Journal of Science and Technology
ISSN: 2456-5660 Volume 06, Issue 03, May-June 2021

www.jst.org.in *DOI: https://doi.org/10.46243/jst.2021.v6.i3.pp102-108*

A Review on Formulation, Development and Evaluation of Cyclizine Hydrochloride Orodispersible Tablet using New Generation Excipients

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To Cite this Article
Kolhe Madhuri Suresh, "A Review on Formulation, Development and Evaluation of Cyclizine Hydrochloride Orodispersible Tablet using New Generation Excipients", Journal of Science and Technology, Vol. 06, Issue 03, May-June 2021, pp102-108

Article Info
Received: 14-01-2021 Revised: 02-05-2021 Accepted: 10-05-2021 Published: 28-05-2021

Abstract: *To improve bioavailability and patient compliance, orodispersible drug delivery systems are used mostly because Orodispersible tablets are thenovel dosage form which quickly disintegrates in the mouth (1-3 min) without chewing upon oral administration and without the need of water. As compared to conventional tablets and capsules orodispersible tablets (ODT) are getting the attention from the last three decades because eithas better patient compliances, better solubility, and stability. Orodispersible tablets have a quality that disintegrates rapidly generally in seconds when put on the tongue because eitcontains mainly medicinal substances in the solid dosage form. This new ODT technologyis enhancing the patient lifecycle and making a convenient dosing system for pediatric, geriatric, and psychiatric patients with dysphagia because itdirectly addresses the pharmaceutical and patient needs. This new technology encourages the academic industry to develop a newer orally disintegrating formulation and technology or evaluation methodology which is suitable for drug candidates forits future prospects.*
Key Word*: Orodispersible Tablets, Bioavailability, Superd is integrants, Orodispersible Technologies, Fast Dissolving Tablets.*

I. Introduction

Direct ingestion is intended in most pharmaceutical dosage forms which are formulated fororal administration. The oral route is the best or convenient way of drug administration forpatients and this way is used by most of the therapeutic agents for producing effects of theoral route. A term used by the "European Pharmacopoeia" orodispersible tablet, this tabled is perses in them out with in 3 seconds beforeswallowingit.Theorodispersibletabletalso called "ODTs" and it is quickly disintegrating tablet or it dissolves in the mouth quicklybecause it is a mouth dissolving tablet and also a fast responding tablet with porous and rapidmelting nature. Freezing & drying, tablet molding, spray drying, mass extrusion, sublimation,and direct compression are the conventional methods that are used for the preparation oforally disintegrating tablets. ODTs response time is very fast & its disintegration time is fewsecondstoa minuteandaccording to the United States, FoodandDrug Administration (FDA) ODTsisaSolidformsubstance havingactive ingredient& medicinal substance which dissolve in a mouth fastly when placed on a tongue in a few seconds. Because, when ODTs comeincontactwithsalivaitreleasesactivedrugsthatprovidemaximum drugbioavailability in comparison to conventional dosage form due to this tablet getting dispersedor disintegrated. The hydrophilic nature excipients are used in ODT technology and it is selected on the basis of drugphysico chemical property mainly hydrophilicityorhydrophobicity.Insaliva,theactiveagentdissolvesrapidlyandnomatterwhatevermembrane encounter, unless it is protected by pre-gastric absorption and the current review isaimed to study present development of ODT technology and sustainability of drug candidatesandtheircharacterization ofODT.

Objective:

- To improve patient compliance
- To increase bioavailability

- To enhance stability
- To test masking
- To hormone adjusting blood glucose level

Orodispersible tablets(ODTs):

Oral dispersible tablets (ODTs) are the novel dosage form which quickly disintegrates in the mouth (1-3 min) without chewing upon oral administration and without the need of water, different other conventional oral solid dosage form. The best time for an orodispersible tablet to get separate is measured to be fewer than a minute. Mostly the degeneration times vary from 5 to 30 seconds and are prepared to recount; direct compression, solid dispersion,lyophilizationormoldingtechniques.ODTsarerecognizedbytheadditionofsuperdisintegrants alike cross-linked cellulose imitative; carboxy methyl cellulose, sodium starch glycolate, poly vinyl pyrrolidone, which provides rush breakdown when gets in exchange with water or salivary secretions. Bioavailability of drugs mayriseduetooralandpregastric absorption,reducingthefirst-passmetabolisminthegastrointestinaltract[8].

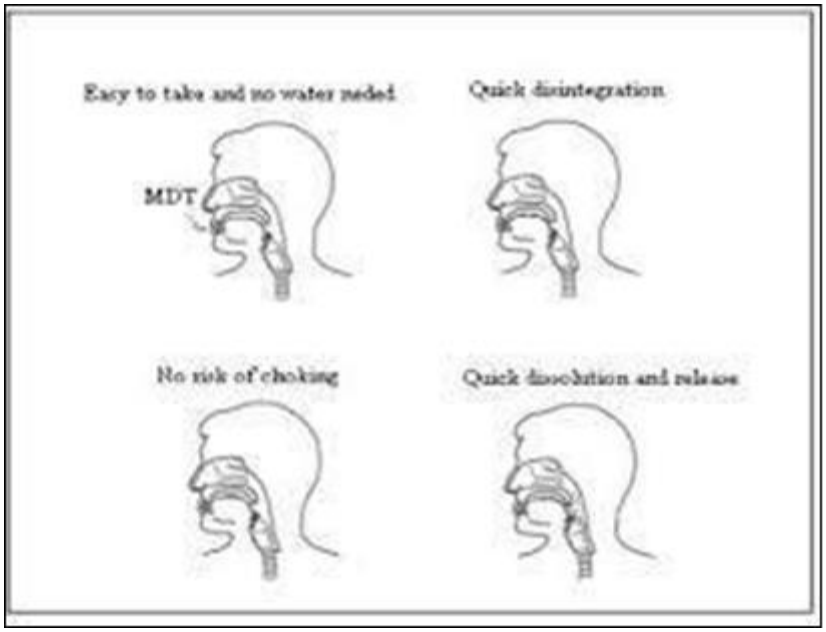

Figure no 1: Mechanism of action of orodispersible tablet

Ideal Properties of Orodispersible Tablets[5]:

- Notrequirewatertoabsorbandshoulddissolveordisintegrateinthemouthwithinafewseconds
- High drug loading
- Have a pleasant mouth feel
- Be agreeable with taste masking and other excipients[13]
- Mainly in the condition of insoluble and hydro phobic drugs increase the bioavailability, due to rapid disintegration and dissolution of these tablets.

Limitations of Orodispersible Tablets(Odts)[14]

- ManytimesthesolublediluentsusedforformulatingtheODTsmightgivehygroscopicdosagewhich maylead to stabilityissues
- Thetablets areunpleasanttotasteand/orroughnessinthemouthifnotformulatedproperly
- Specializedpackingmightberequiredforhygroscopicandlight-sensitive drugs[1]
- Precautionsto betakenwhile administeringimmediatelyafter removingfrom thepack.

AdvantageofOrodispersible Tablets (Odts)[15]

- Improvedstability
- Suitable for controlled/sustained Offers improved compliance and convenience to patients and prescribers.

- Itimprovespatientadherenceandreducesthedevelopmentofresistanceinthecaseofantimicrobials.
- Simplifiesthelogisticsofprocurementanddistribution
- ForRapiddrugdelivery,ODTs areconsidered tobepreferreddosageform[16]
- The drug is released quickly from thisdosageformandgetsdissolveinGITtractwithoutgettinginto the stomach, increased bioavailability can be achieved
- ODTsareveryconvenientforadministeringtovariousclassesofpatientsfromdisabled,travelersand busypeople, whodo not always haveaccessto water.
- Some drugs are absorbed from the pharynxandesophagusasthesalivapassesdownintothestomach; in such cases, the bioavailabilityof drugs is increased[4]
- Nowaterneeded[3]
- Nochewingneeds
- Bettertaste
- releaseactives
- Allow high drugloading

Disadvantageof OrodispersibleTablets(ODTS)[17]

- Rapid drugtherapyintervention is not possible
- Sometimesmayrequiremorefrequencyof administration
- Dosedumpingmayoccur
- Reducedpotentialfor accurate doseadjustment
- Forproperlystabilizationandsafetyofthestableproduct,ODTrequiresspecialpackaging
- Usuallyhaveinsufficientmechanicalstrength. Hence,carefulhandlingisrequired
- Leaveunpleasant taste and/or grittiness inthe mouth ifnot formatted properly[18]

RecentTrendof ManufacturingODTs[19]

The technologies used for preparation of orodispersible tablets include elyophilization, moulding, direct compression, cottonc and y process, spray drying, sublimation and nanonization. These methods are produced on the principles of increasing absorbency and/or addition of the superd is integrants and the water-soluble excipients in the tablets. List of some expressed and marketed drugs.

Table no 1: Some examplesof recentlypreparedOrodispersiblestablets

Drug	Method	Reference
Ofloxacin	Taste masked microspheres of the ofloxacin werepreparedasausingEudragitandorodispersibletabletsoftheformulated microphereswereusingthe nature ofthe superdisintegrant.	[51]
Nimesulide	Orodispersibletabletswere thencompleted usinglocust bean gumasanaturalof thesuperdisintegrant.	[52]
Cetirizine dihydrochloride	Tabletswereorganizedusingcetirizinealongwith camphorandmannitolindifferent quantity	[53]
Pheniramine maleate	Effervescentmethod	[54]
Diazepam	ODTs were organized using different types ofsuperdisintegrantsatchangedconcentrationusingwet granulationanddirectcompressionmethods.	[55]
Valsartan	Tabletswerearranged byfreeze-dryingmethod	[56]
OndansetronHCl	Directcompressiontechnique	[57]
Roxithromycin	ODTswerearrangedusingmodifiedpolysaccharidesas fastdisintegratingexcipients.	[58]
Indomethacin	The tablets were complete by the non-aqueous wetgranulationmethodwithsuperdisintegrantincludedboth oftheintragranularlyand extragranularly.	[59]

VariousTechniquesUsedInPreparationofOrodispersibleTablets:

Varioustechnologiesused inthemanufactureoforodispersibletablets consistof:

- Directcompression
- Sublimation
- Freeze-dryingorlyophilization

- TabletMolding
- Spraydrying
- Cottoncandyprocess
- Massextrusion
- Phasetransition
- Nanonization
- Fastdissolvingfilms

Direct compression:

Direct compression characterizes the simplest and most cost-effective tablet manufacturing technique. This method can now be practical to the research of ODT because of the accessibility of enhanced excipients mostly super disintegrants and sugar-based excipients.[20] The mixture to be compressed must have suitable flow of the properties and cohere under pressure thus assembly pretreatment as the wet granulation is excessive.Limited drugs can be directly compressed into tablets of standard quality. The disintegrant addition technology is cost-effective and easy to implement at the industrial level.[21] Figure no 2. shown in direct compression method.[22]

Sublimation method:

The slow dissolution of the compressed tablet containing even highly water-soluble ingredients is due to the low porosity of the tablets.[23] This volatile material is then removed by sublimation separation to the behind as a highly porous matrix. Tablets manufactured by this method have generally disintegrated in 10-20 sec. Even solvents like cyclohexane, benzene can be used as pore-forming agents. Figure no 3. shown in Sublimation Method.[24]

Freeze-drying or lyophilization:

A process in which water is sublimated as of the product after freezing is so-called freeze- drying. Freeze-dried methods offer more quick dissolution than other available hard products.[18] Freeze-dried forms offer more rapid dissolution than other available solid products. The lyophilization method imparts a smooth amorphous structure to the bulking agent and sometimes to the drug, thereby improving the dissolution physical characteristics of the formulation.[25]

Tablet Moulding:

Tablets produced by molding are solid dispersions. The physical form of the drug in the tablets can be determined by whether and to what extent it dissolves in the molten carrier. The drug can exist as discrete particles or microparticles dispersed in the matrix.[26] The molded tablets shaped by compression molding are air-dried. As the molding process is employed usually with soluble ingredients (saccharides) which offer better mouthfeel and breakdown of the tablets. But, molded tablets have low mechanical strength, which results in erosion and flouting during handling.[27]

Spraydrying:

The preparation limited hydrolyzed and unhydrolyzed gelatin as a supporting agent for themedium,mannitolasabulkingagentandsodiumstarchglycolate/croscarmelloseasadisintegrant.[3] For getting immediate dissolution (<20 sec) this method is used, but thisapproach involves both high cost and time of production and produces tablets of very poormechanical strength.[28] This then mixed with the active ingredient and compressed intotablets. Figureno 4. Shown in spraydrying.[29]

Cottoncandyprocess:

This process contains the formation of a matrix of polysaccharides by simultaneously actionofflashmeltingandspinning.[30] Thematrixisthencuredorpartiallyrecrystallizedtoprovide a compound with good flow properties and compressibility. The candyfloss can thenbemilledandblendedwithactiveingredientsandotherexcipientsandsubsequentlycompressedintoODT.However,the highprocessingtemperaturelimits theuseofthistechnologyto thermostable compounds only.[31]

Massextrusion:

This technology contains softening the dynamic blend using the solvent mixture of water-solublepolyethyleneglycolandmethanolandensuingremovalofmakingsoftermassthrough the extruder or syringe to get a cylinder of the product into even segments using aheatedbladeto form tablets.[32]Figureno 4.Shown in Mass Extrusion.[33]

Phasetransition:

In this method mixture of the low and high melting point sugar alcohols, as well as a phasetransition in the manufacturing method, is main for the creating ODTs without any differencein the apparatus.Tabletis preparedin twophases.[34]FDT wasprepared by decreasingpowder comprising xylitol (melting point: 93 95 °C) and erythritol (melting point: 122 °C)and then heating at about 93 °C for 15 min. After heating, the medium pore size of the

tabletswasincreasedandtablethardnesswasalsoimproved.Theincreaseofthetablethardnesswith heating and the storage did not depend on the crystal state of the lower melting point ofthesugar alcohol.[35]

Nanonization:

The ionization process contains a reduction in the particle size of the drug to nano-size bymillingtechnique.Thedrugsarestabilizedagainstagglomerationsurfaceabsorptiononselectedstabilizers. This process is suitableforpoorlywater-soluble drugs.[28]

Fastdissolvingfilms:

It contains a nonaqueous solution having water-soluble film-forming polymers (pullulan,carboxymethylcellulose,hydroxypropylmethylcellulose,hydroxyethylcellulose,hydroxypropyl cellulose polyvinyl pyrrolidone, polyvinyl alcohol or sodium alginate.), a drugandanothertaste-maskingagentwhichareusedtodevelopafilmasthesolventevaporates.In the case of bitter-tasting drugs resin adsorbate or coated microparticles of a drug can beused in a film.[36] Characteristics: These are thin films of 2×2 inches dimensions; dissolve fastwithin5 seconds,

ManufacturingprocessofODT[49]:

- Drugwasgeometricallymixedwithmicrocrystalline cellulose, lactose,andsifted throughsieveno.40.
- Thisblendwasfurthermixedwithstarchandferricoxideyellowinarapidmixergranulator.
- Bindersolutionwaspreparedbydissolvinghydroxypropylmethylcelluloseunderstirringinpurified water.
- Thisbindersolutionwas addedtothemixtureintherapidmixergranulator.
- Thegranularmasswasair-driedfor5to10minutesandfurtherdriedat450C-550CFor5to10 min.and passed through sieveno.10.
- Drygranulesweresiftedthroughsieveno.30using vibratorysifted.
- In a clean dryblender, the dried granules were mixed with hydroxypropylmethylcelluloseand magnesium stearate.
- Theselubricatedgranuleswerecompressedto formtabletsinatabletingmachine.
- Thetablet wascoatingwith acoatingpan.

Packaging[50]:

Packaging special care is required during manufacturing and storage to protect the dosage ofother quick-dissolving routeof administration.Fast-dispersing and/ordissolving oralroute, the method can be packagedusingvariouspotential,suchassinglepouch,blistercardwith multipleunits,multipleunitdispenser,andcontinuousrolldispenser,dependingontheapplicationand marketingtargets.

II. Industrial Applications

IndustrialApplicationsIncludeTheFollowing

- Todevelop anorallydisintegratingdosageformsand towork withexistingdisintegrants
- Tofurtherimproveuponthe existingtechnologyof ODTs
- Tooptimizethe blendofdisintegrants orexcipientsto achieveODTs
- Toselectanddeveloppropertpackagingmaterialandsystemforenhancedstabilityoftheproductand also developacosteffectiveproduct
- Toarriveatdifferenttaste-maskingagentsandpreparepalatablerouteofadministrationtherebyincreasingpatient compliance
- Todevelopdisintegrantsfromdifferentpolymerswhichareusedascoatingmaterialsbycertainmodificati ons anduse them forformulating ODTs.

FutureProspects:

These dosage forms may be suitable for the oral delivery of drugs such as protein andpeptidebasedtherapeuticsthathavelimitedbioavailabilitywhenadministeredbyconventionaltablets.Theseproductsus uallydegraderapidlyinthestomach.Thenextgeneration drugs Should be peptide based or predominantly protein, tablet may no longer bethe dominant format for dosing such moieties.Injections generally are not preferred for use bypatients unusually facilitated by twist autoinjectors. Inhalation is one of the correct approachsystems to deliver these drugs, but the enhanced research into biopharmaceuticals so far hasgenerated predominantly chemical units with low molecular weights. The developments ofenhanced oral protein delivery technology by ODTs which may release these drugs in the oralcavityareveryencouragingfor thedeliveryof highmolecularweight proteinand peptide.

III. Conclusion

Orodispersibletablets(ODTs)areinnovativedrugdeliverysystemsandhavepotentialadvantagesoverconventionaldosagef orms,withtheirimprovedpatientcompliance,convenience, bioavailability andrapid onset of action .Though considerable research has been done in the formulation development and technologiesforODTs,moreintensiveinvestigations are to be carried out in this promising area to result in newer cost effectivetechnologies and better products. The potential of dosage forms is promising because of theavailabilityofnewtechnologiescombinedwithstrongmarketacceptanceandpatient compliance.The consideration takesplace intechnologies, pharmaceuticalcompaniescantake advantage of ODTs for product line extensions or for first-to-market products. Withcontinued development of new pharmaceutical excipients, one can expect the appearance ofmorenovel technologiesforODTs in thedays tocome.

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