



Date: November 12th, 2015

RELEASE STATEMENT

PRODUCT:	DUPHALYTE*10X500ML RUM
CODE:	137664
FILLING M.O.:	E21252
BATCH No.:	21252
MANUFACTURING DATE:	07/2015
EXPIRY DATE:	07/2018
MANUFACTURING, TESTING & BATCH RELEASE SITE:	ZOETIS MANUFACTURING&RESEARCH SPAIN SL (Formerly Pfizer Olot SLU). 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: 63589

FILLING M.O.: E21252

	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 B₁ HCl	201 µg/ml	180 - 220 µg/ml
Vitamina B₂	81.4 µg/ml	75.6 - 92.4 µg/ml
Vitamin B₆ HCl	192 µg/ml	180 - 220 µg/ml
Valine-DL	53 µg/ml	45 - 55 µg/ml
Phenylalanine-DL	30 µg/ml	27 - 33 µg/ml
Leucine	41 µg/ml	36 - 44 µg/ml
Dextrose	45.6 mg/ml	43.2 - 47.7 mg/ml
Phenol	0.101 mg/ml	Not more than 0.110 mg/ml
Methyl p-Hydroxybenzoate	1.857 mg/ml	1.620 - 1.980 mg/ml
Propyl p-Hydroxybenzoate	0.202mg/ml	0.180 - 0.220 mg/ml
Nicotinamide	2.25 mg/ml	2.03 - 2.48 mg/ml
D-Panthenol	0.10mg/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 Banyà - Girona

Date: 24 August 15