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REVIEW ON FORMULATION AND EVALUATION OFFLUOXETINE CAPSULE

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ABSTRACT

This review article focuses on the anxiolytic medication fluoxetine capsule formulation and evaluation parameters. Anxiety is a normal emotional response to stress but it requires medicationandpropertreatmentwhentheanxietybecomesexcessivebyinterferingwithdaily life. This article focuses on anxiety and anxiolytics and briefly discuss the formulation and evaluation parameters of Fluoxetine capsule. Fluoxetineis an anxiolytic under selective reuptake serotonin inhibitors which work by increasing serotonin level in the brain. Manufacturing of hard gelatin capsule and Capsule filling methods are described. Evaluation parameterssuchasphysicalevaluationtest,weightvariationtest,contentuniformity,dissolutiontest, disintegrationtestarethoroughlyexplained.

KEYWORDS: Fluoxetinecapsule,evaluation,anxiolytic.

ANXIETY

Anxiety is a normal emotional response to stress, characterized by feelings of fear, apprehension, and nervousness. However, when excessive and persistent, it becomes pathological and may lead to anxiety disorders.

SYMPTOMS

- Palpitations
- Sweating
- Tremblingorshaking
- Sensationsofshortness ofbreath

- Feelingofchoking
- Chestpainordiscomfort

ANXIOLYTICS

Anxiolyticsaremedicationsusedtoreduceanxietysymptoms,suchasfear,dread,uneasiness, andmuscletension,bymodulatingneurotransmitterslikeGABAorserotoninthenervous system.

FLUOXETINE

Commonlyknown as**Prozac**,whichisused totreatdepressionandvarioustypesofanxiety.

MECHANISMOFACTION

Fluoxetine effectively blocks the reuptake of serotonin into the presynaptic neuron. This inhibition leads to an increased concentration of serotonin in the synaptic cleft. This leads to elevated levels of serotonin in the brain. Thus improves mood and reduce the symptoms of anxiety.

FORMULATIONOFFLUOXETINE CAPSULE

Formulation is the process by which different chemical substances, including the active pharmaceutical ingredient(API)andexcipients,arecombinedtoproduceafinalmedicinal product suitablefor patient use.

COMPOSITION

TABLENO:1COMPOSITIONOFFLUOXETINECAPSULE.

S. No.	Ingredients	Category	Typical Quantity	Function
1	FluoxetineHCl	Active ingredient	22.4mg(≡20mg base)	Antidepressant(SSRIaction)
2	Lactose/MCC	Diluent (Filler)	q.s. to fill capsule	Adds bulk forproper filling
3	Sodiumstarch glycolate	Disintegrant	2–5%oftotal weight	Promotescapsule disintegration
4	Colloidalsilicon dioxide	Glidant	0.2–0.5%	Improvespowderflow
5	Magnesiumstearate	Lubricant	0.5–1%	Preventsstickingduring processing

MANUFACTURINGOFFLUOXETINECAPSULE

1. **Manufacturingof hardgelatincapsuleshell:**

- Dipping
- Spinning

- Drying
- Stripping
- Trimmingangjoining
- Polishing

DIPPING

Pairs of the stainless-steel pins are dipped into the dipping solution to simultaneously forms the caps and bodies.

Thedippingsolution is maintained ata temperatureabout 50□C ina heated, jacketed dippingpan.

SPINNING

The pins are rotated to distribute gelatin over the pins uniformlyand to avoid the formation of a bead at the capsule ends.

DRYING

Thegelatin is dried byablast of cool airto form ahard shell.

Thepinsare removedthrough aseriesofdryingstages toremovewater.

STRIPPING

Afterthe gelatin isdried,the capsandbodiesarestrippedofffromthe pins.

TRIMMINGANDJOINING

Thestripped capsand bodiesaretrimmed to therequired length bystationaryknives.

Aftertrimmingtotherightlength,thecapsandbodies arejoinedand ejectedfromthemachines.

POLISHING

Panpolishing:Acelo-cotapanisusedtodustandpolish. Cloth dusting: capsules are rubbed with cloth.

Brushing:capsulesarefeedundersoftrotatingbrush.

2. Capsulefillingmethod

a) Manualcapsule fillingmethod

b) Semi-automaticcapsulefillingmethod

c) Fully-automaticcapsule fillingmethod

MANUALCAPSULE FILLING METHOD

Manual capsule filling is the most basic method and is often used for small-scale production or when creating custom formulations.

PROCEDURE

1. Separatethe capsulesintobodyandcap sections.
2. Placethe capsulebodies into aholdingtraywith holes sized to fit the capsules.
3. Filleachcapsulebodywiththepowder orcontent usingasmallscoop orspatula.
4. Tampdown thepowder toensureconsistent filling.
5. Placethe capsback ontothefilledbodies andpress to seal.

SEMIAUTOMATICCAPSULEFILLINGMETHOD

Semi-automatic capsule filling machine, capsule separation, powder filling and capsule closing operations to achieve mechanical automatic completion, only manual operation in each process step, greatly improve the output and save labor costs.

PROCEDURE

1. Load emptycapsulesintothemachine'stray.
2. Themachineseparates thecapsulebodies andcaps.
3. Fillthepowderhopper with yourproduct.
4. Themachine dispensesthe powder toeach capsule ina set amount.
5. Optionally,youcanaddatampingsteptocompressthepowder.
6. Themachine reattachesthecapstothefilled bodies.
7. Finishedcapsules areejectedfromthemachine.

FULLYAUTOMATICCAPSULEFILLING METHOD

Automatic capsule machine output of up to 468000pcs/h, suitable for mass production, with vacuum powder feeder and hollow capsule feeder can achieve no manual intervention production.

PROCEDURE

1. Emptycapsules areloaded into ahopper.
2. Themachineorientsandseparatesthe capsules.
3. Capsulebodies arepositioned in the fillingarea.
4. Thepowder or contentis preciselydosedinto each capsulebody.

5. Capsulesareoptionallytamped toensure consistent density.
6. Synchronizethecapsulecap tothefilledvalvebody.
7. Completethelock combination ofcapsulecover and shell to automaticallypop out andcollect.
8. Qualitycontrol,qualityprosecutionofweight,appearanceandmetal detection.

EVALUATIONOFFLUOXETINECAPSULE

- **PHYSICALEVALUATION**

Thisinvolves checkingtheappearanceand size of thecapsulesto ensure uniformity.

Color and appearance: The capsules should be consistent in color and appearance. Anydiscrepancies might indicate contamination or issues during manufacturing.

Shapeandsize: Capsulesshould haveaconsistentshapeand sizeto ensure accurate dosing.

- **WEIGHTVARIATION TEST**

Thistest checkstheuniformityofthe capsulecontent.

A sample of fluoxetine capsules is weighed, and the average weight is calculated. The weight of individual capsules is then compared with the average weight. Any significant deviation could suggest issues with the filling process.

Acceptable limit: Variations in weight should not exceed a certain percentage (typically 10% for capsules).

- **CONTENT UNIFORMITY**

To perform the test, randomly selected 10 fluoxetine capsules from the batch to ensure a representative sample. Each capsule is carefully opened, and the contents are removed and weighed accurately. The content of the active ingredient in each capsule is the determined using appropriate analytical method, such as High-Performance Liquid Chromatography (HPLC) or UV Visible spectroscopy. The average content and the relative standard deviation (RSD) of the active ingredient across the 10 capsules are calculated to assess uniformity. The preparation complies with the test if: the content of the active ingredient in each capsule is between 85% and 115% of the label claim, no more than one capsule has a content outside the range of 85% to 115%, no capsule has a content outside the range of 75% to 125%.

If more than one capsule falls outside the 85% to 115% but within 75% to 125%, an additional 20 capsulesareanalyzed.Thepreparationcompliesif,inthetotalof30capsules,nomorethanone

capsulefalls outside the85%to 115%range, andnonefall outside the75%to 125% range.

- **DISSOLUTION TESTING**

Dissolution refers to the process by which the capsule releases its active ingredient into the gastrointestinal tract. The capsule is placed in the basket, which is then submerged in the 0.1 N HCL. The basket rotates at the specified speed, allowing the capsule to dissolve over time. Atpredeterminedintervals,samplesofthedissolutionmediumarewithdrawn andanalyzedtodetermine the amount of API released. This is performed to evaluate how a drug dissolves and becomes available for absorption. Pharmacopoeial standards specify the percentage of drug that should be released within a certain time (e.g. 80% within 30 minutes). If the dissolution rate is too slow or inconsistent, it can lead to poor bioavailability.

- **DISINTEGRATIONTEST**

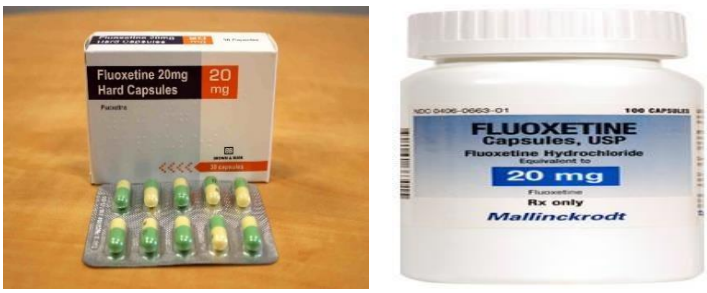
Six capsules are placed in the basket tubes, and the apparatus is operated under the specified conditions. The capsules are observed at the end of prescribed time limit (usually 30 minutes).

Disintegration is considered complete when the capsule shell is no longer visible, and onlyfragments of the shell remain. If 1 or 2 capsules fail to disintegrate completely, the test is repeated on an additional 12 capsules, and the requirement is met if not fewer than 16 of the total 18 capsules disintegrate completely.

PACKAGING OF ALPRAZOLAM TABLET

Packagingmeans acollection ofdifferent packaging materials which encasethe pharmaceuticalproduct from the timeof manufacturingto the end of the user.

TYPES OF PACKAGING



BLISTERPACKING **HDPEPACKING**

FIG.NO1: TYPES OF PACK AGINGOFFLUOXETINE CAPSULE.

LABELLING

Alabel isany written, printed, or visual material that is displayed on the immediate container of an article, or that is attached to a consumer good or that is attached to or visible on a package that contains a consumer good.

FLUOXETINECAPSULELABEL

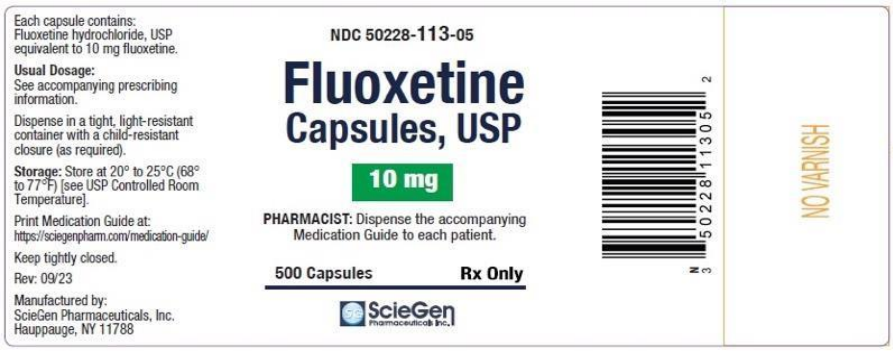


FIG.NO2: LABEL OF FLUOXETINE CAPSULE.

INFORMATIONSON LABEL

- Drugname:Fluoxetinecapsule
- Drugstrength:10 mg
- Dosageform:Capsule
- Batchnumber
- Manufacturingdate
- Expirydate
- Route ofadministration
- Prescriptionstatus:RX only
- Manufacturernameandaddress
- Storagecondition: Storeat20ºCto25ºC

STORAGE OF FLUOXETINE CAPSULE

Fluoxetine capsules should be stored at room temperature between 20°C and 25°C (68°F to 77°F). Keep them in their original packaging, tightly closed, in a cool, dry place away from light, moisture, and heat (avoid storing in the bathroom).

CONCLUSION

This review highlights the formulation and evaluation of Fluoxetine capsule, emphasizing their role in ensuring safe, effective, and stable dosage forms. Fluoxetine is a widely using

anxiolyticforthemanagement ofdifferenttypeofanxietydisorder.Formulation ofFluoxetine capsule requires proper excipient and method selection for effective stable product.Evaluation parameters help in ensuring development of stable and effectivedosage form.

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