

CERTIFICATE OF ANALYSIS



Generated Date
Mar 5, 2020

ZOETIS MANUFACTURING & RESEARCH SPAIN, S.L.
Ctra. Camprodon, s/n-Finca "La Riba"
17813 VALL DE BANYA (Girona)

AUTHORIZATION NUMBER 4233E
GMP certificate ES/072HV/17

Item: 10008140
Title: DUPHALYTE INJECTABLE SOLUTION *10X500ML
Expiration Date: 12/2022
Date Of Manufacture: 30/01/2020
Market: BG-RO-SI
Lot Number: 414271 Associated Lots: 414267

TEST NAME	SPECIFICATION	UNIT	RESULT
Appearance	Clear yellow solution	N/A	Meets Specification
Identification (others)	Positive for Dextrose	N/A	Meets Requirements
Identification (HPLC)	Positive for Vitamin B1HCl, Vitamin B2, Vitamin B6 HCl, Valine-DL, Phenylalanine-DL, Leucine, Phenol, Methyl p-hydroxybenzoate and Propyl p-hydroxybenzoate	N/A	Meets Requirements
Identification (HPLC)	Positive for Nicotinamide, D-pantenol	N/A	Meets Requirements
Dextrose mg/mL	43.2 - 47.7 mg/mL	mg/mL	44.9
D-Pantenol mg/mL	0.09 - 0.11 mg/mL	mg/mL	0.10
Leucine µg/mL	36 - 44 µg/mL	µg/mL	42
Methyl p-Hydroxybenzoate mg/mL	1.620 - 1.980 mg/mL	mg/mL	1.767
Nicotinamide mg/mL	2.03 - 2.48 mg/mL	mg/mL	2.27
pH	4.3 - 4.7	N/A	4.6
Phenol mg/mL	0.090 - 0.110 mg/mL	mg/mL	0.108
Phenylalanine-DL µg/mL	27 - 33 µg/mL	µg/mL	30
Propyl p-Hydroxybenzoate mg/mL	0.180 - 0.220 mg/mL	mg/mL	0.193

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Expiration Date:	12/2022		
Date Of Manufacture	30/01/2020		
Market:	BG-RO/SI		
Lot Number:	414271	Associated Lots:	414287

TEST NAME	SPECIFICATION	UNIT	RESULT
Valine-DL µg/mL	45 - 55 µg/mL	µg/mL	55
Vitamin B1 HCl µg/mL	180 - 220 µg/mL	µg/mL	202
Vitamin B2 µg/mL	75.6 - 92.4 µg/mL	µg/mL	82.5
Vitamin B6 HCl µg/mL	180 - 220 µg/mL	µg/mL	203
Volume	Not less than the declared quantity	N/A	>500 ml
Endotoxins EU/mL	Not more than 0.5 EU/mL	EU/mL	< 0.5
Stability	Sterile	N/A	Pass
Identification (HPLC)	Positive for Vitamin B12, Calcium Chloride 6H2O, Magnesium Sulphate 7H2O and Potassium Chloride	N/A	Meets Requirements
Vit B12 (Cyanocobalamin) µg/mL	0.09 - 0.11 µg/mL	µg/mL	0.11
Calcium Chloride 6H2O mg/mL	0.22 - 0.24 mg/mL	mg/mL	0.22
Magnesium Sulphate 7H2O mg/mL	0.27 - 0.30 mg/mL	mg/mL	0.28
Potassium Chloride mg/mL	0.19 - 0.21 mg/mL	mg/mL	0.20
Total Antioxidants µg/mL	124.8 - 152.6 µg/mL calculated based on amine groups	µg/mL	130.7

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Date Of Manufacture: 30/01/2020

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Lot Number: 414271

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TEST NAME	SPECIFICATION	UNIT	RESULT
Total number of containers	N/A	Bottle	9850

After reviewing all manufacturing and testing data, I hereby certify that the above information is authentic and accurate. The batch has been tested and manufactured including packaging and quality control in full compliance with Good Manufacturing Practices and in compliance with methods and standards, as described in the applicable quality agreements, the local regulatory requirements and those requirements stipulated in the marketing authorization.

Batch Release Authorized by Electronic Signature: Anna Pairo

Position/Title: Qualified person

Lot Release System Timestamp: Mar 5, 2020 12:25:48 PM UTC