

**Final Report SAM2816i*****HEAVY METALS EN 71-3:2002***

Study Program No: SAM2816

Contract: E05/0137.4MISponsor: ANDROMEDICAL S.L.  
Mar Mediterraneo, 19  
28220 Majadahonda  
MADRID – (ES)Test substance: ANDRO-PENIS-----  
Study Director: ..... Date of issue: .....  
(Dr. E. Mapelli)-----  
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## SUMMARY

A study was performed on the test substance ANDRO-PENIS to determine potential heavy metal traces bioavailability. The test was performed according EN 71-3:2002 (*Safety of toys - Migration of certain elements*). In addition nickel, zinc and copper, not provided 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 and copper is lower than the corresponding analytical quantitation limit for every sample except for metal bar material (ID 5) which reports a 107 µg/kg nickel concentration.

## **INTRODUCTION**

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

The study was performed in Biolab Assay Centre, Vimodrone (MI), Via B. BuoZZi n. 2.

The study started on September 05<sup>th</sup> 2005 and ended on September 09<sup>th</sup>, 2005.

### **FILING**

Raw data and a copy of the final report will be kept in the archives of Biolab S.p.A. for a period of 10 years from the end of the study.

The control samples of the test substances have not been filed.

The Sponsor, upon drafting a suitable contract, may request an extension of the archiving period of all (or part of) the materials or their restitution.

### **PROCEDURES**

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

**TEST SUBSTANCE DESCRIPTION**

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

**ANALYSED SAMPLE**

The analysed sample, representative of the test substance, is identified by the following numbers:

Name: ANDRO-PENIS

Acceptance number: 05.16494

Receiving number: R03758.05

Receiving date: August 22<sup>th</sup>, 2005

**Experimentation Report SAM2816i.A1****HEAVY METALS EN 71-3:2002****CHIEF INVESTIGATOR: S. Sanguinetti**

## **EXPERIMENTAL PROCEDURE**

### ***Heavy Metals according to EN 71-3:2002***

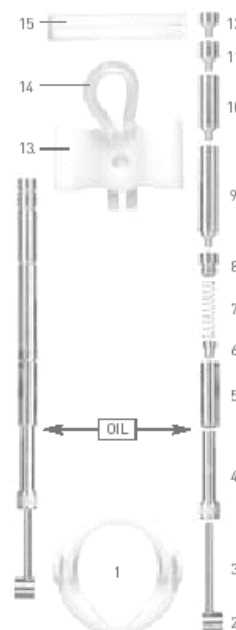
The bioavailability of heavy metals from **test substance ANDRO-PENIS** material was studied according to EN 71-3:2002 (*Safety of toys - Migration of certain elements*).

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)



### ***Sample preparation***

The sample was mechanically comminuted so that surface dimension did not exceed about 6 mm.

0.5 g of comminuted sample was 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 and 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 and copper.

***Reactants***

- purified water (Fluka)
- hydrochloric acid concentrated (Merck)
- nitric acid concentrated (Suprapur Merck)
- standard solution for each metal 1000mg/ml (Merck)

***Equipment***

- Analytical balance Mettler AS100 B0089
- Inductively coupled plasma optical emission spectrometry (ICP-OES) – Perkin Elmer mod. OPTIMA 2000 DV
- Standard laboratory equipment

## 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	<b>72</b>	<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	-	<b>107</b>	<2.5	<2.5	<2.5	<2.5
Zinc	-	2.8	<2.5	<2.5	<2.5	<2.5