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Colestipol Hydrochloride for Oral Suspension

» Colestipol Hydrochloride for Oral Suspension is a mixture of Colestipol Hydrochloride with a suitable flow-promoting agent. Each g binds not less than 1.1 mEq and not more than 1.6 mEq of sodium cholate, calculated as the cholate binding capacity.

Packaging and storage—Preserve in tight, single-dose or multiple-dose containers.

USP Reference standards ⟨11⟩—
USP Colestipol Hydrochloride RS

Change to read:

Identification, ▲**Spectroscopic Identification Tests ⟨197⟩, *Infrared Spectroscopy*: 197K**▲ (CN 1-May-2020) —Prepare the test specimen and the Standard specimen by mixing about 5 mg of Colestipol Hydrochloride for Oral Suspension and 5 mg of USP Colestipol Hydrochloride RS, respectively, with about 100 to 125 mg of potassium bromide.

Minimum fill ⟨755⟩: meets the requirements for powders.

Water-soluble substances—Transfer 5.0 g of Colestipol Hydrochloride for Oral Suspension, accurately weighed, to a glass-stoppered, 125-mL conical flask, add 80.0 mL of water, insert the stopper in the flask, and mount the flask in a water-bath shaker maintained at 37 ± 1°. Operate the shaker for 72 hours, remove the flask from the shaker, and filter the contents twice—first through a premoistened 0.45-µm nylon membrane filter and then through a 0.45-µm PVDF filter, collecting the filtrate in a tared 100-mL fused quartz crucible. Rinse any residual test material in the flask with two 5-mL portions of water, pass the washings through the filters, and combine the filtrates from the washings with the filtrate from the test mixture. Evaporate the filtrate to dryness, filtered air or nitrogen being used, if necessary, to aid in the evaporation. Dry the residue in a vacuum oven maintained at 75° for 1 hour, allow to cool in a desiccator, and weigh. Calculate the initial percentage of water-soluble substances in the portion of Colestipol Hydrochloride for Oral Suspension taken. Again heat the residue in a muffle furnace maintained at 800 ± 25° for 4 hours, allow to cool in a desiccator, and weigh. Calculate the percentage of inert ingredients present. Calculate the actual percentage of water-soluble substances in the portion of Colestipol Hydrochloride for Oral Suspension taken by subtracting the percentage of inert ingredients from the initial percentage of water-soluble substances found. Not more than 0.5% of water-soluble substances is found.

Other requirements: meets the requirements of the tests for *Cholate binding capacity* and *pH* under *Colestipol Hydrochloride*.

Auxiliary Information - Please check for your question in the FAQs before contacting USP.

Topic/Question	Contact	Expert Committee
COLESTIPOL HYDROCHLORIDE FOR ORAL SUSPENSION	Documentary Standards Support	SM22020 Small Molecules 2

Chromatographic Database Information: Chromatographic Database

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