

BATCH CERTIFICATE

No. 040000678193

✓
8.12.16

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

Batch No	: 26364106	Manuf. date	: 10.2016
Code	: 7280	Expiry date	: 10.2020
Quantity	: 126 pcs		

Test	Requirement			Result
Appearance	white, smooth and homogeneous cream without clots and foreign matter			
pH	4,5	5,5		complies 4,9
Loss on drying	65	75	%	73,1
Hydroxyl value	max	10,0		4,7
Iodine value	max	2,0		0,3
Identification of benzyl alcohol	Rt (sample) ≈ Rt (standard)			
Content of benzyl alcohol	9,0	11,0	mg/g	complies 9,72
Content of benzyl alcohol	90,0	110,0	%	97,24
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
30.11.2016

This document contains e-signature.

BATCH CERTIFICATE

No. 040000647841

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

Batch No : 25694076
Code : 7279
Quantity : 250 pcsManuf. date : 07.2016
Expiry date : 07.2020✓
15.12.16

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	%	71,4
Hydroxyl value	max	10,0		4,7
Iodine value	max	2,0		0,4
Identification of benzyl alcohol	Rt (sample) ≈ Rt (standard)			
Content of benzyl alcohol	9,0	11,0	mg/g	complies 9,88
Content of benzyl alcohol	90,0	110,0	%	98,80
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
27.07.2016

This document contains e-signature.

BATCH CERTIFICATE

No. 040000666209

15.12.16

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

Batch No : 26067096
Code : 7279
Quantity : 250 pcsManuf. date : 09.2016
Expiry date : 09.2020

Test	Requirement			Result
Appearance	white, smooth and homogeneous cream without clots and foreign matter			complies
pH	4,5	5,5		4,98
Loss on drying	65	75	%	70,8
Hydroxyl value	max	10,0		7,7
Iodine value	max	2,0		0,3
Identification of benzyl alcohol	Rt (sample) ≈ Rt (standard)			complies
Content of benzyl alcohol	9,0	11,0	mg/g	9,73
Content of benzyl alcohol	90,0	110,0	%	97,32
MICROBIOLOGICAL PURITY				
Total aerobic microbial count (TAMC) + total combined yeasts/moulds count (TYMC)	max	100	cfu/g	5
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

This document contains e-signature.

27.09.2016