

Form no. : F-SZJ-SOP-16-01 Ver. No.:6 as of. 04.01.2021	FINISHED PRODUCT SPECIFICATION	Gofarm Sp. z o.o. Sp. k.
SPG No. 322/WM	Maregal IIa	Page 1 of 5
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1. Product name:

Maregal

Index: ENT09/30

2. Product description:

Form: Solution

Content in direct packaging: 30 ml

Feature & Benefits: invasive medical device for short-term use through body orifices: nasal cavity and sinuses – class IIa rule 5.

The medical device intended for children over 3 years of age and adults.

3. Composition: Sea water, demineralized water.

4. Packaging:

Direct packaging:

No.	Parameter		Requirements
1.	Bottle		
	Appearance		Clean, smooth, without damages, in accordance with accepted pattern
	Material		HDPE
	Maximal capacity [ml]	30 ml	35
	Dimensions (diameter x height) [mm]	30 ml	31,00 ± 0,40 x 65,20 ± 0,70
	Colour		White
	Weight of empty bottle [g]		6,00 ± 0,5
2.	Atomizer		
	Appearance		Clean, smooth, without damages, in accordance with accepted pattern
	Material		PE
	Colour		White
3.	Cap		
	Appearance		Clean, smooth, without damages, in accordance with accepted pattern
	Material		PP
	Colour		Transparent

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	Mass [g]	6,70 ± 10%
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Label:

No.	Parameter	Requirements
1.	Appearance	Clean, no damages
2.	Overprint	According to accepted pattern, glossy, CMYK
3.	Paper type	PE material
4.	Dimensions (length x height) [mm]	94,00 x 35,00
5.	Weight [g]	0,40 ± 15%

Unit Box:

No.	Parameter	Requirements
1.	Appearance	Clean, no damages
2.	Varnish	In accordance with accepted pattern, UV glossy
3.	Overprint	In accordance with accepted pattern, CMYK
4.	Dimensions (length x height x width) [mm]	45,00 x 120,00 x 45,00
5.	Paper type	Alaska plus 235g or Tambrite 230 or Aegle Pro 235 or Allyking 235 or Carta Dedicata 230 or Panca Brite 270
6.	Weight [g]	7,90 ± 10%

Instructions for use:

No.	Parameter	Requirements
1.	Appearance	Clean, no damages
2.	Overprint	According to accepted pattern, 1 color
3.	Dimensions (L x H) [mm]	210,00 x 140,00
4.	Paper type	Polarbright 50g/m ²
5.	Weight [g]	1,50 ± 10%

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Outer case:

No.	Parameter	Requirements
1.	Appearance	Clean, no damages
2.	Overprint	Without overprint with label (1 colour Pantone)
3.	Cardboard type	cardboard
4.	Dimensions (L x H x W) [mm]	280,00 x 128,00 x190,00
5.	Weight [g]	108,00 ± 10%

5.The way of packaging:

Packaging type	Requirements
Direct packaging	Plastic bottle 30ml
Sales packaging	Bottle with label and instructions for use
Outer case	24 units
Packaging on the palette	Euro palette, 24 unit boxes x 16 outer cases x 10 layers = 3840 units on palette, palettes with height 160 cm ±3%, weight 245 kg ±3%

6. Qualitative and quantitative requirements: Research carried out for each batch:

No.	Parameter	Requirements for release	Analytic method
1.	Form, colour, scent	Transparent, clear, toneless, odourless solution without mechanical contaminations	IS-11/03
2.	pH at temp. 20° C	6,5 – 8,5	IS-11/03
3.	Density d ₂₀ [g/ml] at temp 20° C	1,00 - 1,04	IS-11/03
4.	TAMC (CFU/g or CFU/mL)	Max 2 x 10 ²	FP XIII/Ph. Eur. XI
5.	TYMC (CFU/g or CFU/mL)	Max 2 x 10 ¹	
6.	<i>Staphylococcus aureus</i>	Not present in 1 g or 1 mL	
7.	<i>Pseudomonas aeruginosa</i>	Not present in 1 g or 1 mL	
8.	Content declared in the unit box [ml]	Not less than 30	IS-11/03
9.	Chloride content [mg/l]	14.200 – 14.800	IS-11/03

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7. Storage, transport conditions and precautions:

Store in the original container at temperature 15 -25°C.

Store in a dry and dark place out of the reach and sight of children.

Transport in controlled temperature 15-25°C.

8. Batch number and expiration date notation format:

On unit box and bottle:

LOT MNSBBYY

MNS - product name

BB - number of batch in the year

YY - manufacturing year

EXP – YYYY-MM

YYYY-MM – expiration year / month (commencing from a batch manufacturing)

And additionally on the bottom of the bottle the third line:

DDYYHHmm

DDD – manufacturing day

YY – manufacturing year

HH – manufacturing time (hours)

mm – manufacturing time (minutes)

9. Shelf life:



36 months commencing from a batch manufacturing

10. Sampling:

Archive batch – 5 boxes

Reasons of changing	
Document edition	Changes in relation to previous version
Version 06	Removing the colour parameter Pharmacopoeia edition update

— End of the document —

	Name	Signature	Date
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