

CERTIFICATE OF ANALYSIS



PRODUCT: Diltiazem HCl 2% Cream (Anoheal)

BATCH NUMBER: 86469

Dales Pharmaceuticals

DATE OF MANUFACTURE: October 2016

DATE OF TESTING: November 2016

EXPIRY DATE: September 2019

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	4.8
5 Assay: Diltiazem HCl	1.90 – 2.10 %w/w	2.04%
6 Assay Phenoxyethanol	0.90 – 1.10 % w/w	1.02%
7 Deacetyl Diltiazem Content	<0.5% of diltiazem content	0.003%
8 Microbial Contamination		
Total aerobic microbial count	<100cfu/g <10cfu/g	Complies Complies
Total yeast and mould count	Absent Absent	Absent Absent
Pseudomonas Aeruginosa		
Staphylococcus Aureus		

PT

Signed.....  
R D Burton BSc CBIol MRSB  
Qualified Person

Date..... 14 Nov 2016



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