



Date: August 31st, 2015

RELEASE STATEMENT

PRODUCT:	DUPHALYTE*10X500ML MUL
CODE:	137647
FILLING M.O.:	E21086
BATCH No.:	21086
MANUFACTURING DATE:	06/2015
EXPIRY DATE:	06/2018
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

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PRODUCT: DUPHALYTE * 500

CODE: 63589

FILLING M.O.: E21086

	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	199 µg/ml	180 - 220 µg/ml
Vitamina B₂	83.2 µg/ml	75.6 - 92.4 µg/ml
Vitamin B₆ HCl	188 µg/ml	180 - 220 µg/ml
Valine-DL	45 µg/ml	45 - 55 µg/ml
Phenylalanine-DL	29 µg/ml	27 - 33 µg/ml
Leucine	37 µg/ml	36 - 44 µg/ml
Dextrose	45.7 mg/ml	43.2 - 47.7 mg/ml
Phenol	0.101 mg/ml	Not more than 0.110 mg/ml
Methyl p-Hydroxybenzoate	1.798 mg/ml	1.620 - 1.980 mg/ml
Propyl p-Hydroxybenzoate	0.199 mg/ml	0.180 - 0.220 mg/ml
Nicotinamide	2.27 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:

Date: 27 July 15

PO


E.Serra

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Vall de Bianya - Girona