

# TECHNICAL DATA SHEET

**Product:** Alpha-Pro<sup>®</sup> Acidulated Phosphate Fluoride (APF) Gel

**Product Description:** A 1.23% acidulated phosphate fluoride (APF) topical gel intended to aid in the prevention of dental caries.

**Indications for Use:** Designed to aid in the prevention of dental caries.

**Appearance:** A soft gel available in red and orange colors.

**Curing Mechanism:** Not applicable.

**Shelf-Life:** 36 months.

**Filler Type:** None.

**Main Composition (%w/w):**

<u>Components</u>	
Deionized Water	90-95
Thickener	<5
Acid	<2
Flavoring	<1
Colorants	<1
Preservative	<1
Sweetener	<1

Active Ingredient

1.23% Fluoride Ion (1.17% from Sodium Fluoride and 0.06% from Hydrogen Fluoride) in 0.1 molar Phosphoric Acid solution.

**Physical /Mechanical Properties:** (Typical Values)

Appearance:	Homogeneous, opaque to semi-translucent gel
Flavor:	Strawberry and vanilla orange
Color:	Red and orange
pH:	3.58
Specific Gravity:	1.0275
Viscosity, cP:	10,000
Fluoride Ion, %:	1.305

**Regulatory Classification:**

This product is in conformity with the following standard(s) or other normative documents:

*Code of Federal Regulations, 21 CFR Part 211 – Current good manufacturing practice for finished pharmaceuticals*

*USP36 (2013) – Sodium Fluoride and Phosphoric Acid Gel*