

CERTIFICATE OF ANALYSIS

PRODUCT: Malaseb 250ml Shampoo (CZ/HU/SK)
BATCH NO: 96174
DATE OF MANUFACTURE: June 2017
DATE OF TESTING: July 2017
EXPIRY DATE: May 2019

At the time of testing the results below were obtained for the above product.

<u>Test</u>	<u>Specification</u>	<u>Result</u>
1. Appearance	A clear to slightly unclear light yellow to light brown liquid	Complies
2. pH	5.5 – 6.1	5.8
3. Identification:		
Chlorhexidine Digluconate	Retention time same as standard	Complies
Miconazole Nitrate	Retention time same as standard	Complies
Methylchloroisothiazolinone	Retention time same as standard	Complies
Methylisothiazolinone	Retention time same as standard	Complies
4. Specific gravity	1.00 – 1.10g/ml	1.06g/ml
5. Viscosity	1.0 – 5.0Pa.s	2.6Pa.s
6. Assay:		
Chlorhexidine Digluconate	19.0 – 21.0mg/ml	20.5mg/ml
Miconazole Nitrate	19.0 – 21.0mg/ml	20.2mg/ml
Methylchloroisothiazolinone	6.8 – 8.3mcg/ml	7.7mcg/ml
Methylisothiazolinone	2.3 – 2.8mcg/ml	2.5mcg/ml
7. Impurities:		
4-chloroaniline	≤ 0.05mg/ml	0.02mg/ml
Impurity 1	≤ 1.0%	0.4%
Impurity 2	≤ 1.0%	ND
Impurity 3	≤ 1.0%	ND
Impurity 4	≤ 1.0%	ND
Single unknown impurities	≤ 1.0%	ND
Total Impurities	≤ 3.0%	0.4%
8. Microbial limit test		
TAMC	≤ 10 ² CFU/g	Complies
TYMC	≤ 10 ¹ CFU/g	Complies
Ps Aeruginosa	Absence	Absent
Staph. Aureus	Absence	Absent

Signed 
 R D Burton BSc CBIol MRSB
 Qualified Person

Date 25 Jul 17



CERTIFICATE OF CONFORMITY

Manufacturing Company: Dales Pharmaceuticals
Address: Snaygill Industrial Estate, Skipton, North Yorkshire, BD23 2RW

Manufactured For: Dechra Veterinary Products A/S
Address: Mekuvej 9
7171 Uldum
Denmark

Product Name: Malaseb 250ml Shampoo (CZ/HU/SK)

Packed Product Code: 91340

Lot Number: 96174 Packaging Date: July 2017


Batch Record Review

The documentation for the above mentioned product has been reviewed by a Qualified Person and it has been determined that this lot was manufactured and packaged in accordance with master production documents.

The product has been manufactured in accordance with the Dales Manufacturers Licence ManA 123 and the Product Licence and Product Authorisation Licence as defined in the Technical Agreement.

All details relating to any Process Amendments and Material Reviews are attached.

Produced according to GMP. This batch is released into the market.

Signature: 
R D Burton BSc CBiol MRSB
Qualified Person

Date: 25 JUL 17

