

Product Specification

No.: TS-F-04

Product Code	SMV-130A	Version No.	1
Product Name	Multi-Vitamin Softgel 130A	Filling Weight	900mg (18 # oblong)
Effective Date	2020/09/22	Standard	Inner Standard
Remark	None		

Ingredient	Input (mg)	Providing
Actives:		
*Vitamin A Acetate (1 million IU/g)	4.4	Vitamin A 1000µg
Vitamin C (L-Ascorbic Acid)	74.0	Vitamin C 61mg
*Vitamin D3 (1 million IU/g)	0.48	Vitamin D3 7.5µg
Vitamin E (dl-Alpha-Tocopheryl Acetate)	85.4	dl-Alpha-Tocopherol 68mg, equivalent to d-Alpha-Tocopherol (α-TE) 50mg
Vitamin B1 (Thiamine Mononitrate)	5.7	Thiamine 3.4mg
Vitamin B2 (Riboflavin)	2.3	Riboflavin 2mg
Vitamin B3 (Nicotinamide)	24.6	Nicotinamide 20mg
Vitamin B6 (Pyridoxine Hydrochloride)	49.6	Pyridoxine 33mg
Biotin	0.11	Biotin 90µg
Ferrous Fumarate	83.1	Iron 25mg
Magnesium Oxide	140.2	Magnesium 76mg
Zinc Oxide	26.5	Zinc 20mg
Selenium Yeast	30.0	Selenium 60µg
Excipients:		
*Lecithin	1.8	
Glyceryl Monostearate	18.0	
Beeswax	9.0	
Soybean Oil	344.9	
Dry Shell:		
Gelatin	283.0	
Glycerine	113.2	
Titanium Dioxide	0.59	
Caramel Colour	10.2	
Water	33.0	

Specification		
Item	Standard	Method
Appearance and Color	Opaque brown oblong softgel, filled with brownish yellow oily paste.	SOP-QS-1101
Capsule weight variation	1340mg±10%	USP<2091>
Fill weight variation	900mg±5%	USP<2091>
Vitamin A (µg/cap)	1000 (90-165%)	BP<Natural Vitamin A Ester Concentrate>Method B
Vitamin C (mg/cap)	61 (90-150%)	SOP-QS-1011
Vitamin D3 (µg/cap)	7.5 (90-165%)	BS EN 12821
dl-Alpha-Tocopherol (mg/cap)	68 (90-165%)	BS EN 12822
Thiamine (mg/cap)	3.4 (90-150%)	USP<Oil- and Water-Soluble Vitamins with Minerals Tablets>

Riboflavin (mg/cap)	2 (90-150%)	USP<Oil- and Water-Soluble Vitamins with Minerals Tablets>
Nicotinamide (Calculated as whole softgel) (mg/cap)	20 (90-150%)	USP<Oil- and Water-Soluble Vitamins with Minerals Tablets>
Pyridoxine (Calculated as whole softgel) (mg/cap)	33 (90-150%)	USP<Oil- and Water-Soluble Vitamins with Minerals Tablets>
Biotin (µg/cap)	90 (90-150%)	SOP-QS-1167
Iron (Calculated as filling) (mg/cap)	25 (90-125%)	USP<Oil- and Water-Soluble Vitamins with Minerals Capsules>
Magnesium (Calculated as filling) (mg/cap)	76 (90-125%)	USP<Oil- and Water-Soluble Vitamins with Minerals Capsules>
Zinc (Calculated as filling) (mg/cap)	20 (90-125%)	USP<Oil- and Water-Soluble Vitamins with Minerals Capsules>
Selenium (Calculated as filling) (µg/cap)	60 (90-160%)	USP<Oil- and Water-Soluble Vitamins with Minerals Capsules>
Heavy metals		
Lead (mg/kg)	≤1.5	USP<233> Elemental Impurities-Procedure 2: ICP-MS
Arsenic (mg/kg)	≤1.0	USP<233> Elemental Impurities-Procedure 2: ICP-MS
Mercury (mg/kg)	≤0.1	USP<233> Elemental Impurities-Procedure 2: ICP-MS
Cadmium (mg/kg)	≤1.0	USP<233> Elemental Impurities-Procedure 2: ICP-MS
Microbial Limit		
Total aerobic microbial count (cfu/g)	≤3000	USP<2021>
Mold and Yeast (cfu/g)	≤100	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 spotlight.		
Shelf life		
1.Bulk-packaged product recommended 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.		
Others		
1.If you require a specific bulk-packaged product configuration, please provide us with the detailed packaging requirements, in advance and in writing, and ensure that it has been confirmed in writing by Sirio. 2.The methods given in the product specification are based on our current knowledge and experience, and may be different from the final methods. 3.The product color may change by exposure to sunlight or spotlight. 4.Black spots or color changes caused by vitamin C oxidation may occur during storage. 5.* means the compounds used contain more than one ingredient.		

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Position: Pharmacist

Date: 22/09/2020

22/09/2020

Allergen Information

Product Name: Multi-Vitamin Softgel 130A

ALLERGENS (Please consider all derivatives and by-products)	Does the product contain any of the following allergens or their derivatives?	
	YES	NO
Cereals containing gluten and products thereof at levels above 10mg/kg		✓
- Wheat (such as spelt and khorasan wheat) or its hybridised strains		✓
- Rye or its hybridised strains		✓
- Barley or its hybridised strains		✓
- Oats or its hybridised strains		✓
Crustaceans and products thereof at levels above 10mg/kg or 10mg/L		✓
Eggs and products thereof at levels above 10mg/kg or 10mg/L		✓
Fish and products thereof at levels above 10mg/kg or 10mg/L		✓
Peanuts and products thereof at levels above 10mg/kg or 10mg/L		✓
Soybeans and products thereof at levels above 10mg/kg or 10mg/L	✓	
Milk and products thereof (including lactose) at levels above 10mg/kg or 10mg/L		✓
Nuts and products thereof at levels above 10mg/kg or 10mg/L		✓
- Almond (<i>Amygdalus communis</i> L.)		✓
- Hazelnuts (<i>Corylus avellana</i>)		✓
- Walnuts (<i>Juglans regia</i>)		✓
- Cashews (<i>Anacardium occidentale</i>)		✓
- Pecan nuts (<i>Carya illinoensis</i> (Wangenh.) K. Koch)		✓
- Brazil nuts (<i>Bertholletia excelsa</i>)		✓
- Pistachio nuts (<i>Pistacia vera</i>)		✓
--Macadamia or Queensland nuts (<i>Macadamia ternifolia</i>)		✓
Celery and products thereof at levels above 10mg/kg or 10mg/L		✓
Mustard and products thereof at levels above 10mg/kg or 10mg/L		✓
Sesame seeds and products thereof at levels above 10mg/kg or 10mg/L		✓
Sulphur dioxide and sulphites at concentrations of more	✓	

<Allergen Information>

than 10 mg/kg or 10 mg/litre in terms of the total SO ₂ which are to be calculated for products as proposed ready for consumption or as reconstituted according to the instructions of the manufacturers		
Lupin and products thereof at levels above 10mg/kg or 10mg/L		✓
Molluscs and products thereof at levels above 10mg/kg or 10mg/L		✓

1. Note: the exceptions of substances or products causing allergies shall refer to REGULATION (EU) No 1169/2011

2. Regulatory Reference: REGULATION (EU) No 1169/2011

3. Different products with or without allergen may be manufactured in the same production line. However, site cleaning will be conducted after each batch of product according to GMP.