



规格单 SPECIFICATION SHEET

CR0202-20231114

品名 Product Name: Fish Oil Softgel 鱼油软胶囊		原产国 Country Of Origin: China	
形状 Shape: 10# Oval			
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)	500mg±7.5%	明胶 Gelatin	220mg±7.5%
DL-α-生育酚醋酸酯 Dl-Alpha-Tocopheryl Acetate	2.5mg±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	502.5mg±7.5%	USP-2021<2091>	
总重 Total Weight Variation	722.5mg±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, EE)	≥18%	USP-2021<401>	
二十二碳六烯酸 DHA (As Area, EE)	≥12%	USP-2021<401>	
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	USP-2021<2021>	
霉菌及酵母菌 Moulds And Yeasts	≤100cfu/g	USP-2021<2021>	
大肠菌群 Coliforms	<10cfu/g	GB 4789.3-2016	
大肠杆菌 E.Coli	<10cfu/g	USP-2021<2022>	
沙门氏菌 Salmonella	Not Detected/25g	USP-2021<2022>	
金黄色葡萄球菌 Staphylococcus Aureus	Not Detected/25g	USP-2021<2022>	
黄曲霉毒素 Aflatoxins	≤2μg/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	10,000pcs/Carton.	

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