

biolab	Assay Centre	Report N°: SAM2817i-3 Version: English Page: 1 of 17 Print date: October 13 th , 2005
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Final Report SAM2817i-3


SKIN IRRITATION TEST

Study Program: SAM2817

Contract n.: E05/0137.4MI

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

Test substance: ANDRO-PENIS

Study Director 
 (Dr. P. Consonni)

Released on: 10/14/05

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RESULTS

60 minutes after the treatment, in all animals treated with eluate of the test material in vegetable oil, slight erythema without edema was observed.

The erythema has totally disappeared in all animals treated with eluate of the test material in vegetable oil 24 hours after the treatment.

In all animals treated with eluate of the test material in physiological solution no edema or erythema was observed.

Results referring to the single animals and mean values of erythema and edema referring to each observation time are shown in appendix n. 1.

INDEX SKIN IRRITATION: 0.00

CONCLUSIONS

On the basis of the results, interpreted according ISO 10993-10:2002, the test substance ANDRO-PENIS must be considered **NOT IRRITANT** for skin.