

Ingredients Statements

Approved Ingredients Statements*

Each [unit] contains: [established name] 000 mg.

Contains no preservatives.

Design Guidelines for Ingredients Statements

Font family Helvetica Neue Std.

Font weight Light.

If space constraints: Light Condensed.

Font size

7–10 point suggested. Panel size dependent.

Relational size

All Descriptive Text must be the same size.

Placement

Preferred: Back panel within Descriptive Text block (see Preferred Order of Descriptive Text).

Alternate: Left side panel.

Spacing between lines (leading): When statements are longer than one line, baseline to baseline spacing between lines will be 110–120% of font size.

Spacing between paragraphs (paragraph leading): Baseline to baseline spacing between paragraphs will be 150–200% of font size.

Alignment: Left aligned.

Margins

Margins from all edges of carton panels must range from 1/8" (3 mm; 9 points) to 1/4" (6 mm; 18 points).

Spacing between columns of Descriptive Text (gutter) must range from 5/32" (4 mm; 12 points) to 1/4" (6 mm; 18 points).

Color

Light background color: Black.

Dark background color: Reverse to white.
Font weight should change to Medium.

Preferred Order of Descriptive Text

- 1) Ingredients Statements
- 2) Dosage Statements
- 3) Product Storage, Handling, and Use Statements
- 4) Temperature Storage Statements
- 5) Patient's Instructions for Use Statements
- 6) Warning Statements
- 7) Child Caution Statements

Paragraph treatment: Ingredients Statements, as well as each Descriptive Text category, should be a separate paragraph.

Reference

21 CFR Section 201.10. Drugs; statement of ingredients.

*Other formulation ingredients may be needed.