



Date: 10 November, 2016

RELEASE STATEMENT

PRODUCT:	DUPHALYTE*10X500ML MUL
CODE:	10006875
FILLED UNLABELED BATCH No:	190269
FINAL BATCH No:	190076
MANUFACTURING DATE:	05/OCT/16
EXPIRY DATE:	05/OCT/19
BATCH RELEASE SITE:	ZOETIS MANUFACTURING&RESEARCH SPAIN SL Ctra. Camprodon, s/n. - "La Riba" 17813 VALL DE BIANYA (Girona) - SPAIN

I hereby certify that the above information is authentic and accurate. This batch of product has been manufactured, including packaging/labeling and quality control at the above mentioned site in full compliance with the 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.

Núria Juanola Bassols

Qualified Person

ZOETIS MANUFACTURING & RESEARCH SPAIN, S.L.

CERTIFICATE OF ANALYSIS

zoetis

PRODUCT: DUPHALYTE * 500

CODE: 40010761

FILLED UNLABELED BATCH NUMBER: 190269

	Results	Release Specification
Appearance	Meets requirements	Clear yellow solution
Identification	Meets requirements	Positive for: Vit. B ₁ , Vit. B ₂ , Vit. B ₆ , Valine-DL, Phenylalanine-DL, Nicotinamide, D-Panthenol, Leucine, Dextrose, Phenol, Methylparaben, Propylparaben
pH	4.5	4.3 - 4.7
Vitamina B ₁ HCl	198 µg/ml	180 - 220 µg/ml
Vitamina B ₂	81.7 µg/ml	75.6 - 92.4 µg/ml
Vitamin B ₆ HCl	198 µg/ml	180 - 220 µg/ml
Valine-DL	50 µg/ml	45 - 55 µg/ml
Phenylalanine-DL	31 µg/ml	27 - 33 µg/ml
Leucine	39 µg/ml	36 - 44 µg/ml
Dextrose	46.7 mg/ml	43.2 - 47.7 mg/ml
Phenol	0.096 mg/ml	Not more than 0.110 mg/ml
Methyl p-Hydroxybenzoate	1.867 mg/ml	1.620 - 1.980 mg/ml
Propyl p-Hydroxybenzoate	0.194 mg/ml	0.180 - 0.220 mg/ml
Nicotinamide	2.27 mg/ml	2.03 - 2.48 mg/ml
D-Panthenol	0.10 mg/ml	0.09 - 0.11 mg/ml
Sterility	Sterile	Sterile
Endotoxins	Meets requirements	Not more than 0.5 EU/ml
Volume	Meets requirements	Minimum 500 ml

OBSERVATIONS:

Quality Control Manager:



E.Serra

zoetis

Ctra. Camprodon, s/n
Vall de Bianya - Girona

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