

TEST RESULT CERTIFICATE

Sponsor	Autoroll Print Technologies	Technical Initiation	12/12/01
Address	11 River Street Middleton, MA 01949	Technical Completion	12/19/01
Contact	Clif Treco	Report Date	01/02/02
P.O. Number	P851035-00	Project Number	01-6723-N1

Test Article	Tampapur (TPU)	Ratio	120 cm ² per 20 mL
Lot # / Part #	980 Black	Vehicles	0.9% USP Sodium Chloride for Injection (NaCl), Cottonseed Oil (CSO), 1:20 Alcohol in NaCl (EtOH), Polyethylene Glycol 400 (PEG)
Study	Biological Test for Plastics Class VI (4 Extracts)	Temp/Time	70±2° C for 24 hours

REFERENCE: USP 24, NF19, 2000, pp. 1832-1835.

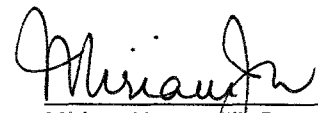
GENERAL PROCEDURE: The test article extracts and corresponding blanks were injected systemically and intracutaneously in mice and rabbits, respectively. The injections were in the amounts and routes set forth by USP 24; including the further dilution of the extracts prepared with PEG. The animals were 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, encapsulation, and infection.

RESULTS: None of the mice injected with the test article 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, encapsulation, or infection compared with the control sites.

CONCLUSION: The test article meets the requirements of USP 24, NF19, 2000, for the Biological Test for Plastics, Class VI-70° C.

AUTHORIZED PERSONNEL:


Stacy Pitt, DVM
Study Director


Miriam Kummailil, B.S.
Quality Assurance

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Address	11 River Street Middleton, MA 01949	Technical Completion	12/19/01
Contact	Clif Treco	Report Date	01/02/02
P.O. Number	P851035-00	Project Number	01-6722-N1

Test Article	Tampastar (TPR)	Ratio	120 cm ² per 20 mL
Lot # / Part #	980 Black	Vehicles	0.9% USP Sodium Chloride for Injection (NaCl), Cottonseed Oil (CSO), 1:20 Alcohol in NaCl (EtOH), Polyethylene Glycol 400 (PEG)
Study	Biological Test for Plastics Class VI (4 Extracts)	Temp/Time	70±2° C for 24 hours


REFERENCE: USP 24, NF19, 2000, pp. 1832-1835.

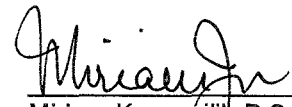
GENERAL PROCEDURE: The test article extracts and corresponding blanks were injected systemically and intracutaneously in mice and rabbits, respectively. The injections were in the amounts and routes set forth by USP 24; including the further dilution of the extracts prepared with PEG. The animals were 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, encapsulation, and infection.

RESULTS: None of the mice injected with the test article 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, encapsulation, or infection compared with the control sites.

CONCLUSION: The test article meets the requirements of USP 24, NF19, 2000, for the Biological Test for Plastics, Class VI-70 C.

AUTHORIZED PERSONNEL:


Stacy Pritt, DVM
Study Director


Miriam Kummälli, B.S.
Quality Assurance

TEST RESULT CERTIFICATE

Sponsor	Autoroll Print Technologies	Technical Initiation	04/05/02
Address	11 River Street Middleton, MA 01949	Technical Completion	04/12/02
Contact	Clif Treco	Report Date	04/19/02
P.O. Number	PB15408-00	Project Number	02-1515-N1

Test Article	Marabu's Ink – Maraprop PP 073	Ratio	6 cm ² per 1 mL
Lot #	Not Supplied by Sponsor	Vehicles	0.9% USP Sodium Chloride for Injection (NaCl), Cottonseed Oil (CSO), 1:20 Alcohol in NaCl (EtOH), Polyethylene Glycol 400 (PEG)
Study	Biological Test for Plastics Class VI (4 Extracts)	Temp/Time	70±2°C for 24 hours

REFERENCE: USP 25, NF 20, 2002, <88> Biological Reactivity tests, *In Vivo*.


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 25; including the further dilution of the extracts prepared with PEG. 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, encapsulation, and infection.

RESULTS: None of the mice injected with the test article 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, encapsulation, or infection compared with the control sites.

CONCLUSION: The test article meets the requirements of USP 25, NF 20, 2002, for the Biological Test for Plastics, Class VI-70°C.

AUTHORIZED PERSONNEL:


 Stacy Pitt, DVM
 Study Director


 Felice Randi LaMadeleine, B.S.
 Quality Assurance