

Issued: 08/23/2018

Product Code:

C-SKGHEALTH-PRECAP

Batch Lot: 18F094

Manufacture Date: 07/2018

Product:

Optimal Prenatal 240c

Lot Number: 087H18

Expiration Date: N/A

Physical Characteristics

Capsule Size	"00"/23.30 ± 0.30 mm	Visual	N/A	Pass
Appearance	Clear capsule containing light brown powder with yellow specks	Visual	N/A	Pass
Weight Average	999.377 mg ± 10%	USP <2091>	N/A	1000.2 mg
Disintegration (min.)	NMT 30 minutes	USP <2040>	min.	10 minutes
Weight Variation	Meets USP Requirements	USP <2091>	N/A	Pass

Notebook References: LN 269 page 35

Analytical Specifications

Vitamin A (as beta-carotene and retinyl palmitate)	NLT 100% per 8 capsules (1500 mcg RAE)	HPLC	1500 mcg RAE	08/03/2018	115%	71897-01 (2)
Vitamin C (ascorbic acid)	NLT 100% per 8 capsules (350 mg)	HPLC	350 mg	07/21/2018	108%	LN 255 page 166-167, 169-175
Vitamin D3 (cholecalciferol)	NLT 100% per 8 capsules (50 mcg)/(2000IU)	HPLC	50 mcg	08/03/2018	100%	71897-01 (2)
Vitamin E (as d-alpha tocopheryl succinate)	NLT 100% per 8 capsules (130 mg)	HPLC	130 mg	08/03/2018	106%	71897-01 (2)
Vitamin K2 (as menaquinone -7)	NLT 100% per 8 capsules (100 mcg)	HPLC	100 mcg	08/03/2018	109%	71897-01 (2)
Thiamin (as thiamine hydrochloride)	NLT 100% per 8 capsules (5 mg)	HPLC	5 mg	08/03/2018	119%	71897-01 (2)
Riboflavin (as riboflavin and riboflavin 5-phosphate sodium)	NLT 100% per 8 capsules (20 mg)	HPLC	20 mg	08/03/2018	127%	71897-01 (2)
Niacin (as niacinamide)	NLT 100% per 8 capsules (25 mg)	HPLC	25 mg	08/03/2018	133%	71897-01 (2)
Vitamin B6 (as pyridoxal 5'-phosphate and pyridoxine HCl)	NLT 100% per 8 capsules (20 mg)	HPLC	20 mg	08/03/2018	104%	71897-01 (2)
Folate (as Quatrefolic (6S)-5-methyltetrahydrofolate, glucosamine salt and calcium folinate)	NLT 100% per 8 capsules (800 mcg DFE)	HPLC	800 mcg DFE	08/03/2018	116%	71897-01 (2)
Vitamin B12 (as methylcobalamin)	NLT 100% per 8 capsules (120 mcg)	HPLC	120 mcg	08/03/2018	110%	71897-01 (2)
Vitamin B12 (as dibenzoyl)	NLT 100% per 8 capsules (30 mcg)	HPLC	30 mcg	08/03/2018	135%	71897-01 (2)
Biotin	NLT 100% per 8 capsules (500 mcg)	HPLC	500 mcg	08/03/2018	134%	71897-01 (2)
Pantothenic Acid (as d-calcium pantothenate)	NLT 100% per 8 capsules (150 mg)	HPLC	150 mg	08/03/2018	102%	71897-01 (2)
Calcium (as DimaCal® Dicalcium Malate)	NLT 100% per 8 capsules (400 mg)	ICP-MS	400 mg	07/13/2018	126%	LN 252 page 147
Iodine (as potassium iodide)	NLT 100% per 8 capsules (250 mcg)	Titration	250 mcg	08/03/2018	100%	71897-01 (2)

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Magnesium (as Albion® DiMagnesium Malate)	NLT 100% per 8 capsules (250 mg)	ICP-MS	250 mg	07/13/2018	123%	LN 252 page 147
Zinc (as TRAACS® Zinc Bisglycinate Chelate)	NLT 100% per 8 capsules (20 mg)	ICP-MS	20 mg	07/13/2018	125%	LN 252 page 147
Selenium (as SelenoExcell High Selenium Yeast)	NLT 100% per 8 capsules (200 mcg)	ICP-MS	200 mcg	07/13/2018	101%	LN 252 page 147
Copper (as TRAACS® Copper Bisglycinate Chelate)	NLT 100% per 8 capsules (0.75 mg)	ICP-MS	0.75 mg	07/13/2018	121%	LN 252 page 147
Manganese (as TRAACS® Manganese Bisglycinate Chelate)	NLT 100% per 8 capsules (5 mg)	ICP-MS	5 mg	07/13/2018	134%	LN 252 page 147
Chromium (as Chromium Nicotinate Glycinate Chelate)	NLT 100% per 8 capsules (120 mcg)	ICP-MS	120 mcg	07/13/2018	155%	LN 252 page 147
Molybdenum (as Molybdenum Glycinate Chelate)	NLT 100% per 8 capsules (100 mcg)	ICP-MS	100 mcg	07/13/2018	101%	LN 252 page 147
Potassium (as Albion Potassium Glycinate Complex)	NLT 100% per 8 capsules (99 mg)	ICP-MS	99 mg	07/13/2018	126%	LN 252 page 147
Betaine HCl	NLT 100% per 8 capsules (150 mg)	HPLC	150 mg	08/03/2018	137%	71897-01 (2)
Silymarin (from Milk thistle extract)	NLT 100% per 8 capsules (60 mg)	HPLC/UV-Vis	60 mg	08/02/2018	105%	71897-01 (2)
Coenzyme Q10	NLT 100% per 8 capsules (75 mg)	HPLC	75 mg	08/03/2018	121%	71897-01 (2)
Red Raspberry (Rubus idaeus)(leaf)	See Note (1)	Input	250 mg	08/03/2018	100%	Batch Record
Inositol	NLT 100% per 8 capsules (150 mg)	HPLC	150 mg	08/03/2018	106%	71897-01 (2)
L-Carnosine	NLT 100% per 8 capsules (150 mg)	HPLC	150 mg	08/03/2018	100%	71897-01 (2)
Ginger Extract 10:1 (Zingiber officinale)(root)	See Note (1)	Input	100 mg	08/03/2018	100%	Batch Record
Taurine	NLT 100% per 8 capsules (50 mg)	HPLC	50 mg	08/03/2018	112%	71897-01 (2)
Mixed Tocopherols (from mixed tocopherols complex)	NLT 100% per 8 capsules (45 mg)	HPLC	45 mg	08/03/2018	102%	71897-01 (2)
Choline (as choline bitartrate)	NLT 100% per 8 capsules (250 mg)	HPLC	250 mg	08/03/2018	104%	71897-01 (2)
Lutein (from marigold extract) (Tagetes erecta)(flowers)	NLT 100% per 8 capsules (5 mg)	HPLC	5 mg	08/03/2018	110%	71897-01 (2)
Zeaxanthin (from marigold extract) (Tagetes erecta)(flowers)	NLT 100% per 8 capsules (5 mg)	HPLC	5 mg	08/03/2018	135%	71897-01 (2)

References: (1) Confirmed by input through process controls and raw material identification. (2) The above results are from an independent laboratory.

Microbial Specifications

Total Plate Count	NMT 10,000 CFU/g	USP <2021>/QC-017	08/22/2018	<10,000 CFU/g	Batch Record
Yeast & Mold	NMT 1,000 CFU/g	USP <2021>/QC-017	08/22/2018	<1,000 CFU/g	Batch Record
Bile-Tolerant Gram-Negative Bacteria	NMT 1,000 CFU/g	USP <2021>/QC-017	08/22/2018	<1,000 CFU/g	Batch Record
E.Coli	Negative/10 g	USP <2022>/QC-017	08/22/2018	Negative/10 g	Batch Record
Salmonella	Negative/10 g	USP <2022>/QC-017	08/22/2018	Negative/10 g	Batch Record
Staphylococcus Aureus	Negative/10 g	USP <2022>/QC-017	08/22/2018	Negative/10 g	Batch Record

Heavy Metal Specifications

Arsenic (As)	<10 µg/8 capsules	ICP/MS	07/16/2018	1.04	LN 242 page 148-149
Cadmium (Cd)	<4.1 µg/8 capsules	ICP/MS	07/16/2018	0.52	LN 242 page 148-149
Lead (Pb)	<0.5 µg/8 capsules	ICP/MS	07/16/2018	0.44	LN 242 page 148-149
Mercury (Hg)	<15 µg/8 capsules	ICP/MS	07/16/2018	NMT 0.01	LN 242 page 148-149

