

Pharmaceutical Products – Melamine Content Certification

The following products are not manufactured utilizing melamine and nothing in the raw materials, process or chemistry of these polymers generates melamine as residuals, by-products, or from side reactions. As explained in the FDA guidance document, "*Pharmaceutical Components at Risk for Melamine Contamination*," "the term *at-risk components* (for melamine contamination) include those ingredients or raw materials that rely on a test for nitrogen content for their identity or purity or strength and that contain nitrogen in amounts greater than 2.5%."

Test for nitrogen content is not part of testing conducted for their identity or purity or strength and they are not considered at-risk components for melamine contamination. Consequently, melamine is neither expected nor tested for in these products. We do not routinely analyze purchased raw materials or products we manufacture for melamine; however, melamine is not expected to be present in the products at 0.1 wt.% or greater, either intentionally or as an impurity, based on information received from our suppliers and knowledge of our manufacturing processes.

Carbopol [®] 71G NF polymer	Carbopol [®] Ultrez 10 NF polymer	
Carbopol [®] 971P NF polymer	Carbopol [®] ETD 2020 NF polymer	
Carbopol [®] 974P NF polymer	Noveon [®] AA-1 Polycarbophil USP	
Carbopol [®] 980 NF polymer	Pemulen™ TR-1 NF polymer	
Carbopol [®] 981 NF polymer	Pemulen™ TR-2 NF polymer	

Carbopol[®] 5984 EP polymer

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