

CERTIFICATE OF ANALYSIS

PRODUCT: Diltiazem HCL 2% Cream (Anotop)

BATCH NUMBER: 99819


DATE OF MANUFACTURE: October 2017

DATE OF TESTING: November 2017

EXPIRY DATE: September 2020

At the time of testing the results below were obtained for the above product. This product has been manufactured using materials compliant with the CHMP guidelines relating to minimising the risk from transmissible spongiform encephalopathies (TSE) via medicinal products. The product has been manufactured in accordance with the Dales Specials Manufacturers Licence MS 123.

<u>Test</u>	<u>Specification</u>	<u>Result</u>
1 Description	Smooth, white cream	Complies
2 Identification: Diltiazem HCl	Retention time of peak in assay is same as standard	Complies
3 Identification: Phenoxyethanol	Retention time of peak in assay is same as the standard	Complies
4 pH	4.0 – 7.0	4.7
5 Assay: Diltazem HCl	1.90 – 2.10 %w/w	2.04%
6 Assay Phenoxyethanol	0.90 – 1.10 % w/w	1.03%
7 Deacetyl Diltiazem Content	<0.5% of diltazem content	0.02%
8 Microbial Contamination		
Total aerobic microbial count	<100cfu/g	<10 cfu/g
Total yeast and mould count	<10cfu/g	<10 cfu/g
Pseudomonas Aeruginosa	Absent	Absent
Staphylococcus Aureus	Absent	Absent

Signed 
R D Burton BSc CBiol MRSB
Qualified Person

Date 17 Nov 17



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