



规格单 SPECIFICATION SHEET

CR0144-20240724

品名 Product Name: Evening Primrose Oil Softgel 月见草油软胶囊			
形状 Shape: 20# Oblong		原产国 Country Of Origin: China	
有效成分 Active Ingredients		辅料 Excipient	
名称 Name	添加量 Quantity	名称 Name	添加量 Quantity
月见草油 Evening Primrose Oil (9%)	1000mg±7.5%	明胶 Gelatin	380mg±7.5%
维生素 E (dl- α -生育酚醋酸酯) Vitamin E (dl-alpha Tocopherol Acetate) (98%)	10mg±7.5%	甘油 Glycerin	
		纯水 Pure Water	
检测项目 Testing Item	规格 Specification	检测方法 Test Method	
Physicals & Chemicals			
外观和颜色 Appearance And Color	Transparent Softgel With Light Yellow Liquid Inside	Organoleptic	
装量 Filling Weight Variation	1010mg±7.5%	CP 2020	
总重 Total Weight Variation	1390mg±7.5%	CP 2020	
胶皮水分 Moisture Of Shell	8.0%-13.0%	GB 5009.3-2016	
崩解时限 Disintegration Time	≤30min	CP 2020	
酸值 Acid Value	≤3mgKOH/g	GB 5009.229-2016	
过氧化值 Peroxide Value	≤10mmol/kg	GB 5009.227-2016	
Assay			
γ -亚麻酸 GLA (AS Area)	≥9%	GB 5009.168-2016	
Heavy Metals			
砷 Arsenic	≤0.1mg/kg	GB 5009.11-2014 (AFS)	
铅 Lead	≤0.1mg/kg	GB 5009.12-2023 (AAS)	
镉 Cadmium	≤0.1mg/kg	GB 5009.15-2023 (AAS)	
汞 Mercury	≤0.1mg/kg	GB 5009.17-2021 (AFS)	
Microbiologicals			
菌落总数 Aerobic Plate Count	≤1,000cfu/g	ISO 4833-1: 2013	
霉菌及酵母菌 Moulds And Yeasts	≤100cfu/g	GB 4789.15-2016	
大肠菌群 Coliforms	<10cfu/g	GB 4789.3-2016	
大肠杆菌 E.Coli	<10cfu/g	ISO 16649-2: 2001	
沙门氏菌 Salmonella	Not Detected/25g	GB 4789.4-2016	
金黄色葡萄球菌 Staphylococcus Aureus	Not Detected/25g	GB 4789.10-2016	
黄曲霉毒素 Aflatoxins	≤2 μ g/kg	HPLC	
Polycyclic Aromatic Hydrocarbons (PAH)			
苯并芘 4 项 Sum Of Benz(a)anthracene, Chrysene, Benzo(a)pyrene, Benzo(b)fluoranthene	<10 μ g/kg	GC-MS	
苯丙 A 芘 Benzo(a)pyrene	<2 μ g/kg	GC-MS	
Pesticide Residue			
二噁英与类二噁英多氯联苯总和 Sum	≤1.25pg/g	GC-MS/MS	



Of Dioxins And Dioxin-Like PCBS (WHO PCDD/F-PCBTEQ)		
多氯联苯 Sum Of PCB28, PCB52, PCB101, PCB138, PCB153 And PCB180	≤40ng/g	GC-MS/MS
二噁英 Sum Of Dioxins (WHO-PCDD/F-TEQ)	≤0.75pg/g	GC-MS/MS
有效期 Shelf Life	3 Years When Properly Stored.	
储存条件 Storage	The Product Should Be Stored In A Sealed Container, Temperature: 15-25°C, Humidity: 35-65%. Keep Away From Strong Light And Heat.	
包装 Package	5000pcs/Carton.	



Allegens:- When purchased in bulk size original packaging, manufacturer allergen policy will apply.
When purchased in quantities that need re-packaging, our allergen policies will apply.

Component	Manufacturer			Nuts in Bulk (Applies when bought in small quantities that need re-packaging)		
	In Product	Processed in Same Equipment	Handled on Site	In Product	Processed in Same Equipment	Handled on Site
Cereals containing GLUTEN and products thereof	NO	NO	NO	NO	YES	YES
EGGS or its derivatives	NO	NO	NO	NO	NO	NO
FISH or its derivatives	NO	NO	NO	NO	NO	NO
CRUSTACEANS / SHELLFISH	NO	NO	NO	NO	NO	NO
MOLLUSCS	NO	NO	NO	NO	NO	NO
PEANUTS or derivatives	NO	NO	NO	NO	YES	YES
SOYA BEANS or derivatives	NO	NO	NO	NO	YES	YES
MILK (LACTOSE) or its derivatives	NO	NO	NO	NO	YES	YES
NUTS , tree nuts:	NO	NO	NO	NO	YES	YES
CELERY, including celeriac and its derivatives	NO	NO	NO	NO	YES	YES
MUSTARD, referring to all parts of the plant and derivatives thereof	NO	NO	NO	NO	YES	YES
SESAME SEEDS or derivatives	NO	NO	NO	NO	YES	YES
SULPHITES >10ppm – Sulphite quantity to be given in ppm	NO	NO	NO	NO	YES	YES
LUPIN seeds or derivatives	NO	NO	NO	NO	NO	NO