



规格单 SPECIFICATION SHEET

CR0120-20240429

品名 Product Name: Omega 369 Softgel Omega 369 软胶囊		原产国 Country Of Origin: China	
形状 Shape: 20# Oblong			
有效成分 Active Ingredients		辅料 Excipient	
名称 Name	添加量 Quantity	名称 Name	添加量 Quantity
鱼油 Fish Oil (EPA18%/DHA12%, EE)	400mg±7.5%	明胶 Gelatin	400mg±7.5%
亚麻籽油 Flaxseed Oil (50% ALA)	300mg±7.5%		
葵花籽油 Sunflower Seed Oil	287.5mg±7.5%	甘油 Glycerin	
维生素 E (dl- α -生育酚醋酸酯) Vitamin E (dl-alpha Tocopherol Acetate)	12.5mg±7.5%	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	1000mg±7.5%	USP-2021<2091>	
总重 Total Weight Variation	1400mg±7.5%	USP-2021<2091>	
胶皮水分 Moisture Of Shell	7.0%-13.0%	GB 5009.3-2016	
崩解时限 Disintegration Time	≤30min	BP-2021<Appendix XII A>+Disks	
酸值 Acid Value	≤3mgKOH/g	USP-2021<401>	
过氧化值 Peroxide Value	≤10mmol/kg	USP-2021<401>	
茴香胺值 Anisidine Value	≤20.0	USP-2021<401>	
总氧化值 TOTOX	≤26.0	USP-2021<401>	
Assays			
二十碳五烯酸 EPA (As Area)	≥7.2%	USP-2021<401>	
二十二碳六烯酸 DHA (As Area)	≥4.8%	USP-2021<401>	
α -亚麻酸 ALA (As Area)	≥15%	GB 5009.168-2016	
亚油酸 Linoleic Acid	≥20%	GB 5009.168-2016	
油酸 Oleic Acid	≥15%	GB 5009.168-2016	
Heavy Metals			
砷 Arsenic	≤0.1mg/kg	USP-2021<233>	
铅 Lead	≤0.1mg/kg	USP-2021<233>	
镉 Cadmium	≤0.1mg/kg	USP-2021<233>	
汞 Mercury	≤0.1mg/kg	USP-2021<233>	
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	<10µg/kg	GC-MS
苯丙 A 芘 Benzo(a)pyrene	<2µg/kg	GC-MS
有效期 Shelf Life	3 Years When Properly Stored. 1. Bulk-Packaged Product Is Recommended To Be Packaged Into Retail Packaging Within Six (6) Months After The Manufacture Date. 2. The Overall Product Shelf Life Is Three (3) Years After The Manufacture Date If The Product Is Stored At The Storage Conditions Shown Herein And Packaged Into Retail Packaging As Described Immediately Above.	
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.	

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王艳婷