

ODLUKA O PUŠTANJU U PROMET

PROIZVOD:	BELOBAZA KREMA
SERIJA:	25202046
PARTIJA PROVJERE	40000627572
ROK VALJANOSTI:	04 2020
ŠIFRA:	7279
TRŽIŠTE:	JVN
OBLIK PAKOVANJA:	2 kg
KOLIČINA:	250 kom 249 kom T.H. 2.5.16.
Tehničar OTK - datum/potpis: 29. 04. 16. UB	

PAKIRANJE SERIJE POLUPROIZVODA DOVRŠENO	<input checked="" type="checkbox"/> DA	<input type="checkbox"/> NE	<input type="checkbox"/> NIJE PRIMJENJIVO
Datum/potpis	06.05.16.		Tetec

PROIZVODNA DOKUMENTACIJA	<input checked="" type="checkbox"/> ODGOVARA	<input type="checkbox"/> NE ODGOVARA	<input type="checkbox"/> NIJE PRIMJENJIVO	06.05.16.	Tetec
PAKIRNA DOKUMENTACIJA	<input checked="" type="checkbox"/> ODGOVARA	<input type="checkbox"/> NE ODGOVARA	<input type="checkbox"/> NIJE PRIMJENJIVO	06.05.16.	Tetec
ANALITIČKA DOKUMENTACIJA	<input checked="" type="checkbox"/> ODGOVARA	<input type="checkbox"/> NE ODGOVARA	<input type="checkbox"/> NIJE PRIMJENJIVO	06.05.16.	Tetec

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: 06.05.16.	POTPIS: Tetec
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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. 040000627472

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

Batch No : 25202046
Code : 7279
Quantity : 249 pcsManuf. date : 04.2016
Expiry date : 04.2020

Test	Requirement	Result
Appearance	white, smooth and homogeneous cream without clots and foreign matter	
pH	4,5 5,5	complies 5,0
Loss on drying	65 75 %	72,7
Hydroxyl value	max 10,0	4,1
Iodine value	max 2,0	0,3
Identification of benzyl alcohol	Rt (sample) ≈ Rt (standard)	
Content of benzyl alcohol		complies
	9,0 11,0 mg/g	9,78
Content of benzyl alcohol	90,0 110,0 %	97,8
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	
Staphylococcus aureus in 0,5 g	absence	absence
Pseudomonas aeruginosa in 0,5 g	absence	absence
Candida albicans in 0,5 g	absence	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: TAMARA TETEC, MPharm. Univ. Master
Qualified Person
06.05.2016

This document contains e-signature.