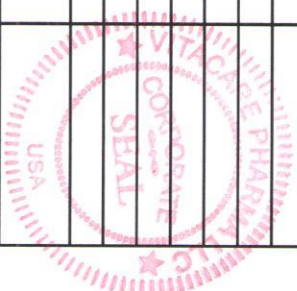


PRODUCT SPECIFICATION

VC Code # VC4005						
Product: VigRx Plus Tablets						
Description: Brownish powder in burgundy red film coated caplet with imprint "VigRx+" on both side						
Size & Shape: 0.320" x 0.750" caplet with imprint "VigRx+"						
Final Weight: 1200 mg (range 1140 - 1260 mg)						
Coating: Film Coated - Burgundy Red						
Disintegration: < 45 min. in water without disks						
Packaging: Bulk - 13,000 Tablets/Box or 16.00 Kg Net/Box						
Distribution Market: Worldwide						
					Effective Date: 11/01/13	
					Revision: 01	
#	Active Ingredients per Tablet:	Claim	Units	Overage	Limit (% Label Claim)	Method of Analysis
1	Korean Panax Ginseng (Root) Powder	100.000	mg	0.00%	100%	By Input
2	Saw Palmetto (Serenoa Repens) (Berry) Powder	100.000	mg	0.00%	100%	By Input
3	Hawthorne (Crataegus laevigata) (Berry) Powder	100.000	mg	0.00%	100%	By Input
4	Ginkgo Biloba (Leaf) Powder	100.000	mg	0.00%	100%	By Input
5	Damiana (Turnera Aphrodisiaca) (Leaf) Powder	100.000	mg	0.00%	100%	By Input
6	Tribulus Terrestris (Fruit) Ext. (Standardized to 20% Saponins)	75.000	mg	0.00%	100%	By Input
7	Catuaba (Erythroxylum Catuaba) (Bark) Ext. 4:1 PE	50.000	mg	0.00%	100%	By Input
8	Muita Puama (Ptychopetalum Olacoides) (Bark) Ext. 4:1 PE	50.000	mg	0.00%	100%	By Input
9	Cuscuta (Cuscuta Chinenses Lam) (Seed) Ext. 4:1 PE	25.000	mg	0.00%	100%	By Input
10	Horny Goat (Epimedium Sagittatum) (Leaf) Ext. 4:1 PE	15.000	mg	0.00%	100%	By Input
11	Black Pepper (Fruit) Ext. (Standardized to 95% piperine) (Bioperine™)	5.000	mg	0.00%	100%	By Input
#	Non-Active Ingredients per Tablet:	Claim	Units			
12	Dicalcium Phosphate					
13	Microcrystalline Cellulose					
14	Croscarmellose Sodium					
15	Stearic Acid					
16	Silicon Dioxide					
17	Magnesium Stearate					
18	HPMC, Triacetin, Titanium Dioxide, FD&C Red # 40 - Coating Agent					



PRODUCT SPECIFICATION

VC Code # VC4005	
Product: VigRx Plus Tablets	
Description: Brownish powder in burgundy red film coated caplet with imprint "VigRx+" on both side	
Size & Shape: 0.320" x 0.750" caplet with imprint "VigRx+"	
Final Weight: 1200 mg (range 1140 - 1260 mg)	
Coating: Film Coated - Burgundy Red	
Disintegration: < 45 min. in water without disks	
Packaging: Bulk - 13,000 Tablets/Box or 16.00 Kg Net/Box	
Distribution Market: Worldwide	
	Effective Date: 11/01/13

- * Recommended Expiration: 3 Years from MFG. Date
- * Precautions: Store in a well closed container at cool, dry room temperature. Not suggested to use for children. As with any supplement, if you are a pregnant, nursing or taking any medication, consult your doctor before use.
- * Sampling Plan: A composite representative retain samples are pulled from beginning, middle and end of each batch produced from each manufacturing stages. Retain samples are to be kept at least one year past the product expiration date.
- * Testing: Potency, Identity and Impurities testing needs to be performed on every batch of Finished Product. At least one potency test is required on every batch on a rotational basis, if applicable.
- * Allergen: NONE

MICROBIOLOGICAL PROFILES:

Total Microbial Count
Total Yeast & Mold
Coliforms
E.coli
Salmonella
Staphylococcus aureus

Specifications
<10,000 CFU/g
<1,000 CFU/g
<100 cfu/g
Negative/10 g
Negative/25 g
Negative/10 g

Method of Analysis
USP/AOAC
USP/AOAC
USP/AOAC
USP/AOAC
USP/AOAC
USP/AOAC
USP/AOAC

HEAVY METALS:

Lead
Arsenic
Mercury
Cadmium

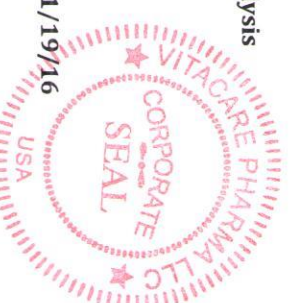
Specifications
<1.0 ppm
<1.5 ppm
<1.5 ppm
<0.5 ppm

Method of Analysis
ICP/MS
ICP/MS
ICP/MS
ICP/MS

VC Formulated By: Dr. Manav Shah

Title: Operation Manager

Date: 01/19/16



VitaCare Pharma, 111 Skyline Drive, South Plainfield, NJ-07080
Phone: 908-754-1792 Fax: 908-754-1793

VITACARE PHARMA

Raw Material Specification

Name of the RM : Korean Panax Ginseng Root Powder	VC RM # 41019	Written By/Date: <i>Navar</i> 11/01/13
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Description:

- Botanical Name:
- Part used:
- Appearance:
- Carrier:
- Identification:
- Extract Ratio:
- Standardization:
- Loss on Drying
(2 hrs @ 105°C)
- Sterilization:
- Solvent:

Specifications

Panax Ginseng
Root
Cream color fine Powder with
Characteristic odor & taste
None
Should meet the requirement
None
None
Not More Than 10.0 %
Non-Irradiation and ETO free
Steam/Heat Sterilization
None

Reference/Method

Visual/Organoleptic
FT-IR/TLC
USP<731>

Heavy metals:

Total Heavy Metals	< 10 ppm	USP/NF <2232>
Lead	< 1.0 ppm	
Arsenic	< 1.5 ppm	
Cadmium	< 0.5 ppm	
Mercury	< 1.5 ppm	

Microbiology:

Total Plate count:	< 100,000 cfu/g	USP/NF <2023>
Yeast & Mold count:	< 10,000 cfu/g	
Enterobacteriaceae:	< 1,000 cfu/g	
E. coli:	Negative/10 g	
Salmonella	Negative/25g	
Staphylococcus	Negative/10 g	

Shelf Life:

2 years when stored in closed and tight containers at cool and dry room temperature.
Keep away from moisture, freezing temperature and excessive heat.



VITACARE PHARMA

Raw Material Specification

Name of the RM : Saw Palmetto Berry Powder	VC RM # 41022	Written By/Date: <i>Manaw</i> = 11/01/13
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Description:

- Botanical Name:
- Part used:
- Appearance:

Specifications

Serenoa Repens
Dry Berries
Off-white to cream color fine
Powder with characteristic odor
& taste

Visual/Organoleptic

- Carrier:
- Identification:
- Extract Ratio:
- Standardization:
- Loss on Drying
(2 hrs @ 105°C)
- Sterilization:

None
Should meet the requirement
None
None
Not More Than 10.0 %

FT-IR/TLC

USP<731>

- Solvent:

Non-Irradiation and ETO free
Steam/Heat Sterilization
None

Heavy metals:

Total Heavy Metals
Lead
Arsenic
Cadmium
Mercury

< 10 ppm
< 1.0 ppm
< 1.5 ppm
< 0.5 ppm
< 1.5 ppm

USP/NF <2232>

Microbiology:

Total Plate count:
Yeast & Mold count:
Enterobacteriaceae:
E. coli:
Salmonella
Staphylococcus

< 100,000 cfu/g
< 10,000 cfu/g
< 1,000 cfu/g
Negative/10 g
Negative/25g
Negative/10 g

USP/NF <2023>

Shelf Life:

2 years when stored in closed and tight containers at cool and dry room temperature.
Keep away from moisture, freezing temperature and excessive heat.



VITACARE PHARMA

Raw Material Specification

Name of the RM : Hawthorn Berry Powder	VC RM # 41020	Written By/Date: <i>Manav</i> = 11/01/13
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Description:

- Botanical Name:
- Part used:
- Appearance:
- Carrier:
- Identification:
- Extract Ratio:
- Standardization:
- Loss on Drying
(2 hrs @ 105⁰C)
- Sterilization:
- Solvent:

Specifications

Crataegus Laevigata
Berries
Light brown color fine Powder
With characteristic odor & taste
None
Should meet the requirement
None
None
Not More Than 10.0 %
Non-Irradiation and ETO free
Steam/Heat Sterilization
None

Reference/Method

Visual/Organoleptic
FT-IR/TLC
USP<731>

Heavy metals:

Total Heavy Metals	< 10 ppm	USP/NF <2232>
Lead	< 1.0 ppm	
Arsenic	< 1.5 ppm	
Cadmium	< 0.5 ppm	
Mercury	< 1.5 ppm	

Microbiology:

Total Plate count:	< 100,000 cfu/g	USP/NF <2023>
Yeast & Mold count:	< 10,000 cfu/g	
Entero-bacteriaceae:	< 1,000 cfu/g	
E. coli:	Negative/10 g	
Salmonella	Negative/25g	
Staphylococcus	Negative/10 g	

Shelf Life:

2 years when stored in closed and tight containers at cool and dry room temperature.
Keep away from moisture, freezing temperature and excessive heat.



VITACARE PHARMA

Raw Material Specification

Name of the RM : Ginkgo Biloba Leaf Powder	VC RM # 41024	Written By/Date: navas 7.11.01/13
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Description:

- Botanical Name:
- Part used:
- Appearance:

Specifications

Ginkgo Biloba
Leaves
Greenish-yellow color fine
Powder with characteristic
odor & taste
None
Should meet the requirement
None
None
Not More Than 10.0 %
Non-Irradiation and ETO free
Steam/Heat Sterilization
None

Reference/Method

Visual/Organoleptic
FT-IR/TLC
USP<731>

Heavy metals:

Total Heavy Metals	< 10 ppm	USP/NF <2232>
Lead	< 1.0 ppm	
Arsenic	< 1.5 ppm	
Cadmium	< 0.5 ppm	
Mercury	< 1.5 ppm	

Microbiology:

Total Plate count:	< 100,000 cfu/g	USP/NF <2023>
Yeast & Mold count:	< 10,000 cfu/g	
Enterobacteriaceae:	< 1,000 cfu/g	
E. coli:	Negative/10 g	
Salmonella	Negative/25g	
Staphylococcus	Negative/10 g	

Shelf Life:

2 years when stored in closed and tight containers at cool and dry room temperature.
Keep away from moisture, freezing temperature and excessive heat.



VITACARE PHARMA

Raw Material Specification

Name of the RM : Tribulus Terrestris Ext. 20% SE - Saponins	VC RM # 41010	Written By/Date: <i>Nawab</i> <i>11/01/13</i>
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Description:

- Botanical Name:
- Plant part used:
- Appearance:
- Identification:
- Carrier:
- Assay (Saponins):
- Extract Ratio:
- Content:
- Loss on Drying
(2 hrs @ 105°C)
- Sterilization:
- Solvent:

Specifications

Tribulus Terrestris L.
Fruits
Brown color fine powder
With characteristic odor & taste
Should meet the requirement
Maltodextrin
Not less than 20.0%
4:1
Saponins
Not More Than 10.0 %
Non-Irradiation and ETO free
Steam/Heat Sterilization
Ethanol & Water

Reference/Method

Visual/Organoleptic
TLC/FT-IR
UV
USP<731>

Heavy metals:

Total Heavy Metals	< 10 ppm	USP/NF <231>
Lead	< 1.0 ppm	
Arsenic	< 1.5 ppm	
Cadmium	< 0.5 ppm	
Mercury	< 1.5 ppm	

Microbiology:

Total Plate count:	< 10,000 cfu/g	USP/NF <2023>
Yeast & Mold count:	< 1,000 cfu/g	
E. coli:	Negative/10 g	
Salmonella	Negative/25g	
Staphylococcus	Negative/10 g	

Shelf Life:

3 years when stored in closed and tight containers at a cool and dry room temperature.
Keep away from moisture, freezing temperature and excessive heat.



VITACARE PHARMA

Raw Material Specification

Name of the RM :
Catuaba Bark Ext. 4:1 PE

VC RM # 41025

Written By/Date:

Nandu
- 11/01/13

Description:

- Botanical Name:
- Appearance:
- Part used:
- Carrier:
- Identification:
- Assay (Tannins):
- Extract Ratio:
- Content:
- Loss on Drying
(2 hrs @ 105°C)
- Sterilization:
- Solvent:
-

Specifications

Erythroxylum Catuaba
Brown color fine powder
Bark
Maltodextrin
Should meet the requirement
Not less than 0.1%
4:1
Tannins/Fatty Acids
Not More Than 10.0 %
Non-Irradiation and ETO free
Steam/Heat Sterilization
Ethanol & Water

Reference/Method

Visual

FT-IR
UV

USP<731>

Heavy metals:

Total Heavy Metals
Lead
Arsenic
Cadmium
Mercury

< 10 ppm
< 1.0 ppm
< 1.5 ppm
< 0.5 ppm
< 1.5 ppm

USP/NF <2232>

Microbiology:

Total Plate count:
Yeast & Mold count:
E. coli:
Salmonella
Staphylococcus

< 10,000 cfu/g
< 1,000 cfu/g
Negative/10 g
Negative/25g
Negative/10 g

USP/NF <2023>

Shelf Life:

3 years when stored in closed and tight containers at cool and dry room temperature.
Keep away from moisture, freezing temperature and excessive heat.



VITACARE PHARMA

Raw Material Specification

Name of the RM : Muiru Puama Bark Ext. 4:1 PE	VC RM # 41018	Written By/Date: <i>nanav</i> 7-11/6/13
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Description:

Specifications

Reference/Method

• Botanical Name:	Ptychopetalum Olacoides	
• Part used:	Bark	
• Appearance:	Brownish fine powder	Visual
• Carrier:	Maltodextrin	
• Identification:	Should meet the requirement	FT-IR/TLC
• Assay (Tannins):	Not less than 0.1%	UV
• Extract Ratio:	4:1	
• Content:	Tannins	
• Loss on Drying (2 hrs @ 105°C)	Not More Than 10.0 %	USP<731>
• Sterilization:	Non-Irradiation and ETO free Steam/Heat Sterilization	
• Solvent:	Ethanol & Water	

Heavy metals:

Total Heavy Metals	< 10 ppm	USP/NF <2232>
Lead	< 1.0 ppm	
Arsenic	< 1.5 ppm	
Cadmium	< 0.5 ppm	
Mercury	< 1.5 ppm	

Microbiology:

Total Plate count:	< 10,000 cfu/g	USP/NF <2023>
Yeast & Mold count:	< 1,000 cfu/g	
E. coli:	Negative/10 g	
Salmonella	Negative/25g	
Staphylococcus	Negative/10 g	

Shelf Life:

3 years when stored in closed and tight containers at cool and dry room temperature.
Keep away from moisture, freezing temperature and excessive heat.



VITACARE PHARMA

Raw Material Specification

Name of the RM : Cuscuta Seed Ext. 4:1 PE	VC RM # 41017	Written By/Date: Mansur = 11/01/13
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Description:

- Botanical Name:
- Part used:
- Appearance:
- Carrier:
- Identification:
- Assay (Flavones):
- Extract Ratio:
- Content:
- Loss on Drying
(2 hrs @ 105°C)
- Sterilization:
- Solvent:

Specifications

Cuscuta Chinenses Lam
Seed
Brown color fine powder
Maltodextrin
Should meet the requirement
Not less than 2.0%
4:1
Flavones
Not More Than 10.0 %
Non-Irradiation and ETO free
Steam/Heat Sterilization
Ethanol & Water

Reference/Method

Visual
FT-IR/TLC
UV
USP<731>

Heavy metals:

Total Heavy Metals	< 10 ppm	USP/NF <2232>
Lead	< 1.0 ppm	
Arsenic	< 1.5 ppm	
Cadmium	< 0.5 ppm	
Mercury	< 1.5 ppm	

Microbiology:

Total Plate count:	< 10,000 cfu/g	USP/NF <2023>
Yeast & Mold count:	< 1,000 cfu/g	
E. coli:	Negative/10 g	
Salmonella	Negative/25g	
Staphylococcus	Negative/10 g	

Shelf Life:

3 years when stored in closed and tight containers at cool and dry room temperature.
Keep away from moisture, freezing temperature and excessive heat.



VITACARE PHARMA

Raw Material Specification

Name of the RM :
Epimedium Sagittatum
(Horny Goat) Leaf Ext. 4:1 PE

VC RM # 41023

Written By/Date:

Mamav
= 11/01/13

Description:

- Botanical Name:
- Appearance:
- Part used:
- Carrier:
- Identification:
- Assay (Icariins):
- Extract Ratio:
- Content:
- Loss on Drying
(2 hrs @ 105⁰C)
- Sterilization:
- Solvent:

Specifications

Epimedium Sagittatum
Brownish color fine powder
Herbal leaves
Maltodextrin
Should meet the requirement
Not less than 4.0%
4:1
Icariins
Not More Than 10.0 %
Non-Irradiation and ETO free
Steam/Heat Sterilization
Ethanol & Water

Reference/Method

Visual

FT-IR/TLC
UV

USP<731>

Heavy metals:

Total Heavy Metals	< 10 ppm	USP/NF <2232>
Lead	< 1.0 ppm	
Arsenic	< 1.5 ppm	
Cadmium	< 0.5 ppm	
Mercury	< 1.5 ppm	

Microbiology:

Total Plate count:	< 10,000 cfu/g	USP/NF <2023>
Yeast & Mold count:	< 1,000 cfu/g	
E. coli:	Negative/10 g	
Salmonella	Negative/25g	
Staphylococcus	Negative/10 g	

Shelf Life:

3 years when stored in closed and tight containers at cool and dry room temperature.
Keep away from moisture, freezing temperature and excessive heat.



VITACARE PHARMA

Raw Material Specification

Name of the RM : Black Pepper Fruit Ext. 95% - Bioperine™	VC RM # 41303	Written By/Date: <i>Manas</i> <i>11/01/13</i>
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Description

Specifications

Reference/Method

• Botanical Name:	Piper Nigrum	
• Part Used:	Fruits	
• Appearance:	Off white to slight yellowish powder with characteristic odor & astringent taste	Visual
• Identification:	Should conform to standard	FT-IR/TLC
• Loss on drying: (2 hrs. at 105°C)	Not more than 2.0 % w/w	USP<731>
• Assay (Piperine):	95.0 – 102.0% on dried basis	HPLC
• Extract Ratio:	50:1	
• Content:	Piperine	
• Loss on Drying (2 hrs @ 105°C)	Not More Than 10.0 %	USP<731>
• Sterilization:	Non-Irradiation and ETO free Steam/Heat Sterilization	
• Solvent:	Ethanol & Water	

Heavy metals:

Total Heavy Metals	< 10 ppm	USP/NF <2232>
Lead	< 1.0 ppm	
Arsenic	< 1.5 ppm	
Cadmium	< 0.5 ppm	
Mercury	< 1.5 ppm	

Microbiology:

Total Plate count:	< 10,000 cfu/g	USP/NF <2023>
Yeast & Mold count:	< 1,000 cfu/g	
E. coli:	Negative/10 g	
Salmonella	Negative/25g	
Staphylococcus	Negative/10 g	

Shelf Life:

3 years when stored in closed and tight containers at a cool and dry room temperature.
Keep away from moisture, freezing temperature and excessive heat.

