laboratorios Karizoo s.a.

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CERTIFICATE OF ANALYSIS

PRODUCT:	**KARIDOX 500mg/g ORAL POWDER 1Kg (HU)**		
CODE:	HU0008	**BATCH:**	160070355
MANUFACTURE DATE:	02/03/2016	**EXPIRY DATE:**	09/2017
QUANTITY:	1000 units	**PACKAGING:**	1 Kg bag

TEST	SPECIFICATIONS	RESULT
Appearance	Yellowish powder	Conforms
Appearance of solution 0.04%	Clear solution and not more intensely coloured than reference solution Y_6	Complies
Relative density *(Ph. Eur. 2.9.34)*		
-Density tapped	0.8 – 1.0 g/ml	0.9 g/ml
-Density bulk	0.6 – 0.8 g/ml	0.7 g/ml
Water content *(Ph. Eur 2.5.12)*	≤3%	2.24%
Particle size	Min 8%>250 µm Max 50%<50 µm	Complies
pH of solution 0,04%	2.5 – 3.5	3.0
Fill Control	98 – 102% (980 -1020g) nominal content	99.8% (998g)
Packaging Control	Complies	Complies
Identification (HPLC)	Positive	Conforms
Doxycycline (hyclate)	47.5% - 52.5% (w/w)	50.3% (w/w)
Related substances		
- 6-epidoxycycline	≤ 2.0%	1.5%
- Metacycline	≤ 2.0%	0.1%
- Any other individual impurity*	≤ 0.5%	0.3%
- Total impurities	≤ 5.0%	1.9%
Microbiological control [1]		
- TAMC *(Ph. Eur. 2.6.12)*	< 10^2 CFU/g	NA
- TYMC	< 10^1 CFU/g	NA
- Escherichia coli (Ph. Eur. 2.6.13)	Absence	NA

*Reporting limit 0.3% of the active substance.
[1]Microbiological control is carried out every 10 batches or at least annually

NA: Not applicable
ND: Not detected

I hereby certify that the above information is authentic and accurate in so far that the specification information is available to us and we confirm that our scientific findings are true. This batch of product has been fabricated/manufactured, including packaging and quality control at the above mentioned site (Manufacturing Authorisation Number 4237-E) in full compliance with GMP requirements of the local Regulatory Authority and with the specifications in the Marketing Authorisation of the importing country. The batch processing, packaging and analysis records were reviewed and found to be in compliance with GMP.

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Analyst :	Qualified person:
Analysis Date: 09.03.2016	Encarna Andrés Date of release: 10.03.16