

Product Specification

No.: TS-F-04

Product Code		Version No.	2
Product Name	Fish Oil Softgel 90D	Filling Weight	1012mg (20 # oblong)
Effective Date		Standard	Inner Standard
Remark	EMP Code: B72-989		

Ingredient	Input (mg)	Providing
Actives:		
Fish Oil (18% EPA/12% DHA, TG)	1000.2	EPA 18%, DHA 12%
Vitamin E (1000IU/g, d-Alpha-Tocopherol, GMO-Free)	11.8	d-Alpha-Tocopherol 6mg
Dry Shell:		
Gelatin	224.6	
Glycerine	89.9	
Water	25.5	

Specification		
Item	Standard	Method
Appearance and Color	Clear yellow oblong softgel, filled with yellow oily liquid.	Organoleptic analysis
Capsule weight variation	1352mg±10%	USP<2091>
Fill weight variation	1012mg±5%	USP<2091>
EPA (Area%)	18.0 (NLT 90%)	AOAC 991.39
DHA (Area%)	12.0 (NLT 90%)	AOAC 991.39
d-Alpha-Tocopherol (mg/cap)	6 (90-165%)	GB/T 5009.82
Acid Value (mgKOH/g)	≤3.0	AOCS Cd 3d-63
Peroxide Value (meq/kg)	≤10.0	AOCS Cd 8-53
Anisidine Value	≤20	AOCS Cd 18-90
TOTOX	≤30	(2×PV)+AV
Disintegration (min)	≤30	BP<Appendix XII A>+Disks
DBP (mg/kg)	≤70	<Detection method of phthalates in food announced by Taiwan Food and Drug Administration> (LC-MS/MS)
DEHP (mg/kg)	≤350	<Detection method of phthalates in food announced by Taiwan Food and Drug Administration> (LC-MS/MS)
DINP (mg/kg)	≤1050	<Detection method of phthalates in food announced by Taiwan Food and Drug Administration> (LC-MS/MS)
Heavy metals		
Lead (mg/kg)	≤0.1	USP<233> Elemental Impurities-Procedure 2: ICP-MS
Arsenic (mg/kg)	≤0.1	USP<233> Elemental Impurities-Procedure 2: ICP-MS
Mercury (mg/kg)	≤0.1	USP<233> Elemental Impurities-Procedure 2: ICP-MS

Cadmium (mg/kg)	≤0.1	USP<233> Elemental Impurities- Procedure 2: ICP-MS
Microbial Limit		
Total aerobic microbial count (cfu/g)	≤1000	USP<2021>
Mold (cfu/g)	≤25	USP<2021>
Yeast (cfu/g)	≤25	USP<2021>
E. coli /10g	Negative	USP<2022>
Salmonella /10g	Negative	USP<2022>
Staphylococcus aureus /10g	Negative	USP<2022>
Remarks		
Storage Condition		
Product should be stored in the original unopened packaging, at 5-25°C temperature, relative humidity of 35-75%, and out of direct sunlight or spotlights.		
Shelf life		
1.Bulk-packaged product is recommended to be packaged into retail packaging (HDPE bottle with aluminum foil seal) 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.		