

BIO CHIC Sp. z o.o.

Microbiological Laboratory

00-872 Warszawa, ul. Chłodna 56-60, tel: 022 654 15 98, tel./fax: 022 654 64 76

Permit No. GIF-IW-4001/12/07

Microbiological Analysis Certificate No. 742/742/07

Name of product:	Dentalite type 100
Serial No./ Code No.:	Serial No.: W 16/07
Sample taken by:	The client
Manufacturer:/ Producer:	NORDISK PERLITE APS HAMMERSHOLT ERHVERSPARK 1-5 3400 HILLEROD DANMARK
Production place:	As above
Customer:	As above
Date of sample delivery:	24 April 2007
Date of starting/finishing the analysis:	24 April 2007 – 30 April 2007
Packaging type of the sample:	1 packaging of 100 grams
Amount of sample packages:	1 packaging

ANALYSIS RESULTS

Type of analysis	Result	Requirements
1. Overall no. of bacterias in 1g of sample:	- less than 10 cfu/g	No more than 5×10^2 cfu/g
2. No. of yeast and mould in 1g of sample:	- less than 10 cfu/g	No more than 5×10^2 cfu/g
3. <i>Enterobacteriaceae</i> and other negative bacilli (-) in 1g of sample:	- less than 1 cfu/g	No more than 10^2 cfu/g
4. <i>Escherichia coli</i> in 1g of sample:	- not present in 1g	Not present in 1g
5. <i>Staphylococcus aureus</i> in 1g of sample:	- not present in 1g	Not present in 1g
6. <i>Pseudomonas aeruginosa</i> in 1g of sample:	- not present in 1g	Not present in 1g
7. <i>Salmonella</i> in 10g of sample:	- not present in 10g	Not present in 10g
Microbiological analysis points 1 – 7 performed according to European Pharmacopeia 5.0 – 2005, PB – 10, published on 20 Nov. 2006. The results of analysis compared with the client's requirements.		

STATEMENT

The tested sample of: Dentalite type 100 Serial No.: W 16/07	Complies with microbiological requirements of EP 5.0 and with Client's requirements
---	---

Analysis performed by: M. Gwiazda**Director of laboratory:** M. Gwiazda, microbiologist**Confirmed by:** dr n. farm. B. Starościk2nd degree specialist in microbiology

Date: 30 April 2007

BIO CHIC Sp. z o.o.

Microbiological Laboratory

00-872 Warszawa, ul. Chłodna 56-60, tel: 022 654 15 98, tel./fax: 022 654 64 76

Conformity of the Performed Analysis Certificate

Product/ Identification code*/Delivery code*Dentalite type 100.....	Phase of production: Analysis of microbiological purity
--	---

Serial No. or Date of sampling:	W 16/07
No. of Certificate	742/742/07

Hereby I state, that the ordered phase of production - **Analysis of microbiological purity of product of the above stated Serial No. or Date of Sampling** – was performed according to European Pharmacopeia 5.0 – 2005, PB – 10, published on 20 Nov. 2006, in conditions that comply with requirements of Good Production Practice.

During testing:

NO DISCREPANCIES

were registered and noted in the OOS Report No. - - - and described the reasons for such an occurrence in a satisfactory way. (Report – attachment to the Certificate).

..... Mariola Gwiazda.....

Director of laboratory signature

.....30 April 2007.....

Date

Hereby I state, that the ordered phase of production - **Analysis of microbiological purity of product of the above stated Serial No. or Date of Sampling** – was performed according to Good Production Practice for medicinal products.

.....dr n. farm. B. Starościak.....

.....2nd degree specialist in microbiology.....

Qualified specialist of Bio Chic laboratory signature

.....30 April 2007.....

Date