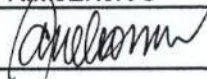

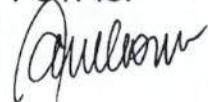


**ODLUKA O PUŠTANJU U PROMET**

PROIZVOD:	BELOBAZA KREMA
SERIJA:	24559016
PARTIJA PROVJERE	40000604254
ROK VALJANOSTI:	01 2020
ŠIFRA:	7280
TRŽIŠTE:	SUN
OBLIK PAKOVANJA:	ā 4kg
KOLIČINA:	125kom
Tehničar OTK - datum/potpis: 02.02.2016. Kragić	

PAKIRANJE SERIJE POLUPROIZVODA DOVRŠENO	<input checked="" type="checkbox"/> DA	<input type="checkbox"/> NE	<input type="checkbox"/> NIJE PRIMJENJIVO
Datum/potpis	08.02.16.		

PROIZVODNA DOKUMENTACIJA	<input checked="" type="checkbox"/> ODGOVARA	<input type="checkbox"/> NE ODGOVARA	<input type="checkbox"/> NIJE PRIMJENJIVO	08.02.16.	
PAKIRNA DOKUMENTACIJA	<input checked="" type="checkbox"/> ODGOVARA	<input type="checkbox"/> NE ODGOVARA	<input type="checkbox"/> NIJE PRIMJENJIVO	08.02.16.	
ANALITIČKA DOKUMENTACIJA	<input checked="" type="checkbox"/> ODGOVARA	<input type="checkbox"/> NE ODGOVARA	<input type="checkbox"/> NIJE PRIMJENJIVO	08.02.16.	

PROIZVOD : <input checked="" type="checkbox"/> SE ODOBRAVA ZA PUŠTANJE U PROMET  <input type="checkbox"/> SE ODOBRAVA ZA TRANSPORT  <input type="checkbox"/> NE ODGOVARA razlog:	DATUM: 08.02.16.	POTPIS: 
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Upotreba ovog obrasca opisana je u SOP000065 „Postupak puštanja u promet serije gotovog lijeka“

Upotreba ovog obrasca elektronički je odobrena.

**BATCH CERTIFICATE**

No. 040000604254

**Product/packing/market:** Belobaza / á 4 kg / SI

<b>Batch No</b>	: 24559016	<b>Manuf. date</b>	: 01.2016
<b>Code</b>	: 7280	<b>Expiry date</b>	: 01.2020
<b>Quantity</b>	: 125 pcs		

Test	Requirement			Result
Appearance	white, smooth and homogeneous cream without clots and foreign matter			
pH	4,5	5,5		complies
Loss on drying	65	75	%	5,0
Hydroxyl value	max	10,0		73,2
Iodine value	max	2,0		6,8
Identification of benzyl alcohol	Rt (sample) ≈ Rt (standard)			0,4
Content of benzyl alcohol	9,0	11,0	mg/g	complies
Content of benzyl alcohol	90,0	110,0	%	9,76
<b>MICROBIOLOGICAL PURITY</b>				
Total aerobic microbial count (TAMC) + total combined yeasts/moulds count (TYMC)	max	100	cfu/g	<10
Escherichia coli in 0,5 g	absence			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

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:** KRISTINA JANEKOVIĆ PETRAS, MPharm. Univ. Master  
 Qualified Person  
 08.02.2016

This document contains e-signature.