Merative Micromedex®

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IV Compatibility Product

Trissel's Drugs and Solutions Data

azaCITIDine

Trade Name(s) VIDAZA

Other Name(s) 5-Azacytidine; Ladakamycin

pH Range [1408]

Reconstituted solution pH range: pH 6.0 to 7.5.

Azacitidine 0.2 mg/mL in lactated Ringer's injection: pH 6.4.

Formulation Vials contain 100 mg of azacitidine and 100 mg mannitol as a sterile lyophilized powder.

Reconstitution Reconstitute each vial with 10 mL sterile water for injection. Vigorously shake or roll the vial until

all solids are dissolved. The resulting solution will contain azacitidine 10 mg/mL. The solution

should be clear.

Storage Store unreconstituted vials at 25 degrees C (77 degrees F); excursions permitted to 15 to 30 degrees

C (59 to 86 degrees F)

Stability (Detailed) Once reconstituted for IV administration, vial may be stored at 25 degrees C (77 degreesF), but

administration must be completed within 1 hour of reconstitution.

pH Effects The pH range of maximum stability for azacitidine (such as it is) is pH 6.5 to 7.0. Azacitidine 0.2

mg/mL in lactated Ringer's injection has a pH of 6.4, which is very near the pH that affords the best

stability.

Interaction with Plastics

[5696] [5697] [1408]

[3954] [1408]

Azacitidine has not been found to undergo substantial sorption to polyvinyl chloride (PVC) or glass

containers or to polypropylene plastic syringes.

Freezing

[3954] [5649]

Duriez et al. evaluated the stability of azacitidine 25 mg/mL reconstituted suspension in sterile water for injection stored frozen at -20 °C for 8 days, thawed, and stored for 8 hours under refrigeration.

No visible changes to the suspension occurred. Stability-indicating HPLC analysis found less than

5% azacitidine loss occurred after 8 days at $-20~^{\circ}\mathrm{C}$ followed by 8 hours under refrigeration.

Walker et al. found that azacitidine reconstituted with refrigerated sterile water for injection and packaged in glass vials and polypropylene syringes stored frozen at -20 °C not protected from

packaged in glass vials and porypropytene syringes stored nozen at 20 °C not protec

exposure to light exhibited no decomposition over 23 days of frozen storage.

LightEffects

[5698]

In an azacitidine solution stability study, Den Hartigh et al. reported that exposure to light did not

cause azacitidine degradation.

pHmax 7.5

pHmean 6.8

pHmin 6

Reference Section

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