Reference No: BB 148
Date: 30/01/2018

Test report
Test for in vitro cytotoxicity (Test by direct contact) of BIONIC dental implant

Summary:
An in vitro cytotoxicity study was conducted to assess the potential for cytotoxicity of the test article: SO 10993-5:2009 describes test methods to assess the in vitro cytotoxicity of medical devices. These methods specify the incubation of cultured cells in contact with a device and/or extracts of a device either directly or through diffusion. These methods are designed to determine the biological response of mammalian cells in vitro using appropriate biological parameters. Under the condition of this study, the viability of 100% extract of the test articles was 83%, it had not a cytotoxic potential

Materials

Cells	G292 human osteoblast
Cell culture medium	**GIBCO's Minimum Essential Medium, with 10% calf serum**

Methods:
1X 10^6 human osteoblast G292 cells (Iranian institute Pasture cell bank) where cultured in 10 cm petri dish containing MEM supplement with 10% calf serum and one BIONIC dental implant and incubated for 24, 48 and 72 hr. the viability of cells reaction to implant secretion evaluated by light microscope and cell counting. three replicate were prepared for each groups.

Conclusion:
Under the conclusion of this study, the viability of cells was 89%±2, It had not a cytotoxic potential

Authorized by
Dept. of Laboratory services of Medzist

شرکت مد زیست سامانه پیشرو
سهامی خاص
شماره ثبت ۴۱۶۸۴۸

Certification body *MedZist samaneh pishro company, No: 3 Shahid Nosrati*
Address: *Aly. Southern Sheikh Bahaei St. Mollasadra Ave.*
Tehran-Iran Tel:+98 21 88622361
To check this cer cate validity please contact +98 21 88622361

Reference No: BB 193
Date: 30/01/2018

Test report
Test for in vitro cytotoxicity (Test on extracts) of BIONIC dental implant

Summary:
An in vitro cytotoxicity study was conducted to assess the potential for cytotoxicity of the test article: SO 10993-5:2009 describes test methods to assess the in vitro cytotoxicity of medical devices. These methods specify the incubation of cultured cells in contact with a device and/or extracts of a device either directly or through diffusion. These methods are designed to determine the biological response of mammalian cells in vitro using appropriate biological parameters. Under the condition of this study, the viability of 100% extract of the test articles was 83%, it had not a cytotoxic potential

Materials

Cells	G292 human osteoblast
Extraction vehicle	**GIBCO's Minimum Essential Medium, with 10% calf** serum.
Test Extract Preparation:.	Based on ISO , one BIONIC dental implant immersed in **1 ml extraction vehicle for 24 hr. at 37° C.**
Negative control preparation	The same as 3 but one commercial dental implant instead of the BIONOC dental implant one used.
Positive control preparation	Normal buffer saline used as extracted solution.

Methods:
1X 10^4 human osteoblast G292 cells (Iranian institute Pasture cell bank) where cultured in 96 well plate containing MEM supplement with 10% calf serum and 100 ul. extraction solutions and incubated for 24, 48 and 72 hr.. The cell stained with Trypan blue and count the living cells under light microscope. three replicate were prepared for each groups.

Conclusion:
Under the conclusion of this study, the viability of 100% extract of the test article was 89%, it had not a cytotoxic potential.

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