

Pharmaceuticals and Cosmetics Inc., Koprivnica, Croatia Quality Control Department

BATCH CERTIFICATE

No. 040000796689

Product/packing/market: Belobaza / á 2 kg / SI

Batch No :

: 29542028

Manuf, date

: 02.2018

Code

: 7279

Expiry date

: 02.2022

Quantity: 242 pcs

Test	Requirement			Result
Appearance	white, smooth	and homoge	neous cream with	out clots and foreign matter complies
рН	4,5	5,5		5,0
Loss on drying	65	75	%	71,5
Hydroxyl value	max	10,0		6,9
lodine value	max	2,0		0,32
Identification of benzyl alcohol	Rt (sample) ≈ Rt (standard)			
Content of benzyl alcohol	9,0	11,0	mg/g	complies 9,99
Content of benzyl alcohol	90,0	110,0	%	99,9
MICROBIOLOGICAL PURITY				
Total aerobic microbial count (TAMC) + total combined yeasts/moulds count (TYMC)	max	100	cfu/a	<10
Escherichia coli in 0,5 g	absence		•	
Staphylococcus aureus in 0,5 g	absence			absence
Pseudomonas aeruginosa in 0,5 g	absence			absence
Candida albicans in 0,5 g	absence			absence
MICROBIOLOGICAL PURITY Total aerobic microbial count (TAMC) + total combined yeasts/moulds count (TYMC) Escherichia coli in 0,5 g Staphylococcus aureus in 0,5 g Pseudomonas aeruginosa in 0,5 g	90,0 max absence absence absence	·	mg/g % cfu/g	99, <1 absence absence

I hereby certify that the above information is authentic and accurate.

This batch of product has been produced and released at the above mentioned site in full compliance with the GMP requirements and with the specifications in the Marketing Authorisation of the importing country.

The batch records were reviewed and found to be in compliance with GMP.

Released by:

IVANA KRAJINA, MPharm.

Qualified Person

This document contains e-signature.

07.03.2018