

ODLUKA O PUŠTANJU U PROMET

PROIZVOD:	BELUBAZA KDEMA
SERIJA:	25151046
PARTIJA PROVJERE	40000625596
ROK VALJANOSTI:	04-2020
ŠIFRA:	7279
TRŽIŠTE:	SVN
OBLIK PAKOVANJA:	2 kg
KOLIČINA:	249 kom
Tehničar OTK - datum/potpis: 21.04.2016 <i>[Signature]</i>	

PAKIRANJE SERIJE POLUPROIZVODA DOVRŠENO	<input checked="" type="checkbox"/> DA	<input type="checkbox"/> NE	<input type="checkbox"/> NIJE PRIMJENJIVO
Datum/potpis:	26.04.16.	<i>[Signature]</i>	

PROIZVODNA DOKUMENTACIJA	<input checked="" type="checkbox"/> ODGOVARA	<input type="checkbox"/> NE ODGOVARA	<input type="checkbox"/> NIJE PRIMJENJIVO	26.04.16.	<i>[Signature]</i>
PAKIRNA DOKUMENTACIJA	<input checked="" type="checkbox"/> ODGOVARA	<input type="checkbox"/> NE ODGOVARA	<input type="checkbox"/> NIJE PRIMJENJIVO	26.04.16.	<i>[Signature]</i>
ANALITIČKA DOKUMENTACIJA	<input checked="" type="checkbox"/> ODGOVARA	<input type="checkbox"/> NE ODGOVARA	<input type="checkbox"/> NIJE PRIMJENJIVO	26.04.16.	<i>[Signature]</i>

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: 26.04.16.	POTPIS: <i>[Signature]</i>
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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. 040000625596

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

Batch No	: 25151046	Manuf. date	: 04.2016
Code	: 7279	Expiry date	: 04.2020
Quantity	: 249 pcs		

Test	Requirement			Result
Appearance	white, smooth and homogeneous cream without clots and foreign matter			complies
pH	4,5	5,5		4,94
Loss on drying	65	75	%	71,2
Hydroxyl value	max	10,0		5,4
Iodine value	max	2,0		0,4
Identification of benzyl alcohol	Rt (sample) ≈ Rt (standard)			complies
Content of benzyl alcohol	9,0	11,0	mg/g	9,70
Content of benzyl alcohol	90,0	110,0	%	97,0
MICROBIOLOGICAL PURITY				
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.M.Spec.
Qualified Person
26.04.2016

This document contains e-signature.