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This **RESIDUAL SOLVENT STATEMENT** is being provided to confirm residual solvents for the material listed below based on guidance relating to residual solvents in medicinal products and their components (commonly referred to as Q3C) in accordance with The International Conference on Harmonization (ICH).

Product Name: Ticaloid GF 313

Product Number (New): 385|4929

**Product Code (Old):** TICA GF-313 Ingredients: Cellulose Gum, Xanthan Gum Ticaloid GF 313 is a blend of Blend Components.

## **Isopropyl Alcohol**

Isopropyl alcohol is used as a processing aid during the manufacture of this ingredient. Isopropyl alcohol is considered a Class 3 solvent in accordance with USP<467>. No class one, two or other solvents are used during the manufacture of this ingredient. The maximum concentration of isopropyl alcohol meets the FCC specification of no more than 750 ppm.

## **Formic Acid**

Formic Acid is used as a processing aid during the manufacture of this ingredient. Formic Acid is considered a Class 3 solvent and is present at less than the 0.5% allowable limit listed in USP<467>.

Thank you for your continued interest in our products.

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