



BATCH CERTIFICATE

No. 040001077275

Product/packing/market: Beloderm 0,5 mg/g cream / á 1 kg / SI

Batch No : 27840051
Code : 3772
Quantity : 951 pcs

Manuf. date : 06.2021
Expiry date : 06.2024

Test	Requirement			Result
Appearance	white, homogenous cream without mechanical impurities			complies
pH	4,5	5,5		5,0
Identification of betamethasone dipropionate (HPLC)	Rt (sample) = Rt (standard)			complies
Identification of chlorocresol (HPLC)	Rt (sample) = Rt (standard)			complies
RELATED SUBSTANCES (HPLC)				
Betamethasone-17-propionate	not more than	0,5	%	0,115
Betamethasone-21-propionate	not more than	0,5	%	<LOQ
Individual unknown related substance	not more than	0,5	%	<LOQ
The sum of all known and unknown related substances	not more than	2,5	%	0,115
Content of betamethasone (HPLC)	0,475	0,525	mg/g	0,499
Content of betamethasone (HPLC)	95,0	105,0	%	99,9
Content of chlorocresol (HPLC)	0,9	1,1	mg/g	1,001
Content of chlorocresol (HPLC)	90,0	110,0	%	100,1
MICROBIOLOGICAL PURITY				
Total aerobic microbial count (TAMC)	not more than	10 ²	cfu/g	<10
Total combined yeasts/moulds count (TYMC)	not more than	10 ¹	cfu/g	<10
Pseudomonas aeruginosa in 1g	absence			absence
Staphylococcus aureus in 1g	absence			absence



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

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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
05.07.2021

This document contains e-signature.