

ROCHESTER MEDICAL CORPORATION
TEST SUMMARY

**Blood Stream Absorption of Nitrofurazone
in Patients Catheterized with a Release-NF[®] Foley Catheter**

TEST PURPOSE

- 1.1 The test was conducted to determine if detectable amounts of nitrofurazone are present in the blood of patients using a Rochester Medical Release-NF Foley Catheter.

TEST TYPE

- 2.1 A quantitative measurement of nitrofurazone in biological specimens
2.2 Reporting limit: 0.05mcg/mL
2.3 Test was conducted by an independent laboratory.

DESCRIPTION OF SPECIMENS TESTED

- 3.1 Twenty-seven (27) blood test samples from seven (7) patients catheterized with a Rochester Medical Release-NF Foley Catheter.
3.2 Specimens were taken at seven (7) day intervals
3.2 Specimen requirements included:

Specimen	Requested Amount	Required Amount	Minimum Amount
Serum	2.5 mL	0.5 mL	0.25 mL
Plasma	2.5 mL	0.5 mL	0.25 mL
Urine	2.5 mL	0.5 mL	0.25 mL

PROCEDURE

- 4.1 Serums or plasma proteins are precipitated with acetonitrile.
4.2 The supernatant is evaporated to dryness.
4.3 The residue is reconstituted in mobile phase and analyzed by HPLC with UV detection.

RESULTS

- 5.1 No detectable blood levels of nitrofurazone were found. See Table 1 on reverse side.

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Table 1:

PATIENT ID	DAYS WITH RELEASE-NF® FOLEY CATHETER	BLOOD LEVELS OF NITROFURAZONE
SMK	0	None Detected
	7	None Detected
	14	None Detected
	21	None Detected
	28	None Detected
SM	0	None Detected
	7	None Detected
	14	None Detected
	21	None Detected
	28	None Detected
DM	7	None Detected
	14	None Detected
	21	None Detected
LL	7	None Detected
	14	None Detected
	21	None Detected
	28	None Detected
MB	7	None Detected
	14	None Detected
	21	None Detected
	28	None Detected
CB	7	None Detected
	14	None Detected
CU	0	None Detected
	7	None Detected
	14	None Detected



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