〈 467 〉 : meets the requirements.

(Official January 1, 2007)

Assay for fatty acids— Transfer about 8.6 g of Sorbitan Trioleate, accurately weighed, to a 500-mL conical flask, cautiously add 100 mL of alcohol and 3.5 g of potassium hydroxide, then add a few glass beads, and mix. Proceed as directed for [Assay for fatty acids](#) under [Sorbitan Monooleate](#), beginning with “Connect a suitable condenser.”

Assay for polyols— Proceed as directed for [Assay for polyols](#) under [Sorbitan Monooleate](#).

Auxiliary Information— *Staff Liaison* : [Catherine Sheehan, B.Sc., Scientist](#)

Expert Committee : (EM105) Excipient Monographs 1

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Phone Number : 1-301-816-8262