packaging components than water), additional extractable information may be needed to address safety issues. If additional information is required, perform *Extractable Metals* and *Plastic Additives* tests as directed in *Table 2*.]

Table 1. Guidelines for Application of Tests for Oral and Topical Dosage Forms

Biological Reactivity Tests	Chemical Tests
• Perform *Biological Reactivity Tests, In Vitro* ⟨87⟩ • Materials that meet the requirements of this test are not required to undergo testing as described in *Biological Reactivity Tests, In Vivo* ⟨88⟩ • Materials that do not meet the requirements of the in vitro test are not suitable for these dosage forms	• Perform *Identification*, *Physicochemical*, and *Extractable Metals* tests • Provide appropriate reference to the Indirect Food Additive regulations in 21 CFR 174–186, specifically those addressing the purity criteria and limitations pertaining to use • Materials that do not meet these requirements are not suitable for packaging for these dosage forms unless the materials are established to be suitable by other means that have been approved by an appropriate regulatory authority

Table 2. Guidelines for Application of Tests for All Other Dosage Forms

Biological Reactivity Tests	Chemical Tests
• Perform *Biological Reactivity Tests, In Vitro* ⟨87⟩ • Perform *Biological Reactivity Tests, In Vivo* ⟨88⟩ to obtain the appropriate *Classification of Plastics* • Materials that do not meet the requirements of the in vivo or the in vitro tests are not suitable for containers for these dosage forms	• Perform *Identification*, *Physicochemical*, *Extractable Metals*, and *Plastic Additives* tests • Materials that do not meet these requirements are not suitable for containers for these dosage forms unless the materials are established to be suitable by other means that have been approved by an appropriate regulatory authority

Change to read:

SPECIFICATIONS

Polyethylene

IDENTIFICATION

Low-density polyethylene
Infrared spectrophotometry—Determine the infrared spectrum from 3800 cm^{-1} to 650 cm^{-1} (2.6–15 μm). The specimen exhibits an absorption spectrum that is substantially equivalent to that of the USP Low-Density Polyethylene RS. Substantial, as opposed to exact, equivalence allows for minor spectral differences arising from the natural compositional and/or physical variation among polymers of this class. Substantial equivalence is achieved when all differences between the sample and Reference Standard spectra can be explained in the context of such natural compositional and/or physical variations.
Differential scanning calorimetry—The thermogram of the specimen is similar to the thermogram of USP Low-Density Polyethylene RS, and the transition temperature (T_g) obtained from the thermogram of the specimen does not differ from that of the Reference Standard by more than 8.0°.
High-density polyethylene
Infrared spectrophotometry—Determine the infrared spectrum from 3800 cm^{-1} to 650 cm^{-1} (2.6–15 μm). The specimen exhibits an absorption spectrum that is substantially equivalent to that of USP High-Density Polyethylene RS. Substantial, as opposed to exact, equivalence allows for minor spectral differences arising from the natural compositional and/or physical variation among polymers of this class. Substantial equivalence is achieved when all differences between the sample and Reference Standard spectra can be explained in the context of such natural compositional and/or physical variations.
Differential scanning calorimetry—The thermogram of the specimen is similar to the thermogram of USP High-Density Polyethylene RS, and the transition temperature (T_g) obtained from the thermogram of the specimen does not differ from that of the Reference Standard by more than 6.0°.

PHYSICOCHEMICAL TESTS

Absorbance: Maximum absorbance is 0.2.
Acidity or alkalinity: NMT 1.5 mL of 0.01 N sodium hydroxide is required to change the color of the indicator to blue. NMT 1.0 mL of 0.01 N hydrochloric acid is required to reach the beginning of the color change of the indicator from yellow to orange.
Total organic carbon: The difference between the sample and blank TOC concentrations is NMT 5 mg/L.

EXTRACTABLE METALS

Aluminum: *Solution S3* (see *Table 3*) contains NMT 0.4 mg/L (ppm), corresponding to 1 μg/g.