

ISO 13779-3:2008-02 (E)

Implants for surgery - Hydroxyapatite - Part 3: Chemical analysis and characterization of crystallinity and phase purity

Contents		Page
Foreword		v
Introduction		vi
1	Scope	1
2	Normative references	1
3	Terms, definitions and symbols	1
3.1	Terms and definitions	1
3.2	Symbols	2
4	Analytical methods	2
5	Apparatus, reagents and calibration specimens	2
5.1	Apparatus for chemical analysis	2
5.2	Reagents for chemical analysis	3
5.3	Apparatus and calibration specimens for X-ray diffraction analysis	3
5.4	Infrared apparatus	4
6	X-Ray diffraction pattern collection	4
6.1	General	4
6.2	Identification of the crystallized phases	4
7	Preparation of the test sample	5
7.1	Coatings	5
7.2	Bulk sample	5
7.3	X-ray analysis	5
8	Plotting the calibration curves	6
8.1	General	6
8.2	Plotting the calibration curves for the foreign phases	6
8.3	Plotting the calibration curves for the calculation of the calcium:phosphorus (Ca:P) ratio	7
9	Chemical analysis	8
9.1	General	8
9.2	Expression of results	8
10	Ca:P ratio	8
10.1	General	8
10.2	Procedure	9
10.3	Measurements on the sample	9
10.4	Choice of the diffraction peaks	9
10.5	Expression of results	9
11	Qualitative and quantitative determination of the foreign phases	10
11.1	Procedure	10
11.2	Expression of results	10
12	Determination of the crystallinity ratio	10
12.1	General	10
12.2	Preparation of the sample	10

12.3	Procedure	10
12.4	Expression of results	10
13	Degradation of ceramics	11
14	Test report	11
Annex A (informative) Contamination of calcium phosphate		12
Annex B (normative) Testing of the purity of the phases used in the production of the calibration curves		13
Annex C (informative) Examples of X-ray diffraction patterns collected from various mixtures used to plot the calibration curves		14
Annex D (normative) Positions of lines used to measure the crystallinity ratio		16
Annex E (informative) Examples of methods for the preparation of reference materials		17
Bibliography		19