



TECHNICAL DATA SHEET

Product: Alpha-Pro® 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

Current USP Monograph – Sodium Fluoride and Phosphoric Acid Gel

Signature/ Date: John Pontikis / 10/25/18

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