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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 451 "T" Powder

**Product Number (New):** 38424904

**Product Code (Old):** COLL 451 T

Ticaloid 451 "T" Powder is a blend of Xanthan Gum, Sodium Alginate, Guar Gum.

### **Xanthan Gum**

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 0.075%.

### **Sodium Alginate**

Ethyl alcohol is used as a processing aid during the manufacture of this ingredient. Ethyl 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 ethyl alcohol is no more than 0.5%.

### **Guar Gum**

No class one, two, three or other solvents have been used in the manufacture, handling or storage of this ingredient.

Thank you for your continued interest in our products.

*North America Quality Assurance*

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