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Caramel

DEFINITION

Caramel is a concentrated solution of the product obtained by heating sugar or glucose until the sweet taste is destroyed and a uniform dark brown mass results, a small amount of alkali or of alkaline carbonate or a trace of mineral acid being added while heating.
[NOTE—Where included in articles for coloring purposes, Caramel complies with the regulations of the FDA concerning color additives (21 CFR 73.85, caramel).]

IMPURITIES

Change to read:

- ▲ [ARSENIC \(211\), Procedures, Procedure 2](#) ▲ (CN 1-JUN-2023) : NMT 3 ppm

Change to read:

- ▲ [LEAD \(251\), Procedures, Procedure 1](#) ▲ (CN 1-JUN-2023) : NMT 10 ppm
- ▲ **ASH:** It swells when incinerated, and forms a coke-like charcoal that burns off only after prolonged heating at a high temperature. It yields NMT 8.0% of ash.

SPECIFIC TESTS

- ▲ [MICROBIAL ENUMERATION TESTS \(61\)](#) and [TESTS FOR SPECIFIED MICROORGANISMS \(62\)](#): Meets the requirements of the tests for absence of *Salmonella* species and *Escherichia coli*
- ▲ [SPECIFIC GRAVITY \(841\)](#): NLT 1.30
- ▲ **PURITY:** The addition of 0.5 mL of phosphoric acid to 20 mL of a solution (1 in 20) produces no precipitate.

ADDITIONAL REQUIREMENTS

- ▲ **PACKAGING AND STORAGE:** Preserve in tight containers.

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

Topic/Question	Contact	Expert Committee
CARAMEL	Documentary Standards Support	SE2020 Simple Excipients

Chromatographic Database Information: [Chromatographic Database](#)

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. Information currently unavailable

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