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Final Report SAM2816i

HEAVY METALS EN 71-3:2002

Study Program No: SAM2816

Contract: E05/0137.4MI

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

Test substance: ANDRO-PENIS

Study Director: *X gavi*
(Dr. E. Mapelli)

Date of issue: *12/10/2005*

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RESULTS

The study performed on the **test substance ANDRO-PENIS** aimed at determining potential heavy metal traces migration in solution according to EN 71-3:2002 and at estimating the bioavailability of the tested materials.

The concentration levels of the analytes are lower than the prescribed limit of EN 71-3:2002 for each metal (barium, cadmium, chromium, lead, mercury, arsenic, antimony and selenium); the metal bar material (ID 5) evidenced a lead content of 72 µg/kg.

The quantity of nickel, zinc and copper is lower than the corresponding analytical quantitation limit for every sample except for metal bar material which showed a nickel concentration of 107 µg/kg.

The analytical results are summarised in the following table:

metals	limit EN 71-3:2002 (mg/kg)	metal bar (mg/kg)	axis (mg/kg)	superior plastic support (mg/kg)	silicone band (mg/kg)	andro top (mg/kg)
ID		6	7	8	9	10
Barium	1000	<100	<100	<100	<100	<100
Cadmium	75	<7.5	<7.5	<7.5	<7.5	<7.5
Chromium	60	<6	<6	<6	<6	<6
Lead	90	72	<9	<9	<9	<9
Mercury	60	<6	<6	<6	<6	<6
Arsenic	25	<2.5	<2.5	<2.5	<2.5	<2.5
Antimony	60	<6	<6	<6	<6	<6
Selenium	500	<50	<50	<50	<50	<50
Copper	-	<2.5	<2.5	<2.5	<2.5	<2.5
Nickel	-	107	<2.5	<2.5	<2.5	<2.5
Zinc	-	2.8	<2.5	<2.5	<2.5	<2.5