

Certificate of Analysis

Polysorbate 80

CODE ARTICLE: 93476		BATCH: 0133413			
TEST DATE: 15/01/2025		TEST: QC-00271556			
EXPIRY DATE: 30/04/2027	FABRICATION DATE: 01/04/2024				
CAS: [9005-65-6]					
SYNONYMS / BOTANICAL NAME: Tween 80; E-433; Polisorbato 80					
STORAGE: Store in tightly closed containers in a cool, dry place.					

TEST	RESULTS Units	MIN	MAX	METHOD
APPEARANCE	PASS -		OILY VISCOUS LIQUID	PH.EUR.*
COLOUR	PASS -		YELLOW	PH.EUR.*
SOLUBILITY				
SOLUBLE	PASS		DISPERSIBLE IN WATER, ANHYDRATED ETHANOL, ETHYL ACETATE AND METHANOL.	PH.EUR.
INSOLUBLE	PASS		FATTY ACIDS AND LIQUID PARAFFIN	PH.EUR.
<u>IDENTIFICATION</u>				
IDENTIFICATION A (IR SPECTRUM)	PASS			PH.EUR.*
IDENTIFICACION B (INDICE DE HIDROXILOS)	69 mg KOH/gr	65	80	PH.EUR.
IDENTIFICACION C (INDICE SAPONIFICACION)	50,7 mg KOH/gr	45	55	PH.EUR.
IDENTIFICACION D (COMPOSICIÓN ÁC. GRASOS)	PASS			PH.EUR.
IDENTIFICATION E	PASS			PH.EUR.
VISCOSITY	PASS mPa*S		400	PH.EUR.
RELATIVE DENSITY	PASS G/ML		APROX. 1,10	PH.EUR.
ACIDITY INDEX	0,87 mg KOH/gr	-	2	PH.EUR.
PEROXIDES INDEX	4,98 meq O2/Kg		10	PH.EUR.
ETHYLENE OXIDE	0,0 ppm		0,2	PH.EUR.
DIOXAN	0,0 ppm		5	PH.EUR.
WATER	2,69 %	-	3	PH.EUR.
SULPHATED ASH	PASS %		0.25	PH.EUR.
FATTY ACIDS				
MYRISTIC ACID (C14:0)	PASS %		5,0	PH.EUR.
PALMITIC ACID (C16:0)	PASS %		16,0	PH.EUR.
PALMITOLEIC ACID (C16:1)	PASS %		8,0	PH.EUR.
STEARIC ACID (C18:0)	PASS %		6,0	PH.EUR.
OLEIC ACID (C18:1)	PASS %	58,0	88,0	PH.EUR.
LINOLEIC ACID (C18:2)	PASS %		18,0	PH.EUR.
LINOLENIC ACID (C18:3)	PASS %		4,0	PH.EUR.
COLOUR	4,5 Gardner	-	6	Manufacture's Standard
DENSITY	PASS G/ML	1,06	1,10	Manufacture's Standard

The data expressed in this certificate of analysis is facilitated by our supplier and/or obtained in our control laboratory, in no case being exempted of the controls demanded by each sector. Tests marked with (*) are verified in Guinama.

Manufacturer Batch: 04241771 Manufacturer Code: 48299 Supplier Code: 401338

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STORAGE: Store in tightly closed containers in a cool, dry place.					

TEST	RESULTS Units	MIN	MAX	METHOD
IODINE INDEX	19,90 g l2/100g	18	24	Manufacture's Standard
REDUCING SUBSTANCES	PASS ML		5,0	Manufacture's Standard
VOLATILE ORGANIC IMPURITIES	PASS			Manufacture's Standard
HEAVY METALS	PASS ppm		10	Manufacture's Standard
LEAD	PASS ppm		2	Manufacture's Standard
CADMIUM	PASS ppm		1	Manufacture's Standard
ARSENIC	PASS ppm		3	Manufacture's Standard
MERCURY	PASS ppm		0,1	Manufacture's Standard
ETILENHIDRINA	ABSENCE			Manufacture's Standard
BACTERIAS TOTALES	PASS cfu/g		100	Manufacture's Standard
MOLDS AND YEASTS	PASS cfu/g		10	Manufacture's Standard
PATHOGENS	ABSENCE			Manufacture's Standard
CORRECT BATCH	YES			Manufacture's Standard
SAMPLING	COLLECT			Manufacture's Standard
SPECIFICATION	PH.EUR 11, USP, FCC			Manufacture's Standard

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Silvia Sancho-Tello Ripoll Technical Director.

The product has been handled in NON-sterile rooms, therefore this product IS NOT STERILE

Suitable for oral use. Not valid for the production of food supplements or foods.

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