

2.3.S.6 Container/Closure System

The container closure system for KN035 DS is 50-L LDPE Bioprocess Container (Hyclone, Cat# SH30667.01). According to the manufacturer, This BPC container have been qualified and passed the tests for biological compatibility including cytotoxicity and systemic toxicity as per USP <87> and USP <88>. Its physicochemical testing was tested as per USP <661>.