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QUARTERLY SUMMARY

BIOACTIVE RUBBERS TEA -

FIRST QUARTER 1969

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TEA 85 BIOACTIVE RUBBERS

Budget: \$30,000; Spent Through February: \$6,151; Projected Rate: 106%

856-469 BIOACTIVE RUBBERS

By: C. S. Schollenberger, J. W. Born

This project is to extend our knowledge and capabilities in the use of polymers as media for the regulated release of bioactive agents.

During the first quarter we received, extracted, and analyzed for residual steroid content a set of cylindrical implants. These were returned after implantation in cattle by the collaborating drug company. The matrix polymers involved were Estanes 5701 and 5714, Shell ST-125 (block SBR) and PVC plastisol. Initial steroid loading was 100 mg. per implant.

Results show the ST-125 to have released the most steroid; the Estanes released less and similar amounts; and the PVC released the least. This is about the order found in Brecksville in vitro extractions, but release in the animals was slower than in saline.

The Estane implants showed good biological performance. Performance of the ST-125 and PVC implants was not as good. Microscopic examination of stored 100 mg. implants shows steroid bloom on their surfaces. We feel this could be corrected.

We are now analyzing a group of 55 mg. implants that were implanted in cattle. We have learned how to do these extractions and analyses quite accurately.

At the drug company's request, we provided flat implants of Estane 5714 and ST-125 at two steroid levels for their extraction tests. And, we are coating such implants with the corresponding matrix polymers for similar tests.

Budget: \$30,000; Spent Through February: \$6,141; Projected Rate: 106%

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QUARTERLY SUMMARY

BIOACTIVE RUBBERS TEA
SECOND QUARTER 1969

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TEA 85 BIOACTIVE RUBBERS

Budget: \$30,000; Spent Thru May: \$14,269; Projected rate: 118%.

8564-69 BIOACTIVE RUBBERS

By: C. S. Schollenberger, J. W. Born

With a major drug company, we are studying the in vitro and in vivo release of a steroidal hormone from selected matrix polymers.

During this quarter we provided the collaborating drug company with additional samples of two matrix polymers loaded with a third level of the hormone. Flat implants were cut from these sheets for tests. We also extracted and analyzed five sets of implants, including cylindrical and flat types, after their in vivo exposure by the drug company. Results show the Estane 5714 release rate to exceed that of the other matrix polymer, thermoplastic block SBR. They also show a concentration-release rate dependency.

A research report covering work with cylindrical implants was written.

The results of this project have stimulated plans to commercially exploit a product based on our findings.

Budget: \$30,000; Spent Through May: \$14,269; Projected rate: 118%.

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BIOACTIVE RUBBERS TEA

THIRD QUARTER 1969

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THIRD QUARTER SUMMARY 1969

TEA 85 BIOACTIVE RUBBERS

Budget: \$30,000; Spent Through August: \$18,306; Projected Rate: 82%

8564-69 BIOACTIVE RUBBERS

By: C. S. Schollenberger, J. W. Born

This project is to extend our knowledge and capabilities in the use of polymers as media for the regulated release of bioactive agents. We are studying the in vitro and in vivo release of a steroidal hormone from selected matrix polymers with a major drug company.

During this quarter additional sheets for flat implant fabrication were prepared. They consisted of several steroid levels in Estane 5714 matrix polymer. We have begun to determine the solubility parameters of four thermoplastic matrix polymers used in the steroid release study. This should provide a more quantitative relation of polymer structure/polarity with release rate.

Budget: \$30,000; Spent Through August: \$18,306; Projected Rate: 82%

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BIOACTIVE RUBBERS TEA

FOURTH QUARTER 1969

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FOURTH QUARTER SUMMARY 1969

TEA 085 BIOACTIVE RUBBERS

Budget: \$30,000; Spent Through November: \$24,940, Projected Rate: 89%

8564-69 BIOACTIVE RUBBERS

By: C. S. Schollenberger, J. W. Born, R. S. Varga

This project is to extend our knowledge and capabilities in the use of polymers as media for the regulated release of bioactive agents. We are studying the in vitro and in vivo release of a steroid hormone from selected matrix polymers with a major drug company. The work is expected to lead soon to the only known commercial parenteral application of a BFG material/product.

During this quarter we worked with IPC Development to provide eight-hundred flat implants for critical animal tests by the collaborating drug company. These implants were cut from extruded strips of commercial Estane 5714 and from the stabilizer-free polymer made in the laboratory for this project.

Eight compounds were mixed representing four levels of steroid hormone. Our analyses of the mixes and implants showed that intended levels were achieved. This initial attempt to make implants by the proposed production method went smoothly. But the extruded strip and therefore the implants varied a little in size. This has not interfered with the animal tests which are now underway.

Effort on this project was curtailed this quarter to match a curtailed budget.

Budget: \$30,000; Spent Through November: \$24,940; Projected Rate: 89%

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