



Sterility Testing of Dentin particles

Kometa Bio	Certificate C03/2014
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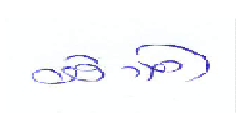


Certificate № C03/2014

Kometa Bio

Test Method: USP <71>

Ordered by: Meir Sahar

Approved by:

	Name	Signature	Date
Pharmaceutical, Medical Devices and Cosmetics laboratories Manager	Hagar Zur		05.03.14
Q.A. Manager	Marina Lerner-Nataf		05.03.14
Laboratory Manager	Dr. Irit Weiser		05.03.14



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The Product:

Product Name	Batch №	№ of Products	Lab №
Dentin particles	Q101-08012014	5	1293-1297
Reception Date		Test Start Date	
18.02.14		18.02.14	

Reference:

USP <71>, last edition.

Internal SOP 13.020.29, Sterility testing of consumer goods, medical devices and sterile products, last edition.

Method:

Each vial contained 2 g of Dentin particles and was divided into two 1g samples. Each 1g sample was tested for sterility by immersion in TSB or FTM.

Validation:

Validation was not performed.

Results:

Table №1: Test results

Lab №	TSB	FTM
1293	No Growth	No Growth
1294	No Growth	No Growth
1295	No Growth	No Growth
1296	No Growth	No Growth
1297	No Growth	No Growth
Control	No Growth	No Growth

Conclusion:

The product, Dentin particles, batch № Q101-08012014, conforms to sterility test requirements.