NAmSA® World Leader in Testing Services
For the Medical Device Industry

2261 Tracy Road
Northwood, OH 43619
Phone 419-666-9455 Fax 419-666-2954

VARISEAL MANUFACTURING CORP
PO BOX 710
15547 MAIN MARKET ROAD
PARKMAN, OH 44080
ATTN: DEBASHISH CHAKRAVARTHY

Lab No. 93T 10060 00

PO NO. 5655
ID NO Not Supplied

HEMOLYSIS TEST *IN VITRO*

Test Article: Comb-18

Procedure: Extraction Method: A 89.7 cm_ portion of the test article was placed in 30 ml of 0.9% sodium chloride solution and extracted at 50º C for 72 hours (s). The extract was divided into individual tubes to 10 ml each and allowed to cool to room temperature.

To duplicate aliquots of the extract and to a similarly treated set of positive and negative control tubes was added 0.2 ml of rabbit blood previously collected in a vacuum tube containing EDTA. The tubes were inverted gently to mix the contents, and then placed in a constant temperature water bath at 37º C for 1 hour. The blood-saline mixture, positive and negative controls were then centrifuged for 10 minutes at a speed of not less than 1000Xg.

The absorbance of each test article solution was determined spectrophotometrically at 545nm. Similarly, absorbances were recorded for the positive control (10 ml water and 0.2 ml blood) and the negative control (10 ml 0.9% sodium chloride solution and 0.2 ml blood).

The blood-saline mixture, positive and negative controls were recentrituged for 10 minutes at a speed of not less than 1000Xg to ensure a constant absorbance reading had been obtained.

To rule out possible background interference, the absorbance of the blank (an aliquot of test extract without blood added) was determined spectrophotochemically at 545 nm.

RESULTS: Test #1 - 2.2% hemolysis
Test #2- 1.6% hemolysis

Mean hemolysis = 2.0%

Under the conditions of this test, the test article would be considered NONHEMOLYTIC

Comment: The test extract was a viscous liquid, slight yellow color and the control solution was clear. The release paper was removed from 2 sides.

Date Prepared: 8-27-93 Date Completed: 8-30-93

ORIGINAL ON FILE

Completed_____Tech_____Approved_____