

## Cytotoxicity Study Using the ISO Elution Method - Ditrion Implants Results – Oct 2014

### NAMSA Test Scoring

Grade	Reactivity	Conditions of all Cultures	NAMSA™
0	None	Discrete intracytoplasmic granules, no cell lysis, no reduction of cell growth.	
1	Slight	Not more than 20% of the cells are round, loosely attached and without intracytoplasmic granules, or show changes in morphology; occasional lysed cells are present; only slight growth inhibition observable.	
2	Mild	Not more than 50% of the cells are round, devoid of intracytoplasmic granules; no extensive cell lysis; not more than 50% growth inhibition observable.	
3	Moderate	Not more than 70% of the cell layers contain rounded cells or are lysed; cell layers not completely destroyed, but more than 50% growth inhibition observed.	
4	Severe	Nearly complete or complete destruction of the cell layers.	

The color of the test medium was observed to determine any change in pH. A color shift toward yellow would have indicated an acidic pH range, and a color shift toward magenta to purple would have indicated an alkaline pH range. For the test to be valid, the reagent control and the negative control must have had a reactivity of none (grade 0) and the positive control must have been a grade 3 or 4. Percent rounding and percent cells without intracytoplasmic granules are not evaluated in the event of 100% lysis. The test article met the requirements of the test if the biological response was less than or equal to grade 2 (mild). The test would have been repeated if the controls did not perform as anticipated and/or if all three test wells did not yield the same conclusion. All times and temperatures reported herein are approximate and are within ranges established by the external standards described in the References section of this report and/or NAMSA standard operating procedures.

### Results of Ditrion Dental Implants:

No cytotoxicity or cell lysis was noted in any of the test wells. No pH shift was observed at 48 hours. The reagent control, negative control and the positive control performed as anticipated. The individual reactivity grades are presented in Appendix 1.