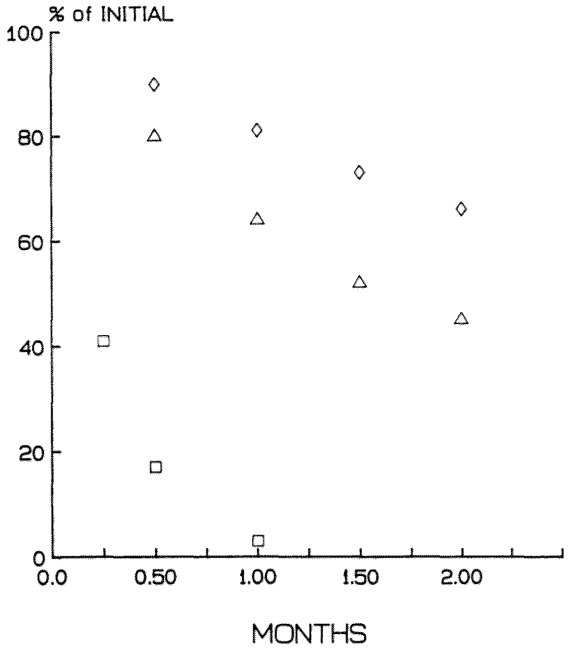


**Figure 10.1** Effect of metal ions in solution at 70°C. Squares, 3.0 μM Zn (II); triangles, 1.0 mM Ni (II); diamonds, 1.0 mM Cr (VI).

### B. Toxicology Supplies

A second useful source of stability information during the preformulation stage comes from the monitoring of toxicology supplies. These represent the first rudimentary formulations of the new drug substance. The objectives are to assure that the potency and level of significant degradation products are documented during the use of the supplies. An important added benefit is the development of supporting data for use during the formulation development stage.

## III. FORMULATION DEVELOPMENT STAGE

The emphasis in the formulation development stage shifts from profiling the physical and chemical properties of the new drug substance to the assessment of the stability of both the bulk drug and its associated dosage forms as they are developed. During this stage, preliminary formulations are manufactured in small-scale lots for use