



Date: July 10th, 2015

RELEASE STATEMENT

PRODUCT:	DUPHALYTE*10X500ML RUM
CODE:	137664
FILLING M.O.:	E20985
BATCH No.:	20985
MANUFACTURING DATE:	05/2015
EXPIRY DATE:	05/2018
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.

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

CERTIFICATE OF ANALYSIS

zoetis

PRODUCT: DUPHALYTE * 500

CODE: 63589

FILLING M.O.: E20985

	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	4.6	4.3 - 4.7
Vitamina B₁ HCl	197 µg/ml	180 - 220 µg/ml
Vitamina B₂	81.4 µg/ml	75.6 - 92.4 µg/ml
Vitamin B₆ HCl	188 µg/ml	180 - 220 µg/ml
Valine-DL	51 µg/ml	45 - 55 µg/ml
Phenylalanine-DL	30 µg/ml	27 - 33 µg/ml
Leucine	39 µg/ml	36 - 44 µg/ml
Dextrose	45.2 mg/ml	43.2 - 47.7 mg/ml
Phenol	0.093 mg/ml	Not more than 0.110 mg/ml
Methyl p-Hydroxybenzoate	1.792 mg/ml	Not more than 1.980 mg/ml
Propyl p-Hydroxybenzoate	0.192 mg/ml	Not more than 0.220 mg/ml
Nicotinamide	2.24 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:

P.O.


E.Serra

zoetis

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

Date: 10 June 15