

10388 COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY

6505-926-9055 (P. D. No. 3)

3.1.4.4 Index of refraction. The index of refraction of the elixir shall be not less than 1.4380 and not more than 1.4430 when measured on a suitable refractometer at 25° C.

3.1.4.5 Free p-aminophenol. The acetaminophen elixir shall contain not more than 0.05 percent of free p-aminophenol based on the amount of acetaminophen present when determined as described in 4.4.1.2.

3.2 Color. The elixir shall be red in color.

3.3 Flavor and palatability. The elixir shall be cherry flavored, and shall be palatable and pleasant to the taste with no unpleasant aftertaste. Not later than the time specified for opening of bids or receipt of proposals, the offeror shall submit to the contracting officer six (6) individually packaged samples (each containing 4 fl oz) of Acetaminophen Elixir representative of the product which the offeror proposes to furnish. Two (2) samples will be subjected to panel testing for a determination of palatability (see 4.4.1.3 Palatability Test). The remaining samples will be used by cognizant Government inspection and quality assurance activities for determining compliance of supplies furnished hereunder with the palatability requirement. Approval as to palatability of any sample submitted by the offeror will not constitute approval of the sample as to any other requirement of this specification. The requirement for submission of samples for use in determining compliance with the palatability requirement may be waived, provided the offeror states, in his bid or proposal, that the product he proposes to furnish is the same product he has offered to the purchasing activity on a previous procurement and the contracting officer determines that such product was previously procured and/or tested by the purchasing activity and found to comply with the palatability requirement.

3.4 Clarity. Shall be clear and free from undissolved or particulate matter.

3.5 Color stability. The color of the elixir shall not decrease in intensity (fade), as measured by visual comparison with fresh elixir after being subjected to the following conditions: Put 15 cc of the Acetaminophen elixir in half-ounce, colorless, flint-glass bottle and place under a G.E. lamp RS 275 Watt, 110-125 volt, 60 cycle, or equivalent lamp, at a distance of 18 inches for 48 hours. Maintain elixir temperature at 27° to 28° C.

3.6 Stability to cold. There shall be no crystallization of any of the ingredients, and no change in clarity of the elixir after being subjected to the following test: Put 15 cc of the Acetaminophen elixir in a half-ounce bottle and place under refrigeration at 5° C. for 5 days.