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**Final Report SAM2817i-2**


**DELAYED-TYPE HYPERSENSIVITY TEST**

Study Program: SAM2817

Contract No.: E05/0137.4MI

Sponsor: ANDROMEDICAL S.L.  
Mar Mediterraneo, 19  
28220 Majadahonda  
MADRID – (ES)

Test substance: ANDRO-PENIS

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Study Director.....  
(Dr. P. Consonni)

Released on: 10/12/05.....

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### INTERPRETATION OF RESULTS

Both frequency and intensity of response were evaluated.  
In case of positive reaction only in treated animals, the frequency of sensitisation was considered, without taking into account the intensity of the response.

### RESULTS

Neither edema nor erythema were observed in the animals treated with the test substance eluates prepared in physiological solution and in vegetable oil.  
No abnormalities were observed in the animals used as control.

% sensitising guinea pigs treated with extract in physiological solution: 0%  
% sensitised guinea pigs treated with extract in vegetable oil: 0%

The data concerning every single animal are reported in appendices 1 and 2.

### CONCLUSIONS

On the basis of the results obtained for all tested components, interpreted according to ISO 10993-10:2002 the test substance ANDRO-PENIS must be considered **NOT SENSITIZING**.