

Recommendation for Pending USP method of Azacitidine for Injection

As the manufacture of Orosil C18 column, we suggest several modifications of the pending USP method of Azacitidine for Injection, based on our own test result and our customers' comments:

1. HPLC column for Impurities: pending method recommends 3 μ m 250x4.6 mm column. This type of column gives very high back pressure, esp. at end of the run with methanol in the mobile phase. We suggest changing the column size to 3 μ m 150x4.6 mm, or 200x4.6mm.
2. Sodium bisulfite is soluble in water; however, it is less soluble in acetonitrile and methanol. Current method uses sodium bisulfite as diluent, which is deposited on the column slowly. We suggest adding a guard column in the method to prevent damage of the HPLC column.
3. Due to the same reason 2, we strongly suggest to add a wash step: Wash the column with HPLC grade water for at least one hour after each batch or every ten injections. Then store the column in 20-40% acetonitrile (or methanol).

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