



NAS 21, NAS 30, NAS 90, ZYLAR® 220, ZYLAR 330, ZYLAR 390 And ZYLAR 530 resins have been tested for cytotoxicity and hemolysis by an independent laboratory.

Cytotoxicity tests determine the degree of cell destruction caused by exposing certain cell cultures to an extract of the polymer.

The hemolysis test determines the degree of destruction of blood cells that occurs when specific extracts of the polymer are introduced into the blood.

Cytotoxicity tests were performed using the L-929 mouse fibroblast cell line. Results show that these resins are **non-toxic**.

The hemolysis test was performed using rabbit blood. Results show that these resins are **non-toxic** and **non-hemolytic**. However, it is the responsibility of the medical device manufacturer to determine the safety of any product in which they are a component.

Resins were tested by an independent laboratory to determine if they meet the specifications of either USP XXI or XXIII Chapter 88, "Biological Reactivity Tests, in vivo". NAS 21, ZYLAR 220 and ZYLAR 530 were tested using USP XXI specifications. NAS 30, NAS 90, ZYLAR 330 and ZYLAR 390 were tested using USP XXIII specifications. All resins met the requirements for a Class VI Plastic at 50°C. A copy of the tests is available upon request.

As formulated and manufactured, these resins meet USP XXI/XXIII specifications and therefore are acceptable for use in medical applications. However, if any alterations in formulation occur from their manufactured resin state to future plastic end-product state, USP XXI/XXIII specifications cannot be guaranteed. In addition, although these resins passed the Class VI test, the customer is responsible for performing USP XXI/XXIII Class VI testing on the final end-product.