



avoset™

Stability Data for Drugs Using the Avoset Medication Reservoir



The Avoset Infusion Pump is a compact, ambulatory pump that provides controlled infusions for the administration of therapies such as antibiotics, chemotherapy, and pain management medications.

Stability testing was performed by independent ISO/ IEC 17025 certified laboratories to ensure the **Avoset Medication Reservoir** is compatible with a dosage form and will not cause unacceptable changes in the quality of the Drug Product (DP) for specific storage condition.

The following table summarizes the results of studies conducted and should be used as a reference guide only. The selection of the appropriate medication, concentration and dose is the sole responsibility of the healthcare professional.

Medication			Storage condition*
Drug Name	Diluent	Concentration	Room temperature (15- 25 °C)
Morphine Hydrochloride	NaCl 0.9%	1 mg/mL	61 days
Morphine Hydrochloride	NaCl 0.9%	10 mg/mL	61 days
Fluorouracil	Undiluted	50 mg/mL	14 days

*Eitan Medical is responsible for the stability data provided herein. These data are not intended to endorse any specific drug product or dosage for medical use. Always refer to the drug manufacturer's prescribing information when administering any drug with the Avoset Infusion Pump and the Avoset Medication Reservoir.

Morphine

The stability of morphine was evaluated in an Avoset medication reservoir at a concentration of 1 mg/mL and of 10 mg/mL upon storage at pre-defined time points and at pre-defined storage conditions by HPLC-UV. Linearity, precision, accuracy and variability of retention time were studied. The tests confirm that:

Morphine HCl STEROP 1 mg/mL in an Avoset medication reservoir stays within 90-110% of the initial measured concentration for 30 days and 61 days at room temperature (15-25 °C).

Morphine HCl STEROP 10 mg/mL in an Avoset medication reservoir stays within 90-110% of the initial measured concentration for 30 days and 61 days at room temperature (15-25 °C).

Results of the test are listed in tables 1 and 2

References:

- Stability Study Protocol: Stability of Drug Products stored in Avoset medication reservoir, EIT-PHA-STAB-001-2022 (28 APR 2022), + AMENDMENT 1(12 JUL 2022)
- Sponsor Specified Procedure (SSP): Stability determination of Morphine hydrochloride, SSP0548 rev. 00 (30 JUN 2022)

Table 1: Stability for Morphine HCl STEROP 1 mg/mL, storage at room temperature for 30 and 61 days

Time point (days)	Sample name	Original concentration (mg/mL)	Mean concentration (mg/mL)	Calculated recovery Formula 1 (%)
0	At0	1.0	0.985	100
	Bt0			
	Ct0			
30	At30*	1.0	0.982	100
	Bt30			
	Ct30			
61	At61	1.0	0.994	101
	Bt61			
	Ct61			

*Sample At30 is not applicable, no impact on stability

Table 2: Stability for Morphine HCl STEROP 10 mg/mL, storage at room temperature for 30 and 61 days

Time point (days)	Sample name	Original concentration (mg/mL)	Mean concentration (mg/mL)	Calculated recovery Formula 1 (%)
0	At0	10.0	9.818	100
	Bt0			
	Ct0			
30	At30	10.0	9.711	99
	Bt30			
	Ct30			
61	At61	10.0	9.770	100
	Bt61			
	Ct61			

5FU

The stability of fluorouracil was evaluated at a concentration of 50 mg/mL upon storage at pre-defined time points and at pre-defined storage conditions by HPLC-UV. Linearity, precision, accuracy and variability of retention time were studied. The tests confirm that:

Fluorouracil at 50 mg/mL in an Avoset medication reservoir stays within 90–110% of the initial measured concentration for 14 days at room temperature (15–25 °C).

Results of the test are listed in table 3

References:

- Stability Study Protocol: Stability of Drug Products stored in Avoset **medication reservoir**, EIT-PHA-STAB-001-2022 (28 APR 2022).
- Sponsor Specified Procedure (SSP): Stability determination of 5-Fluorouracil, SSP0547 rev. 01 (02 JUN 2022)

Contact information:

support@eitanmedical.com
+972.73.238.8888



www.eitanmedical.com

Table 3: Stability for Fluorouracil Accord 50 mg/mL, storage at room temperature for 7 and 14 days

Time point (days)	Sample name	Original concentration (mg/mL)	Mean concentration (mg/mL)	Calculated recovery Formula 1 (%)
0	At0	50	50	100
	Bt0			
	Ct0			
7	At7	50	51	101
	Bt7			
	Ct7			
14	At14	50	51	101
	Bt14			
	Ct14			