chanelle
PHARMACEUTICALS
MANUFACTURING LTD

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CERTIFICATE OF ANALYSIS / CONFORMANCE

Product: Cazitel Plus
Customer: Pfizer, Hungary
Batch No.: E29206/K
Man Date: 05 / 2013
Expiry Date: 04 / 2016

Test	Specification	Result
Appearance	Yellow coloured, uncoated, circular, flat bevelled pork flavoured tablet with cross breakline on one side and plain on the other. Diameter: 13mm ± 0.3mm	Complies 13.1mm
Identification(UV detector): Praziquantel & Febantel Pyrantel Embonate	The chromatography of the HPLC assay exhibits major peaks due to Praziquantel and Febantel the retention times of which are comparable to those exhibited in the chromatogram of the standard. The chromatography of the HPLC assay exhibits major peaks due to Pyrantel Embonate the retention times of which are comparable to those exhibited in the chromatogram of the standard.	Complies Complies
*Identification (PDA detector): Praziquantel & Febantel *Pyrantel Embonate	The chromatography of the HPLC assay exhibits major peaks due to Praziquantel and Febantel the retention times of which are comparable to those exhibited in the chromatogram of the standard. The chromatography of the HPLC assay exhibits major peaks due to Pyrantel Embonate the retention times of which are comparable to those exhibited in the chromatogram of the standard.	*Non routine Test *Non routine Test
Identification of Pork Flavour:	Positive for its odour	Complies
Average Weight:	650 mg/tab ± 5% (617.5 – 682.5mg/tab)	652.1mg Complies
Friability:	Less than 1% after 100 revs	0.16% Complies
Hardness:	Not less than 60N	129N Complies
Moisture:	Not more than 5%	1.9% Complies
Dissolution: Praziquantel: Pyrantel Embonate: Febantel:	 NLT 75%(Q+5) dissolved in 45 mins (as per Ph. Eur) NLT 75%(Q+5) dissolved in 45 mins (as per Ph. Eur) NLT 75%(Q+5) dissolved in 45 mins (as per Ph. Eur)	 100% 94% 90%
Assay: Praziquantel: Pyrantel Embonate: Febantel:	 50 mg ± 5% (Limits: 47.5 – 52.5 mg/tab) 144 mg ± 5% (Limits: 136.8 – 151.2 mg/tab) 150 mg ± 5% (Limits: 142.5 – 157.5 mg/tab)	 49.5mg / tab 141.5mg / tab 150.1mg / tab
Uniformity of Dosage Unit	The requirements are met if the acceptance value of the first 10 dosage units is less than or equal to L1 (15.0). If the acceptance value is greater than L1, the next 20 dosage units are tested and acceptance value calculated. The requirements are met if the final acceptance value of the 30 dosage units is less than or equal to L1 (15.0) and no unit is over the deviation of L2 (25.0) from the calculated value of M in calculation of acceptance value.	Complies
**Microbial Purity	As per Ph. Eur	**Non-routine Test

*Non-routine test every 12th batch
**Non-routine test every 6th batch

This product has been manufactured, packaged and tested in accordance with the Marketing Authorisation No. 2655/11/09/MgSzH Atl (24db) and GMP. The product is fit for use and may be released for sale.

Checked By: _____ Date: 22/10/2013
Quality Assurance (*Signature*)

Approved By: Darren Daly Date: 23/10/2013
Qualified Person (*Signature*)

DARREN DALY
Qualified Person (*Print Name*)