



GECI
RACCORDS & FLEXIBLES
TEST RESULT CERTIFICATE

TEST ARTICLE	Viewline Raw Material Tube	Ratio	120 cm ² per 20 ml.
LOT/PART#	DM275X028	Vehicle	0,9% USP Sodium Chloride for Injection (NaCl) Cottonseed Oil (CSO) 1:20 Alcohol in 0,9% USP NaCl (EtOH) Polyethylene Glycol 400 (PEG 400)
STUDY	Direct Hemolysis – Rabbit Blood	Temp/Time	37°C for 24 hours

REFERENCE : USP 23, NF18, 1995 Pp. 1699-1702

GENERAL PROCEDURE : The test article extracts and corresponding blanks were injected systemically and intracutaneously in mice and rabbits, respectively. The injections were in the amounts and routes set forth by USP 23; Including the further dilution of the extracts prepared with PEG 400. The animals were observed for signs of toxicity and skin reactivity for up to 72 hours post treatment. In addition, the test article was implanted into the paravertebral muscles of rabbits for 7 days and observed for signs of hemorrhage, inflammation, necrosis, discoloration, and encapsulation.

RESULTS : None of the mice injected with the test articles extracts exhibited any signs of toxicity in the Systemic Injection Test. In addition, none of the rabbits injected intracutaneously with the test article extracts exhibited any signs of erythema, edema or clinical toxicity. In both the Systemic and Intracutaneous Tests the controls were normal through 72 hours. Also, the Implant sites exhibited no significant signs of hemorrhage, inflammation, necrosis, discoloration, or encapsulation compared with the control sites.

CONCLUSION : The test article meets the requirements of USP 23, NF18, 1995, for the Biological Test for Plastics, Class VI-37°C.

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