Biocomposites®		Analytical Report	
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Title:	pH Analysis of Two Forms of Calcium Sulfate Bone Void Filler		

Study Summary

Four samples of calcium sulfate bone void filler received. Investigate pH of each sample.

Sample Name	Ref	Lot	Appearance
Synthecure	20-125 20-112	RM118904 RM118901	White Powder, clear liquid White Powder, clear liquid
Stimulan Rapid Cure	620-005D 620-005D	2018-03a 2017-12	White Powder, clear liquid White Powder, clear liquid

Analytical Methods and Results

pH Analysis

pH analysis was carried out on the four samples as formed into beads according to the relevant Instructions For Use (IFU). The beads were then individually ground into a fine powder using a pestle and mortar. 1g of each material was used for this analysis.

The analysis was carried out using reverse osmosis (RO) water using a calibrated Thermo Orion meter (s/n H05161) (Bio number 451).

The pH meter was calibrated before use, using fresh calibration solution pH7 and pH10. Results were recorded on QOP12.0.

Analysis carried out according to QTP1.2.

Results

Table 1. pH

Sample	Lot Number	pH
Synthecure	RM118901	6.43
	RM118904	6.21
Stimulan Rapid Cure	2017-12	7.25
	2018-03a	7.35

Conclusions

Under the conditions tested as detailed above, Synthecure and Stimulan Rapid cure have different pH. The Synthecure samples both have an acidic pH <7.

Signature [redacted]