1. Name of the medicinal Product

1.1 Name of the medicinal Product

Sildenafil Tablets USP 100 mg

1.2 Strength

Each film coated tablet contains:

Sildenafil Citrate USP e.q. to

Sildenafil ..... 100 mg

Excipients ..... Q.S.

Colour: Brilliant Blue FCF

2. Qualitative and Quantitative Composition

2.1 Qualitative declaration

Sildenafil Citrate USP

2.2 Quantitative declaration

Sr. No.	Ingredients	Specifications	Standard Quantity/ Tablet (mg)	Reason for Inclusion
01	Sildenafil Citrate	USP	140.00	Phosphodiesterase Type 5 Inhibitor
02	Starch		268.00	Binder
03	Lactose	BP	60.00	Diluent
04	Dicalcium Phosphate	BP	100.00	Diluent
05	Silica	BP	8.000	Diluent
06	PVPK 30	BP	5.000	Binder
07	Sodium benzoate	BP	1.000	Binder
08	Magnesium Stearate	BP	10.00	Lubricant
09	Talcum	BP	8.000	Lubricant
10	Sodium Starch glycolate	BP	5.000	Lubricant

11	Cross Carmellose Sodium	BP	5.000	Disintegrant
12	Brilliant Blue FCF	BP	12.00	Colouring Agent
13	Isopropyl Alcohol	BP	Q.S.	Solvent
14	Dichloromethane	BP	Q.S.	Solvent
15	Purified water	BP	Q.S.	Solvent

3. Pharmaceutical Form

Solid Oral, Uncoated Tablet

Indigo blue coloured film coated tablet Dimond shape tablet, one side debossed with 100.

4. Clinical Particulars

4.1 Therapeutic Indications

It is indicated for the Treatment of erectile dysfunction of men.

4.2 Posology and Method of Administration

For most Patients, the recommended dose is 50 mg taken, as needed, approximately 1 hour before sexual activity. However, Sildenafil may be taken anywhere from 4 Hours to 0.5 hour before sexual activity. Based on Effectiveness and toleration, the dose may be increased to a maximum recommended dose of 100 mg or decreased to 25 mg. The maximum recommended dosing Frequency is once per day.

4.3 Contraindications

Patient using any type of organic Nitrates (eg, Dinitrate, Isosorbide mono, Nitroglycerin).

Enhanced effects leading to Prolonged hypotension; hypersensitivity.

4.4 Special Warnings and Special Precautions for Use

Caution is advised when Phosphodiesterase Type 5 (PDE5) inhibitors are co-administered with a alpha-blockers. Agents for the treatment of erectile dysfunction should be used with caution in patients with anatomical deformation of the penis or in patients who have conditions which may predispose them to priapism. The safety and efficacy of Combinations of Sildenafil Citrate and other treatments of erectile dysfunction have not been studied. Therefore the use of such Combinations is not recommended..

Pregnancy and Lactation: Sildenafil is not indicated for use by women.

4.5 Interaction with other medicinal products and other forms of interaction

Interaction with erythromycin. cimetidine. ketoconazole, itraconazole, rifampicin is noted.

4.6 Fertility, Pregnancy and Lactation

Pregnancy and Lactation: Sildenafil is not indicated for use by women.

4.7 Effects on ability To Drive and use Machines

No studies on the effects on the ability to drive and use machines have been performed

As dizziness and altered vision were reported in clinical trials with sildenafil, patients should be aware of how they react to VIAGRA, before driving or operating machinery.

4.8 Undesirable Effects

Headache, Flushing, Respiratory Tract Infection, Angina Pectoris AV block, Migraine, Syncope, Tachycardia, Postural hypotension, Myocardial Ischemia, Cerebral Thrombosis, Cardiac Arrest, Paresthesia, Tremor Depression.

4.9 Overdose

In case of Overdose standard Supportive Measures should be adopted as required. Renal Dialysis is not Expected to accelerated Clearance as Sildenafil is Highly bound to plasma proteins and it is not eliminated in the Urine.

5. Pharmacological Properties

5.1 Pharmacodynamic Properties

Sildenafil enhances the effect of NO by inhibiting phosphodiesterase type 5 (PDE-5), which is responsible for degradation of cGMP in the corpus cavernosum; when sexual stimulation causes local release of NO, inhibition of PDE-5 by sildenafil causes increased levels of cGMP in the corpus cavernosum, resulting in smooth muscle relaxation and inflow of blood to the corpus cavernosum; at recommended doses, it has no effect in the absence of sexual stimulation.

5.2 Pharmacokinetic Properties

Sildenafil is metabolized by hepatic enzymes and excreted by both the liver and kidneys. If taken with a high-fat meal. there may be a delay in absorption of sildenafil and the peak effect might be reduced slightly as the plasma Concentration will be lowered.

5.3 Preclinical Safety Data

Non-clinical data revealed no special hazard for humans based on conventional studies of safety pharmacology, repeated dose toxicity, genotoxicity, carcinogenic potential, and toxicity to reproduction.

6. Pharmaceutical Particulars

6.1 List of Excipients

Lactose BP

Starch BP

Dicalcium Phosphate BP

Sipernate BP

Sodium benzoate BP

PVPK 30 BP

Magnesium Stearate BP

Talcum BP

Sodium Starch Glycollate BP

Cross Carmellose Sodium BP

Brilliant Blue FCF IH

Isopropyl Alochol BP

Dichloromethane BP

Purified Water BP

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

36 months

6.4 Special Precautions for Storage

Store below 30°C. Protect from light.

6.5 Nature and Contents of Container

For 10 x 1 x 4 pack style: Indigo blue coloured film coated tablet Diamond shape tablet, one side debossed with 100. Such 4 tablets are packed in Alu-PVC blister pack. Such 1 blister is

packed in a printed baby carton with package insert. Further, 10 baby carton is packed in mother carton.

6.6 Special precaution for disposal and other handling

Any unused product or waste material should be disposed of in accordance with local requirements.

7. Registrant (Marketing Authorization Holder And Manufacturing Site Addresses)

7.1 Name and Address of Marketing Authorization Holder

ARHAM REMEDIES
63, Anupam Shopping Center, Nr.Vivekanand Flat,
Jodhpur Gam Road, Satellite, Ahmedabad-380 015
E.mail – arhamremedies17@gmail.com
Phone : +91-9275012851, +91-6351715625

7.2 Name and Address of manufacturing site(s)

VITAL FORMULATIONS LTD.
I/146, Phase IV, G.I.D.C. Vithal Udyognagar,
Anand-388121, Gujarat, India
Phone-02692-236316
E-mail- vitalformulationsltd@gmail.com

7.3 Marketing Authorization Number

To be included after obtaining first registration.

7.4 Date of First Registration / Renewal of The Registration

It will be applicable after registration of this product.

8. Date of Revision of the Text

Not Applicable

9. Dosimetry (If Applicable)

Not Applicable

10. Instructions for preparation of radiopharmaceuticals (if Applicable)

Not Applicable