MATERIALS COMPOSING NOVAGENIT® IMPLANTS
MATERIALI CHE COMPONGONO GLI IMPIANTI NOVAGENIT®
MATÉRIAUX COMPOSANT LES IMPLANTS NOVAGENIT®
MATERIALIEN AUS NOVAGENIT® IMPLANTATEN
MATERIALES QUE COMPONEN LOS IMPLANTES NOVAGENIT®

REF	Materials	Standard
DAC001200	100% hyaluronic acid cross-linked with poly-DL lactic (*)	ASTM F 1635, ISO 13781, ASTM F 1925, ASTM F 2579, Eu.Ph Monograph 1472
DAC001800	100% hyaluronic acid cross-linked with poly-DL lactic (*)	ASTM F 1635, ISO 13781, ASTM F 1925, ASTM F 2579, Eu.Ph Monograph 1472
DAC003000	100% hyaluronic acid cross-linked with poly-DL lactic (*)	ASTM F 1635, ISO 13781, ASTM F 1925, ASTM F 2579, Eu.Ph Monograph 1472
DAC003002	100% hyaluronic acid cross-linked with poly-DL lactic (*)	ASTM F 1635, ISO 13781, ASTM F 1925, ASTM F 2579, Eu.Ph Monograph 1472
DAC003003	100% hyaluronic acid cross-linked with poly-DL lactic (*)	ASTM F 1635, ISO 13781, ASTM F 1925, ASTM F 2579, Eu.Ph Monograph 1472
2100008	100% Poly L lactide	ISO 13781, ASTM F 1925, ASTM F 2579
2100010	100% Poly L lactide	ISO 13781, ASTM F 1925, ASTM F 2579

(*) Ratio between Hyaluronan and PLA is as follow:
Hyaluronan: 78% ± 8 % w/w
PLA: 22% ± 8 % w/w

EN_To find out the analytical composition of the constituent materials of the implants refer to the following:
IT_Per conoscere la composizione analitica dei materiali costitutivi degli impianti si rimanda a quanto segue:
FR_Pour connaître la composition analytique des matières constitutives des implants, se référer à ce qui suit:
DE_Die analytische Zusammensetzung der Materialien, aus denen die Implantate bestehen, finden Sie im Folgenden:
ES_Para conocer la composición analítica de los materiales constitutivos de los implantes, consulte lo siguiente:
PT_Para saber a composição analítica dos materiais constituintes dos implantes, consulte o seguinte:
NL_Om de analytische samenstelling van de samenstellende materialen van de implantaten te weten te komen, raadpleegt u het volgende:
EL_Για να μάθετε την αναλυτική σύνθεση των συστατικών υλικών των εμφυτευμάτων, ανατρέξτε στα ακόλουθα:

Hyaluronic acid Specifications (in accordance with Eu.Ph Monograph 1472, ASTM F 1635)	
origin	biotecnology
ash	<10% s/s
heavy metals	< 20ppm
Arsenic	<2 ppm
Proteins - (2.2.25 Eur.Ph.)	< 0,2% s/s
Uric acid (UA)	>45 % s/s
preservatives	not presente
molecular weight (SEC-MALS)	0,25-0,45 MDa
BSE/TSE	N/A
OGM	no OGM
Iron (Eu.Pharma 01:2008:20257)	<80 ppm (Eu.Ph Monograph 1472) (≤ 0,008%; <80mg/Kg)
Nucleic acid (Eu.Pharma 01:2008:20224)	<0,5 Abs (Eu.Ph Monograph 1472)

Poly DL lactide Specifications (ISO 13781, ASTM F 1925, ASTM F 2579)	
molecular weight "Mw", "Mn" and polydispersity index "Mw/Mn" - determined by Gel Permeation Chromatography (GPC-RID, THF)	Mw_Report result kg/mol Mn_Report result kg/mol Mw/Mn_Report result
Inherent viscosity – (Choloroform, 25°C-30°C, c=1g/dl) corresponding to molar mass	0,16 – 0,24 dl/g
Specific rotation (Polarimetry chloroform, 20°C)	(-2) – (+2) °
Water content – (By coulometric or gravimetric titration, or Karl Fisher)	< 0,5%
Tin(Sn) content – (By AAS, IPC) – residulal catalyst (optional)	< 50ppm
Residual solvent –total (By GC)	< 0,10% (or <1000 ppm)
Residual solvent - toluene	<890 ppm
Residual solvent, Ethyl acetate	< 5000 ppm (in compliance with ICH Q3C)
Residual monomer – total (By GC-FID)	max. 2,4 %
Residual monomer – DL lactide (By GC-FID)	max. 2,4 %
Residual monomer, meso-lactide (By GC-FID)	Report results %
Elemental impurities - Heavy metal – (USP, <232>) Note: "Parameters not tested in all batches but validated through in-process or final testing"	< 10 ppm
Acid number (titration) - optional	< 6.0 mg KOH/g
Residual monomer – total (By GC-FID)	max. 2,4 %
Residual monomer – DL lactide (By GC-FID)	max. 2,4 %
Residual monomer, meso-lactide (By GC-FID)	Report results %
Elemental impurities - Heavy metal – (USP, <232>)	< 10 ppm

Poly L lactide Specification (ISO 13781, ASTM F 1925, ASTM F 2579)	
Inherent viscosity – (Choloroform, 25°C, c=0,1g/dl)	5.50 – 7.50 dl/g
Specific rotation (chloroform, 20°C)	(-155°) – (-160) °
Water content – (By coulometer)	< 0,5%
Tin content – (By AAS)	< 50ppm
Residual solvent total (by GC)	< 0,010%
Residual solvent, Acetone (GC)	<5000ppm
Residual solvent, Toluene (GC)	<890ppm
Residual monomer total – (By GC)	< 0.10 %
Heavy metal – elemental impurities (USP <232>)	<10 ppm