www.ijarp.com ISSN 2456-9992 Page: 01-08

International Journal Advanced Research Publications

Review Article

Volume: 02
Issue: 06

REVIEW ON FORMULATION AND EVALUATION OF ALPRAZOLAM TABLET

***Manisha P., Najeeba Farahath, Raihanath Safreena, Sadiya K. S.**

Department of pharmaceutics, Malikdeenar college of Pharmacy, Seethangoli, Kasaragod, Kerala, India.

Article Received: 29 April 2026, Article Revised: 19 May 2026, Published on: 09 June 2026

***Corresponding Author: Manisha P.**

Department of pharmaceutics, Malikdeenar college of Pharmacy, Seethangoli, Kasaragod, Kerala, India.

DOI: https://doi-doi.org/101555/ijarp.5648

ABSTRACT

This review article focuses on the anxiolytic medication alprazolam tablet formulation and evaluation parameters. Anxiety is a normal emotional response to stress but it requires medication andpropertreatment whentheanxietybecomesexcessivebyinterfering withdaily life. This article focuses on anxiety and anxiolytics and briefly discuss the formulation and evaluation parameters ofalprazolam tablet.Alprazolam isananxiolytic underbenzodiazepine whichworkbymodulatingGABAinnervoussystem.Directcompression andwetgranulation methodofpreparationisdescribed.Evaluationparameterssuchashardness,thickness,content uniformity, friability,dissolutionrate arethoroughly explained.

KEYWORDS: Alprazolam tablet, evaluation, anxiolytic, direct compression.

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
- Sensationsofshortnessof breath

- Feelingofchoking
- Chestpainordiscomfort

ANXIOLYTICS

Anxiolyticsaremedicationsusedtoreduceanxietysymptoms,suchasfear,dread,uneasiness, andmuscletension,bymodulating neurotransmitterslikeGABAorserotonin inthenervous system.

ALPRAZOLAM

Alprazolam,commonlyknownasXanax,isatriazolobenzodiazepineusedprimarilytotreat anxiety and panic disorders.

MECHANISMOFACTION

Benzodiazepinesbind tothe GABA-Areceptor.Acommon GABA-AreceptorintheCNSis comprisedoftwo alpha-1 subunits, two beta-2 subunits,and onegamma-2 subunit. The benzodiazepinebindingsiteisbetween thealpha-1 andgamma-2subunits. Benzodiazepine binding sites appear to exhibit coupling with GABA-Areceptors, enhancing the effects of gamma-aminobutyricacid(GABA)byincreasing GABAaffinity atthe GABA-Areceptor. Themajor inhibitoryneurotransmitterGABAmediates thecalmingorinhibitoryeffects of alprazolam on the human nervous system.

FORMULATIONOFALPRAZOLAMTABLET

Formulation is the process by which different chemical substances, including the active pharmaceuticalingredient (API)andexcipients, arecombinedtoproduceafinal medicinal product suitablefor patient use.

COMPOSITION

Table1: Ingredient and Composition of Alprazolam Tablet.

INGREDIENT	FUNCTION	QUANTITY PERTABLET
Alprazolam	API	0.5 mg
Crospovidone	Superdisintegrant	5–15 mg
Docusatesodium	Wettingagent/surfactant	0.5–5 mg
Lactose	Diluent (filler)	78–100 mg
Magnesiumstearate	Lubricant	2–8 mg
Microcrystallinecellulose(MCC)	Binder+ diluent	50–150 mg
Silicondioxide(colloidal)	Glidant	0.5–2 mg
Sodiumbenzoate	Preservative	0.15 mg
Cornstarch	Disintegrant/binder	50-150 mg

MANUFACTURINGOFALPRAZOLAMTABLET

A. DirectCompressionMethod Step 1: Weighing of Materials

Accurateliweighalltheingredients includingalprazolamandexcipients; Diluent (lactose) Disintegrant(cornstarch) Glidant (silicon dioxide) Lubricant(magnesiumstearate)

Step2: Sifting

Pass all the ingredientsthrough sieve (#40 or #60)

ToRemovelumpsandtoensureuniformparticlesize

Step3: Blending

MixAlprazolam+lactose+crospovidonebyusing; V cone blender, double blender

Mixthoroughlytoensure**uniform distribution.**

Step4: AdditionofGlidant

Addcolloidalsilicondioxideandmixfor 5–10minutes.

Purpose ofglidantistoImprovepowderflowduringcompression.

Step5: Lubrication

Addmagnesiumstearateandmixgentlyfor**2–3minutes only.**

Avoidovermixingasovermixingcanaffecttablethardnessanddissolution.

Step6: Compression Compressblendusing**tabletcompressionmachine**

Adjustweight,hardness andthicknesstoproduceuniformtablets.

B. Wetgranulationmethod

Alprazolamimmediatereleasetabletsarecommonlypreparedbydirectcompression due to its simplicity and suitability for low-dose drugs. Wet granulation may be employed when flow and content uniformityissues arise.

1. Weighing

- AllingredientsincludingAlprazolam,lactose,MCC,cornstarchandmagnesiumstearate are accurately weighed.

2. Sieving

- Alprazolam, lactose,MCC, and corn starch are passed through #40 sieve. colloidal

silicondioxideandmagnesium stearate arepassedthrough#60sieve.

3. DryMixing.

- Alprazolam ismixed with asmall portion oflactose first, then gradually mixed with remaining diluents toensure uniform distribution.Geometric dilution isemployed for mixingthealprazolam withdiluent asitisalowdosedrug.Microcrystallinecellulose and starch are added and blended for 10–15 minutes.

4: BinderSolutionPreparation

- Cornstarchisdissolvedinpurifiedwatertoprepare bindersolution.

5. Granulation

- Bindersolutionis added slowly to powderblend with continuous mixing untila cohesive wetmass isformed. Planetary mixer, rapidmixer granulator andsigma blademixers are used in this step.

6. WetScreening

- Thewetmassispassedthrough#16or#20sievetoformgranules.

7. Drying

- Granules aredriedindryerat50–60°Cuntil moisturecontentisreduced(LOD~1–2%).
- **Dryersusedaretraydryer,vaccumdryerandfluidizedbeddryer.**

8. DryScreening

- Driedgranulesarepassedthrough#20sievetoobtainuniformgranules.

9. FinalBlending

- Crospovidone isaddedextragranularlyandmixedfor 5–10minutes.

Thencolloidalsilicondioxideandmagnesiumstearateareaddedandmixed gently for3–5 minutes.

10. Compression

- Finalblendiscompressedintotablets usingcompression machine. Hardness, weight, and thicknessare adjusted.

EVALUATIONOFALPRAZOLAMTABLET

In-vitroEvaluationofthePreparedTablets

Thep repared tablets are evaluated by the following tests: Appearance, Thickness, Hardness,

Weightvariation, Friability, Disintegration,Drugcontent,Invitrodissolution,andStability studies.

1. Appearance

Thegeneralappearanceoftablet isitsvisualidentityandoverallelegance,includingshape, colour,andsurface texture. Theseparameters are essential for consumer acceptance.

2. Thickness

Thethicknessofthetablets wasdeterminedusingverniercallipers.Randomly,10tablets wereselectedfordeterminationof thickness, expressed as Mean ± SD in mm.

3. Hardness

Thehardness ofatablet indicates its strengthagainst resistancetocapping, abrasion, or breakageduringstorage,transportation,andhandling.Itismeasuredastheforcerequiredto breakthetablet.Hardnessof10tablets(randomlyselected) wasdeterminedusinga Monsanto hardness tester and expressed in kg/cm².

4. WeightVariation

Theweightvariationtest iscarriedouttoensureuniformityintablet weightwithinabatch. Twentytablets wererandomly selected,weighedindividually,andthe average weightwas calculated.Thedeviation ofindividual tablet weights from theaverage wasdetermined.

5. FriabilityTest

Friabilityisthe loss ofweight oftablets duetomechanical stress during handling or transportation.ARochefriabilatorwasusedfor this test. Fortabletsweighing≤0.65g,a sample equivalent to6.5gwastaken; fortablets>0.65g,10tabletswereused.Theapparatus wasrotated at25rpmfor4minutes (100revolutions).Tablets were dedustedand reweighed.

%Friability=$(W_0 - W_1)/W_0 \times 100$Where:

W_0=Initialweight W_1 = Final weight

6. DisintegrationTest

TheUSPdisintegrationapparatus consistsofsix glass tubes openatthe topandfittedwith a 10-mesh screen atthebottom. Onetablet isplaced in eachtube, andthebasketisimmersedin 1 Lof distilledwater at37 ± 2°C. Tablets should remain below the surface during upward movement and notdescend closer than 2.5 cmfrom the bottom.

7. DrugContent

Ten tablets were powdered, and an amount equivalent to 100 mg drug was dissolved in suitable medium (bufferor0.1NHCl).Thevolume wasmade upto 100ml, filtered, and diluted 100times. Thesolution wasanalysed spectrophotometricallyto determine drug content per tablet.

8. InVitroDrugReleaseStudies(Dissolutionstudy)

Immediate-releasetablets weresubjectedtodissolutionstudies inpH6.8phosphatebufferor 0.1N HClfor30minutes. Thedissolutionwascarriedoutusing 900ml medium at 37±1°C in a dissolutionapparatus with paddle rotationat 100 rpm.

Samples (5 ml)werewithdrawnat5,10,15,and30minutes andreplaced with fresh medium. Thesamples were filtered,diluted, and analysed byspectrophotometry.Drugrelease data wereplottedusingzero-order andfirst-orderkinetics,andparameters suchasdissolutionrate constant andcorrelationcoefficient werecalculated. Immediate-releaseformulationsare expected to release:

~50%drugwithin15minutes≥80% drug within 30 minutes~90% drug within 45 minutes

9. Stabilitystudies

Asperthe ICHGuidelines the stabilitystudies ofpharmaceuticalproducts may be expressed as the time during which the pharmaceutical products retain its physical, chemical, microbiological,pharmacokinetic propertiesandcharacteristics throughouttheshelflifefrom the time ofmanufacture. Shelf life ofthe product can be defined as the substance reduces to 90% of its original concentration.

Table2: Stability Studies of Alprazolam Tablet.

StudyType	StorageCondition	MinimumTimePeriod
Long-term	25°C±2°C/60%RH±5% RH	12 months
Intermediate	30°C±2°C/65%RH±5% RH	6 months
Accelerated	40°C±2°C/75%RH±5% RH	6 months

PACKAGINGOFALPRAZOLAMTABLET

Packagingmeansacollectionofdifferent packagingmaterials whichencasethe pharmaceuticalproduct from thetimeofmanufacturingto theend ofthe user.

TYPES OF PACKAGING

PRIMARY PACKAGING	SECONDARY PACKAGING	TERTIARYPACKAGING
Blister packagin Bottles	Cartons Paperboard boxes	CratesCardboard boxes

Figure1: Packaging of Alprazolam Tablet.

LABELLING

Alabelisanywritten,printed,orvisualmaterial thatisdisplayedontheimmediate container ofanarticle,or that isattachedtoaconsumer goodorthat is attached toor visible ona package that contains a consumer good.

ALPRAZOLAMLABEL

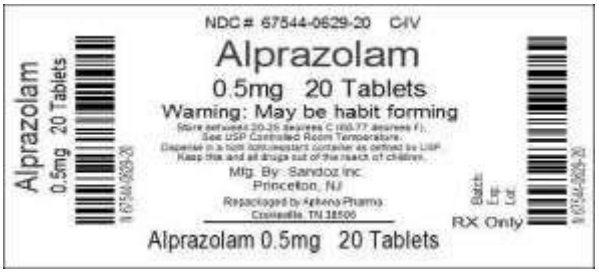

Figure2: label of alprazolam.

INFORMATIONSONLABEL

- Drugname:Alprazolam
- Drugstrength: 0.2,0.5,1,2mg Brand name: e.g., Xanax
- Dosageform:Tablet Batch number
- Manufacturingdate Expiry date
- Route ofadministration
- Prescriptionstatus:RX only
- Manufacturername andaddress

 Storagecondition: storebelow25^{0}C Warnings

STORAGEOFALPRAZOLAMTABLET

Alprazolamtablets should bestored at room temperature,between 68 F to 77 F (20^{0}C to 25^{0}C).It canbeexposed totemperaturesbetween59Fto86F(15^{0}Cto30^{0}C),forshorterperiodsoftime,suchaswhentransporting it.Store in acool,dry placeand protected fromlight.

CONCLUSION

Thisreview highlights theformulation andevaluation ofalprazolam tablet, emphasizing their role in ensuring safe, effective, and stable dosage forms. Alprazolam is a widely using anxiolyticforthemanagement ofdifferenttypeofanxietydisorder.Formulation ofalprazolam tablet requires proper excipient andmethod selection foreffective stable product. Evaluation parameters help in analysing the tablet hardness and integrity and thereby ensuring development of stable and effectivedosage form.

REFERENCE

1. KushwahaN,JainA,JainPK,KhareB,JatYS.Anoverviewonformulationand evaluationaspects oftablets. Asian J DentHealth Sci. 2022;2(4):35-39.
2. BodkeA.Anoverviewofimmediaterelease tablets.IntJPharmResAppl.2024 JanFeb;9(1):260-68.
3. MutiawatiY,RusdianaT,Fitrileni,KhorunisaA.Formulationandevaluationof alprazolam1mgtablets.IndonesJPharmSciTechnol.2014;1(1).
4. DomschkeK,MaronE.Geneticfactorsinanxietydisorders.ModTrends Pharmacopsychiatry.2013;29:24-46.
5. HuybrechtsI.Thepharmacologyofalprazolam: areview.ClinTher.1991;13(1):100-17.
6. GriffinCE,KayeAM,BuenoFR,KayeAD.Benzodiazepinepharmacologyand centralnervoussystem-mediatedeffects.OchsnerJ.2013Summer;13(2):214-23.
7. GreenblattDJ,WrightCE.Clinicalpharmacokineticsofalprazolam:therapeutic implications.Clin Pharmacokinet. 1993 Jun;24(6):453-71.
8. Unitedstatespharmacopeia(USP).USP-NF.Latestedition.
9. U.S.NationalLibraryofMedicine.Alprazolamtablets,USP.Dailymed.2024.
10. Alderborn G. Tabletsand compaction.In:Aulton ME, editor.Pharmaceutics: The Science ofDosageFormDesign.2nded.Edinburgh:Churchill Livingstone;2002.p. 397–440.