

Final Product Specification	Nr.: SP C104	Revision: 5
DEPURAL NEO		
Author: Eva Horakova		

1. PURPOSE

The objective of this specification is to determine product requirements which must Depural Neo comply with before release for distribution. This specification serves for communication with customers.

2. PRODUCT DESCRIPTION

Depural Neo is a cleaning and polishing paste without fluoride.

3. INDICATION FOR USE

Slightly abrasive Depural Neo paste is intended for professional cleaning of the teeth by dental professionals. It is used for final cleaning and polishing of the tooth surface after prophylactic as well as therapeutic removal of dental tartar, for the removal of dental plaque and pigmentations prior to restorative tooth treatment or prior to surgical or controlled tooth whitening.

4. PRODUCT TRADENAME

DEPURAL™ NEO
Cleaning and Polishing Paste

5. MATERIAL FORM

Depural Neo is light green paste.

6. PRODUCT PACKAGING

<i>Depural Neo</i>	min. 70.5 g	75 g of paste in PE tube, IFU in cardboard box
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7. PRODUCT REQUIREMENTS

Requirement	Target	Unit	Test Method
Appearance	Light green paste, free of mechanical impurities, peppermint aroma	-	ZP 4816215
Ca and Al identity test	Comply	-	ZP 4816215

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Ash content	48-53	%	ZP 4816215
Abrasive particles content	Comply	-	ZP 4816215
Film thickness	Max. 60	µm	ZP 4816215
pH	Max. 10.5	-	ISO 11609
RDA	< 250	-	ISO 11609
Stability	No deterioration which may affect appearance, pH	-	ISO 11609
Heavy metals	Max. 20	mg/kg	ISO 11609
Microbiological Safety	Compliant to SOP 10-110	-	SOP 10-110

8. STORAGE CONDITIONS

To be stored in a dry and dark place at 5- 25 °C, in a well-sealed container.

9. SHELF LIFE

Product shelf life is 2 years from the date of manufacturing.

10. ABBREVIATIONS

JKJ	Quality Control and Quality Assurance
SOP	Standard Operating Procedure
SP	Specification
ZP	Testing Instruction

11. RELATED DOCUMENTS

SOP 05-101	Level III controlled documentation
SOP 10-107	Statistical control of products in primary packaging and finished products
SOP 10-110	Microbiological testing and evaluation

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ZP 4816215	Depural Neo
ISO 11609	Dentistry — Dentifrices — Requirements, test methods and marking

12. REVISION SUMMARY				
JKJ manager is responsible for specification modifications according to SOP 05-101.				
Chapter No.	Description	Nr. of Pages	Revision	Date of issue
-	Inner package change, change of components content	5	1	28.07.2004
-	The full text of SP C104 including annexes	3 + 2	2	1.10.2009
-	Removed section 4.4.2, minor modification in the composition (input art. 151212 changed to 151213), updated distribution list.	2 + 2	3	23.04.2015
-	Revision according to the actual template in MasterControl).	2+1	4	06.03.2020
-	New layout implemented, Translated to english Section 1. Purpose - ,specification is part of registration documentation' removed Section 2. Product description updated to be in line with TF & IFU Section 3. Indication for Use added Section 4. Product tradename (orig. 4.1.) updated to be in line with TF Section 6. Product packaging (orig. 4.3. and 4.5.1) section merged and updated to be in line with TF Sampling plan section (orig. 4.4.) and statistic control sections (orig. 4.5.2) removed Section 7. Product requirements (orig. 4.5.3.) updated according to Design Input Summary Section 10. Abbreviations (orig. 3.) updated Section Appendix (orig. 6.) removed Section 12. Revision summary updated (orig. 7. and 7.1. sections merged)	4	5	The date of issue

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	Section Distribution (orig. 9.) removed			
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13. APPROVAL
Master Control