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Test Facility

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Final Report 2008/910-2 SAMi

HEAVY METALS

Study Program: 2008/910 SAM

Contract n.: E08/0432.1MI

Sponsor: ANDROMEDICAL S.L.
EDIFICIO -AMERICA II
28023 C/PROCION,N°7-NUCLEO 4
OFICINALIS I-L
MADRID- (ES)

Test product: ANDROPENIS GOLD

Study Director: *Paolo Pescio*
(Paolo Pescio)

Issued on: *Nov 24th 2008*

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SUMMARY

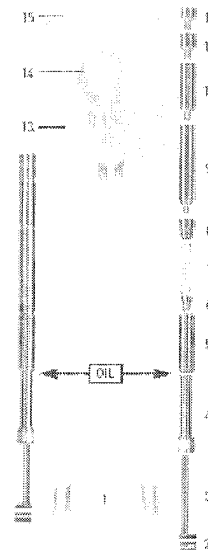
A study was performed on the test product "ANDROPENIS GOLD" to determine potential heavy metal traces bioavailability.

The test was performed according EN 71-3:1994/AC:2002 (Safety of toys - Part 3: Migration of certain elements).

In addition nickel, zinc, copper and gold, not included in the European Standard, was investigated.

The analytical test was accomplished on the five different materials which constitute the device and are in contact with the human skin:

1. metal bar (ID 5)
2. axis (ID 9)
3. superior plastic support (ID 13)
4. silicone band (ID 14)
5. andro top (ID 15)



The analytical results show that heavy metal concentration levels are lower than the prescribed limit of EN 71-3:1994/AC:2002 for each metal (barium, cadmium, chromium, lead, mercury, arsenic, antimony and selenium).

The quantity of nickel, zinc, copper and gold is lower than the corresponding analytical quantitation limit for every sample except for metal bar material (ID 5) which reports a 96 mg/kg nickel concentration.

INTRODUCTION

This study has been carried out on behalf of the Sponsor ANDROPENIS S.L. on the product "ANDROPENIS GOLD".

The study was performed at the Test Facility Biolab S.p.A. of Vimodrone (MI) – Italy via B. Buoizzi n. 2.

The test started on November 19th, 2008 and was completed on November 20th, 2008.

BIBLIOGRAPHY

EN 71-3:1994/AC:2002 Safety of toys - Part 3: Migration of certain elements

RECORD FILING

The study program and all raw data will be retained in Biolab's archives for a period of 10 years from the issue of the final report.

A retained sample has not been kept.

At the end of the conservation period, the Sponsor may request an extension of the conservation of all or part of the substances for a further period, or their restitution. A suitable agreement shall be drafted in this case.

PROCEDURES

All procedures used during this study are recorded in the Biolab Procedures Manual.

TEST SUBSTANCE

The test substance is a device consisting of different parts made of plastic and metallic materials intended to human use in contact with the skin.

Name: ANDROPENIS GOLD

ANALYSED SAMPLE

The specimen analysed, representative of the test product consists of a several part of the device.

Batch: 07/08
Preparation date: July 2008
Sample identification No: 08.10855-S
Receiving No: R05226.08
Receiving date: October 20th, 2008

The characterisation of the test product is under Sponsor responsibility

HEAVY METALS

SENIOR RESEARCHER: V.Paschetta

EXPERIMENTAL PROCEDURE

Heavy Metals

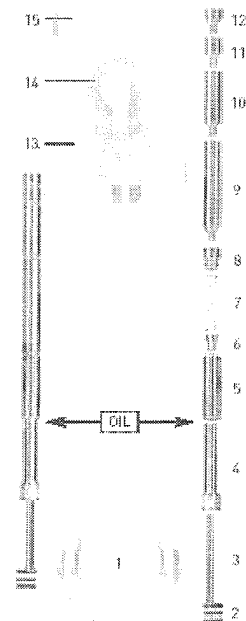
The bioavailability of heavy metals from test product ANDROPENIS GOLD material was studied according to EN 71-3.

In absence of a specific standard it is considered opportune to use the experimental conditions prescribed by the standard for toys, although the conditions of contact simulation are more severe.

The principle of EN 71-3 is to extract soluble metallic elements (oxides, salts, other water soluble forms of heavy metal elements) from materials under conditions that simulate the material remaining in contact with human gastric juices for a specific period after swallowing.

The analytical test was accomplished on the five different materials which constitute the object and are in contact with the human skin:

1. metal bar (ID 5)
2. axis (ID 9)
3. superior plastic support (ID 13)
4. silicone band (ID 14)
5. andro top (ID 15)



andro tc

Reactants

Bidistilled Water Fluka
 Hydrochloric Acid 37% Carlo Erba Reagenti
 Nitric Acid 65% Merck Suprapur

Standard solution for each metal 1000 mg/ml Merck:

Arsenicum
 Barium
 Chromium
 Mercury
 Nickel
 Lead
 Copper
 Zinc
 Cadmium
 Antimony
 Selenium
 Gold

Equipment

- Analytical balance Mettler AS100.
- Inductively coupled plasma optical emission spectrometry (ICP-OES) – Perkin Elmer mod. OPTIMA 2000 DV.
- Standard laboratory equipment

Sample preparation for ID5 , ID9 metallic parts.

The samples were weighted and placed in a 10ml volume of tempered (37°C) solution of hydrochloric acid (0.07 mol/l) for two hours. The migration liquid of each sample preparation was filtered before analysis.

Sample preparation for ID13 ,ID14, ID15 non metallic parts.

The samples were mechanically fragmented so that surface dimension did not exceed about 6 mm.

0.5 g of fragmented samples were placed in a volume of tempered (37°C) solution of hydrochloric acid (0.07 mol/l) equivalent to 50 times the sample weight (25ml); agitated for one hour and left resting for one additional hour. The migration liquid of each sample preparation was filtered before analysis.

Heavy Metals – Analysis

Heavy metals in sample solutions were determined by ICP-OES. The quantitative determinations were performed for the following metals: barium, cadmium, chromium, lead, mercury, arsenic, antimony and selenium, nickel, zinc copper, and gold.

DEVIATIONS

No deviation has been performed from the study program.

RESULTS

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 10 mg/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 96 mg/kg.

The analytical results are summarised in the following table:

metals	limit EN 71- 3:1994/AC:2002 (mg/kg)	metal bar (mg/kg)	axis (mg/kg)	superior plastic support (mg/kg)	silicone band (mg/kg)	andro top (mg/kg)
ID		5	9	13	14	15
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	10	<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	-	96	<2.5	<2.5	<2.5	<2.5
Zinc	-	<2.5	<2.5	<2.5	<2.5	<2.5
Gold	-	<2.5	<2.5	<2.5	<2.5	<2.5