

Status: Currently Official on 14-Feb-2025
Official Date: Official Prior to 2013
Document Type: NF Monographs
DocId: GUID-B2581D5A-6BCF-4773-97BA-E3AC47D6BDF9_1_en-US
DOI: https://doi.org/10.31003/USPNF_M32630_01_01
DOI Ref: kvf2j

© 2025 USPC
Do not distribute

Hard Fat

DEFINITION

Hard Fat is a mixture of glycerides of saturated fatty acids.

IMPURITIES

- [RESIDUE ON IGNITION \(281\)](#): NMT 0.05%
- **ALKALINE IMPURITIES**
Sample: 2.0 g
Analysis: Dissolve the *Sample* in a mixture of 1.5 mL of alcohol and 3.0 mL of ether. Add 0.05 mL of bromophenol blue TS, and titrate with 0.01 N hydrochloric acid to a yellow endpoint.
Acceptance criteria: NMT 0.15 mL of 0.01 N hydrochloric acid

SPECIFIC TESTS

- [MELTING RANGE OR TEMPERATURE, Class II\(741\)](#): The melting temperature does not differ by more than 2° from the nominal value given in *Labeling*.
- [FATS AND FIXED OILS, Acid Value\(401\)](#): NMT 1.0
- [FATS AND FIXED OILS, Hydroxyl Value\(401\)](#): NMT 70
- [FATS AND FIXED OILS, Iodine Value\(401\)](#): NMT 7.0
- [FATS AND FIXED OILS, Saponification Value\(401\)](#): 215–255
- [FATS AND FIXED OILS, Unsaponifiable Matter\(401\)](#): NMT 3.0%

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in tight containers at a temperature that is 5° or more below the melting range stated in the labeling.
- **LABELING:** The labeling includes the nominal melting temperature, which is 27°–44°.

Auxiliary Information - Please [check for your question in the FAQs](#) before contacting USP.

Topic/Question	Contact	Expert Committee
HARD FAT	Documentary Standards Support	CE2020 Complex Excipients

Chromatographic Database Information: [Chromatographic Database](#)

Most Recently Appeared In:

Pharmacopeial Forum: Volume No. Information currently unavailable

Current DocID: GUID-B2581D5A-6BCF-4773-97BA-E3AC47D6BDF9_1_en-US

DOI: https://doi.org/10.31003/USPNF_M32630_01_01

DOI ref: [kvf2j](#)