sa Alcon-Couvreur nv
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CERTIFICATE OF ANALYSIS

EXPIRY DATE	**06/2023**
ITEM ID	**0005090027**
MANUFACTURING DATE	**30/07/20**
PRODUCT NAME	**DURATEARS UNGUENTO 3.5G<RCH**
Country Code	**RCH**
VO (Packaging) Ref number	**201826069**
PRODUCT CODE	**FO OINTMENT**
Batch Number	**20G30E**
Date of DISPOSITIONED	**20-AUG-20**

CHEMISTRY			***Specs at Release***	
Appearance	HOMOGENEOUS OINTMENT		Homogeneous ointment	BEMET-00304\APPEARANCE OINTMENT
Appearance(AUS,NZ)	TRANSLUCENT		Translucent	BEMET-00304\APPEARANCE OINTMENT(AUS,NZ)
Color	LIGHT YELLOW		Light yellow	BEMET-00304\COLOR(-TEXT)
Homogeneity	NO AGGLOMERATION, NO SEPARATION		No agglomeration, no separation	BEMET-00483\HOMOGENEITY
LE 8 metal particles/1 tube	PASS		Pass	BEMET-00304\METAL PARTICLES(2)
Lattice break	2		1 - 4	BEMET-00304\LATTICE BREAK
Opalescence	TRANSLUCENT		Translucent	BEMET-00304\APPEARANCE OPALESCENCE
Tubes with 8 part GE 50 µ	0		LE 1 tube	BEMET-00304\METAL PARTICLES(2)
Metal Particles/10 Tubes	1	Particles	LE 50 Particles GE 50 µm	BEMET-00304\METAL PARTICLES(2)
Acidity or alkalinity	0.24	mL	LE 0.40 ml	BEMET-00574\ACIDITY OR ALKALINITY
MICROBIOLOGY			***Specs at Release***	
Sterility	PASS		Pass	BEMET-00180\STERILITY

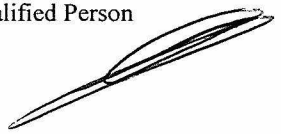
DOCUMENT CONTROL

I hereby certify that the above information is authentic and accurate. This batch of product has been fabricated/manufactured, including packaging and quality control, at the above mentioned site(s) in full compliance with the GMP requirements of the local Regulatory Authority and with the specifications in the Marketing Authorization of the importing country. The batch processing, packaging and analysis records were reviewed and found to be in compliance with GMP. The lot mentioned above meets the requirements of article 51 of the European Parliament and Council Directive 2001/83/EC.

K. Verresen

Industrial Pharmacist,Authorized Qualified Person

August 20, 2020



288F ALB

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CERTIFICATE OF ANALYSIS

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DOCUMENT CONTROL

Fill volume	3.564	g

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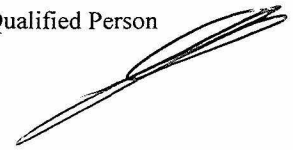

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