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Final Report SAM3646i

HEAVY METALS EN 71-3:2002

Study Program: SAM3646

Contract: E06/0222.1MI

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

Test substance: ANDRO-PENIS GOLD

Study Director:  Date: ...23/10/06..
(Dottorressa E. Mapelli)

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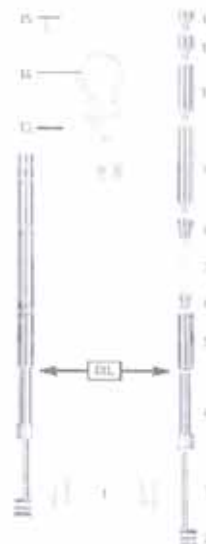
SUMMARY

A study was performed on the test substance ANDRO-PENIS GOLD to determine potential heavy metal traces bioavailability. The test was performed according to EN 71-3:2002 (Safety of toys - 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 71-3:2002 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 79 mg/kg nickel concentration.

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INTRODUCTION

On behalf of Sponsor ANDROMEDICAL S.L. a study was performed on samples of ANDRO-PENIS GOLD. The study is finalised to determine potential heavy metals migration in solution according to EN 71-3:2002.

The study has been conducted in the Biolab S.p.A. Assay Centre located in Vimodrone (MI) – Italy, Via Bruno Buozzi No 2, and started on October 17th, 2006 and ended on October 19th, 2006.

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FILING

The study program and raw data are kept in the archives of Biolab S.p.A. for a period of 10 years after the issue of the final report.

The control sample of the test substance has not been stored.

At the end of the storing period, the Sponsor, upon drafting a suitable contract, may request an extension of the conservation of substances (or part of them) for a further period or their restitution.

PROCEDURES

The procedures used in the study are documented in the Procedure Handbook of Biolab S.p.A.

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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: ANDRO-PENIS GOLD

Stability: until February 2011

ANALYSED SAMPLE

The analysed samples, representative of the test substance is composed of tubes identified as follow.

Batch: 02/06-00022

Expiring: until February 2011

Identification No: 06.21871

Receiving No: R04804.06

Receiving date: September 27th, 2006

HEAVY METALS EN 71-3:2002

Chief investigator: A. Guzzi

EXPERIMENTAL PROCEDURE

Heavy Metals according to EN 71-3:2002

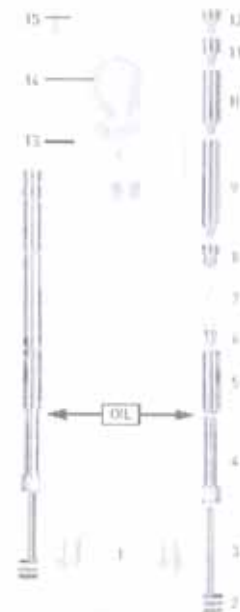
The bioavailability of heavy metals from test substance ANDRO-PENIS GOLD material was studied according to EN 71-3:2002 (*Safety of toys - Migration of certain elements*).

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 71-3:2002 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)



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Reactants

Bidistilled Water Fluka (batch 1114396)
Hydrochloric Acid 37% Carlo Erba Reagenti (batch 6A378096B)
Nitric Acid 65% Merck Suprapur (batch ZU650041)

Standard solution for each metal 1000 mg/ml Merck:

Arsenicum (batch OC561178)
Barium (batch OC567671)
Chromium (batch OC555777)
Mercury (batch OC405366)
Nickel (batch OC499395)
Lead (batch OC404895)
Copper (batch OC405617)
Zinc (batch OC405625)
Cadmium (batch OC528786)
Antimony (batch OC482355)
Selenium (batch OC528489)
Gold (batch OC561178)

Equipment

Analytical balance Mettler AS100 B0089.
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 comminuted so that surface dimension did not exceed about 6 mm.
0.5 g of comminuted 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.

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DEVIATIONS

No deviation has been performed from the study program.

RESULTS

The study performed on the test substance ANDRO-PENIS GOLD 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 58 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 79 mg/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		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	58	<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
<i>Copper</i>	-	<2.5	<2.5	<2.5	<2.5	<2.5
<i>Nickel</i>	-	79	<2.5	<2.5	<2.5	<2.5
<i>Zinc</i>	-	<2.5	<2.5	<2.5	<2.5	<2.5
<i>Gold</i>	-	<2.5	<2.5	<2.5	<2.5	<2.5