

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**

<b>Type of analysis</b>	<b>Result</b>	<b>Requirements</b>
1. Overall no. of bacterias in 1g of sample:	- less than 10 cfu/g	No more than $5 \times 10^2$ cfu/g
2. No. of yeast and mould in 1g of sample:	- less than 10 cfu/g	No more than $5 \times 10^2$ 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
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**Analysis performed by:** M. Gwiazda**Director of laboratory:** M. Gwiazda, microbiologist**Confirmed by:** dr n. farm. B. Starościk2<sup>nd</sup> degree specialist in microbiology

Date: 30 April 2007

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**Conformity of the Performed Analysis Certificate**

Product/ Identification code*/Delivery code* .....Dentalite type 100.....	Phase of production: <b>Analysis of microbiological purity</b>
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Serial No. or Date of sampling:	<b>W 16/07</b>
No. of Certificate	<b>742/742/07</b>

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.....

.....2<sup>nd</sup> degree specialist in microbiology.....

**Qualified specialist of Bio Chic laboratory signature**

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

**Date**