

**TEST REPORT**  
**Cytotoxicity by agar diffusion test**  
**Nr.22/Date: 23.03.2011**

**Test item:** PG-  $\beta$ -TCP. Mineralogical composition : unique phase tricalcium phosphate  $\beta$ - $\text{Ca}_3(\text{PO}_4)_2$ ; apparent density 0,887 g/cm<sup>3</sup>, dimensions: 500-1000  $\mu\text{m}$ . Tricalcium phosphate is a ceramic material used in medicine

**Name/Description :** PG-  $\beta$ -TCP

Cod : 23

Date of receipt : 23.03.2011

**Manufacturer :**

**Client :** INCDIE ICPE-CA

**Order Nr. :** 20

**Order Date :** 02.2011

**Reference documents :** SR EN ISO 10993-5 (2003) ; ASTM F 895-84 (2006)

**Protocol analysis :** PL-BIOVAL-03

**Method :** In vitro tests for cytotoxicity in biological evaluation of materials and medical devices : agar diffusion method

**Cell line :** L929

**Growing medium :** MEM with 10% FBS, 2,2 g/l sodium bicarbonate, P/S

**Test sample :** the powder was sterilized by irradiation with a dose between 30-38 kGy and extracted.

**Extraction conditions :** extraction ratio 3 cm<sup>2</sup>/ml MEM medium with 10% FBS, P/S ; for 24 h in incubator, at 37 °C. It has been used extract itself and its dilutions by : 1/2 ; 1/5 and 1/10

**Negative control :** filter discs Millipore  $\varnothing$  10mm moistened with MEM without FBS

**Positive control :** filter discs Millipore  $\varnothing$  10mm moistened with phenol 0,45% v/v prepared in sterilized distilled water in autoclav

**Sef Laborator BIOEVAL**  
**Dr. Mihai Radu**

**Responsabil Incercare**  
**Dr. Diana Savu**

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