International Journal of Pharmaceutical Research and Applications
Volume 7, Issue 4 July-Aug 2022, pp: 663-671 www.ijprajournal.com ISSN: 2456-4494

Formulation and Evaluation ofHerbal Lozenges HavingAnti-Emetic Activity

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Submitted: 10-07-2022 Accepted: 21-07-2022

ABSTRACT

Introduction: The present work is focused on development of lozenges having anti-emetic activity, for this plant extracts of *KaempferiagalangaL.*and *Zingiberofficianalis*are used which are used to treat several types of stomach problems including motion sickness and morning sickness. The lozenges are evaluated for various quality parameters like hardness, friability, thickness, weight uniformity and disintegration time which comply with the standard mentioned in GMP guidelines. **Aims and objectives :**The aim of the work is to conduct formulationandevaluation ofherballozengeshavinganti-emeticactivityusing*KaempferiagalangaL.*and *Zingiberofficianalis*.**Materialsandmethods:**sugarwasdissolvedinwaterandtheextractsofdrugmixed andheated tillsuitableconsistencyandpouredinlozengesmouldandcooledtoformlozenges.**Observations andresults:**Thelozengeswereevaluatedforvariousqualityparameterslikehardness,friability,thickness, weightuniformityanddisintegration tocomplywithstandardmentioned inGMPguidelines. **Conclusions:**lozengesarecompletelyherbalcontainingnosynthetic ingredientandiseconomical totreat emesis.

KEYWORDS:lozenges,emesis,extract,receptors

INTRODUCTION

Lozengesaresoliddosageformsthatareintendedto bedissolvedor disintegratedslowlyinthemouth. They containoneormoreactiveingredientsandare flavouredandsweetenedsoastobepleasanttasting. Itisgenerallyusedfortheirtopicaleffectbutmay alsohaveingredientsthatproduceasystemiceffect. Lozengeisasolidpreparationconsistingofsugar andgum,thelattergivingstrengthandcohesiveness tothelozengeandfacilitatingslowreleaseofthe medicament.Itisusedtomedicatethemouthand throatfortheslowadministrationindigestionor coughremedies. Lozengesmaycontainan anaesthetic,ademulcent,oranantiseptic.[1]

Lozengesprovideapleasant dosageformfor patientswhoareunableto swallow othertypesof solid dosage forms. Because lozenges are formulatedtotastegood,theymustbekeptoutof thereachofchildren, whomayviewthemascandy. Typesoflozengescanbeorderedashardcandy, chewablegummy gel,andhand-rolledlozenges. Lozenges areproducedmostlyforthechildren. Lozengepreparations,alsoreferredtoastroches,are widelyused forextemporaneouslycompounded prescriptions.58However,there arelimited examplesofapprovedlozengedrugproducts.There arethreebasictypesoflozenges:hard,soft,and chewable.

Hardlozengesaregenerallyformedusingsucroseor othersugarssimilartotheprocess forhardcandy confectionsthat producea hardenedamorphous glassy material. Slow the rate of dissolution,

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polymerssuchasPEGsandHPMCmaybeadded. Anothertypeofhard lozengemaybemadeof compressedpowders. Anexampleofthisis clotrimazoletroches(lozenges)madeasalarge compressedtabletthatisslowlydissolvedinthe mouth.Thetabletbasematerialismade ofdextrose, MCC, andpovidone.[2]

MATERIALSANDMETHODS

Materialsrequired

Chemicals:*KaempferiagalangaL*.,Zingiber*officianalis*,Sugar,honey,distilledwater, cinnamonpowder

Apparatus:tripodstand,waterbath,beaker,glass rod,measuringcylinder,butterpaper,mould

Methadology:

1.Collectionandidentificationofplant material

Theleaves of*KaempferiagalangaL*.and*Zingiberofficianalis*was collectedfrommedicinalgardenof DPS,Puthupally,Kottayam.theplantwas authenticatedby Dr.KRISHNARAJM.V, Assistantprofessorandresearchguide,dept.ofbot any,Baseliuscollege,Kottayam.

2Preparationofplantmaterial

Freshleaves of*KaempferiagalangaL*.and *Zingiberofficianalis*wascollectedandweighed.itisth enwashedandcutintosmallpieces andthen subjectedforextraction.

3.Extractionofplantmaterial

10gofplant materialwassoaked in50mlwaterina beakerandboiled.theextractwascollected filtered.thesameprocedurewasrepeatedforboth *KaempferiagalangaL*.and*Zingiberofficianalis*. *[8,9]*

4.Formulationoflozenges[10]

TABLE:1

SL.NO	INGREDIANTS	QUANTITY
1.	*Zingiberofficinalis*	30ml
2.	*KaempferiagalangaL.*	15ml
3.	Sugar	100g
4.	Cinnamonpowder	q.s
5.	Honey	q.s
6.	Water	q.s

PROCEDURE

Sugarwasdissolvedinq.sofwatertillasufficient consistencywasobtained.Theplant extractwas filteredandcollectedinanothercontainer.These extractswereaddedtothesugarsyrup,honeywas added.Themixturewasheated withconstant stirring.Thepreparationwasthenremovedfrom heatandwaspouredonalozengemouldtoget lozengesofidealsize.Themouldwasallowedto coolandhardenatroomtemperature.Aftercooling thelozengesweretossedover powdercinnamon toavoidgettingstickyinhumidity.Itwasstoredin awidemouthedairtightcontainerinacoolplace. [11,12]

Evaluation:

organoleptic evaluation: Physicalparameters likecolor,odour, taste,shape,texture etcwere examined byvisualexamination

Phytochemical screening

a)DetectionofGlycosides.
Smallquantityofallextractwashydrolysedwith diluteHClfor2 hoursin a waterbathandthe hydroxylatedwassubjected toLegaltesttodetect thepresenceofdifferentglycosides.
LEGALTEST

Tothehydroxylateextract,1mlofpyridineandfew dropsofsodiumnitroprussidewereaddedandthen itwasmadealkalinewithsodiumhydroxide.Pinkto yellow show the presence of glycosides.

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b)DetectionofAlkaloids

Theallextractswereindividuallydissolved indilute HClandfiltered.

DRAGENDROFF'STEST

To0.5mlofextract,added2mlofHCl.Tothis acidicmedium,1 mlofDrangendroff'sreagentwas added. Anorangeredprecipitateproducing immediately indicatethepresenceofAlkaloids.

WAGNER'STEST

10mlofextract acidified byadding1.5%v/vofHClanda fewdropsofWagner'sreagent.Formationof yellow orbrownprecipitatewillconformthe presenceofAlkaloids.

MAYER'STEST

To1mlofacidicaqueousextractaddedfewdrops ofMayer'sreagent.Formation ofwhiteorpale precipitateshowsthepresenceofAlkaloids.

c)detectionofcarbohydrates:Allextract were individuallydissolvedindistilledwaterandfiltered.

MOLISCH'STEST

2mloftheextractweretreatedwithtwodropsof freshly prepared20%alcoholicsolutionof Alpha naphtholwasaddedandmixed.Tothissolution2ml f)detectionoftannins

FERRICCHLORIDETEST

To,1-2mlofextract,fewdropsof5%aqueousferric chloride solutionwasdeformation of bluishblack colour,whichdisappearsonadditionof fewml diluteH2SO4andformation ofayellowish-brown precipitateindicatesthepresenceoftannins.

LEADACETATETEST

Inthetesttubecontainingabout5mlofextract,afew dropsof1%solutionofladacetatewereadded. Formationof yellowprecipitateindicatesthe presenceoftannins.

f)detectionofphenols

FERRICCHLORIDETEST

To1mlextract, 2mlofdistilledwaterfollowedby dopsof10%aqueousferric chloridesolutionwere added.Formationof blueor greenindicatesthe presenceofphenol.

LEADACETATETEST

ofconcentrated H2SO4wasadded.Formation ofthe redvioletring atthejunction ofthesolution indicatesthepresenceofCarbohydrates.

BENEDICTSTEST

To0.5MLOF extrct,1mlofequalpartsofFehling's AandBwereadded.The contentswereboiledfor fewminutes. Formationofredorbrickred precipitateindicatesthepresenceofcarbohydrates

d)detectionofflavonoids

SHINODA'STEST

1.Asmallquantityoftheextractweredissolved in alcoholandtothisaddmagnesiummetalfollowed byconcentratedHClindropwiseandheated.a magentacolourindicatesthepresenceofflavonoids.

2.small quantityof theextractwas dissolvedin chloroform,addedsmallamount offerricchloride andpotassiumferriccyanide.Adeepbluecolourshowe dthepresenceofflavonoids.

e)detectionofsaponins

FOAMTEST

Extracts wereshaken with2mlofwater,foam produced,anditpersistsfor10minutesindicatesthe presenceofsaponins.

1mlofextractwasdilutedto5mlwithdistilled waterandtothesefewdropsof1%aqueoussolution ofleadacetate wasadded.Formationof yellow precipitateindicatesthepresenceof phenol[11,13,14]

Averageweight:

20Lozenges ofeachbatchwereselected and weighedonanelectronicbalance. Fromthe collectiveweight,averageweightwascalculatedwith± SD.

AverageWeight=Total weight ofLozenges/20

Weightvariation:

Weightvariation wasconductedtoensureeach lozengescontaintheproperamountofdrug.Thetest wasconductedbyweighing 20lozenges individuallybyusing analytical balancethen calculating the averagewt.,andby comparing the individualtabletweighttotheaverage. The percentageofweightvariationiscalculatedbyusing theformula.

%deviation=averagewt.–individualwt/average wtx100

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Theaveragewtoftablet[mg]	Maximum%differenceallowed
130orless	+/-10
130-324	+/-7.5
Morethan324	+/-5.0

Friabilitytest: _

Thefriabilityofthe5Lozengesfromeachbatchwas evaluatedbyafriabilator(Total30Lozengeswere used).Ataspeedof25rpmfor4min.Thelozenges werethendedusted, reweighedandpercentage weightlosswascalculatedbytheequation,

%Friability=(InitialWt.-Wt.afterfriability)×100

Hardnesstest:

Evaluatethediametricalcrushingstrength,3tablets fromeachformulationweretestedusingaPfizer hardnesstester. Themean±SDvalueswere calculated.

Drugcontentuniformity:

Thedrugcontentuniformitywasassessed by powderingonelozengein amortarpestleand dissolvingthepowdercontentin60mlofmethanol ina200mlvolumetricflaskandshaken until completelydissolvedandthenmake upthevolume byusingphosphatebufferofpH6.8.Fromthis10ml wastakeninanothervolumetricflask dilutedwith phosphatebuffer ofpH6.8upto100mland sonicatedfor30 minandthenthesolutionwas filtered,andtheabsorbancewasrecordedat226nm.

Percentmoisturecontent:

Thepreparedlozengeswerecrushedinamortar(3 lozengesofeachbatch)andweighed.Fromeach crushlozenge1gmofsamplewasweighedand placed ona butterpaperandthenplacedinthe desiccatorfor24hours.Afterthat,thesamplewere removedandweighedagain.Theweightreduced wasthencalculatedforthe%moisturecontentby thefollowingformula:

%MoistureContent= Initialweight-Finalweight ×100/Initialweight[15]

In-vitrodissolutionstudy:

InvitrodissolutionwasconductedinUSPXXIV dissolution testapparatus.900mlPhosphatebuffer ofpH6.8solutionwasusedasdissolutionmedium. Thestirrerwas adjustedtorotateat100rpm.The temperatureofdissolutionmediumwasmaintained at37± 0.5°Cthroughouttheexperiment. One lozengewasusedineachtest.5mlofsamplesfrom the dissolutionmedium werewithdrawnby means ofsyringe.The volumewithdrawnateachtime intervalwasreplacedwith freshquantityof dissolutionmediumtomaintainthesinkcondition. SolutionwasfilteredwithWhatmanfilterpaper. Samples werewithdrawnafter5,10,15,20,25,30, 35,45-minuteintervalsoftimeandanalysedfor drugreleasebymeasuringtheabsorbance at226nm [15].Thevolumewithdrawnateachtimeintervalwas replacedwithfreshquantityofdissolutionmedium tomaintainthesinkcondition.[16]

Stabilitystudy:

In thepresentstudy, stabilitystudieswere conductedatRoomTemperatureandAccelerated testing:40°C±2°C/75%RH±5%RHfor3 monthsfortheoptimizedformulation. The optimizedformulationwasanalysedforthePhysical appearance,Drugcontent, DisintegrationTime, average weight,percentfriability,moisturecontent. Theoptimizedformulationwaswrapped in aluminiumfoilforthestudiesandthenkeptinthe testingchamberfor90days andthetestingwas conductedinevery15daysforupto3months.[17]

SURVEY

A surveywasdoneon 10volunteersthrougha questionnairetocheck acceptabilityofdifferent parametersandqualityofthelozengeshavinganti-emeticactivity.

Q1:colouracceptability oflozenges,comment.

Q2:tasteandpalatability,chooseone

a}toosweetb}toobitterc}acceptable

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Q3:howoften doyoufeelmotionsickness

Q4: did you find any relief from taking lozenges?

Q5: did you find it better compared to other marketedlozenges?

Q6: is the duration of action is quick and satisfactory?

Q7:didyoufeeluneasinessaftertakingit?

Q8:ifYES,sitethesame

Q9:isdissolutioninmouthiseasy?

Q10:wouldyouliketorecommendittootheremetic patients?

RESULT

1-ORGANOLEPTICEVALUATION:

Colour:yellowto goldenbrown Odour:

pleasantsmell

Sweet:sweetandpungent

Shape: oval

Texture:hard

2-PHYTOCHEMICALSCREENING

TABLE:2PhytochemicalscreeningofKaempferiagalangaL

SL.NO	TEST	RESULT
1.	Alkaloids	+ve
2.	carbohydrate	+ve
3.	proteins	-ve
4.	Steroidsandtriterpenoids	-ve
5.	glycosides	+ve
6.	saponins	-ve
7.	phenols	+ve
8.	tannins	+ve
9.	flavonoids	-ve

TABLE3:Phytochemicalscreeningofzingiberofficinalis

SL.NO	TEST	RESULT
1.	Alkaloids	+ve
2.	carohydrate	+ve
3.	proteins	-ve
4.	Steroidsandtriterpenoids	+ve
5.	glycosides	-ve
6.	saponins	+ve
7.	phenols	-ve
8.	tannins	-ve
9.	flavonoids	+ve

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TABLE4:Averageweight

SL.NO	INDIVIDUAL WEIGHT[g]	AVERAGE WEIGHT[g]
1.	3.17	
2.	3.26	
3.	3.21	
4.	3.10	
5.	3.49	
6.	3.78	
7.	3.11	
8.	3.24	
9.	3.13	
10.	3.31	
11.	3.25	
12.	3.55	
13.	3.45	
14.	3.16	
15.	3.24	
16.	3.44	
17.	3.97	
18.	3.82	
19.	3.43	
20.	3.22	Avgwt:3.36

TABLE5:Weight variation

SL.NO	INDIVIDUAL WEIGHT	WEIGHTDEVIATION FROM AVERAGE WEIGHT	PERCENTAGE WEIGHTDEVIATION
1.	3.17	-0.19	-5.65
2.	3.26	-0.1	-5.65
3.	3.21	-0.15	-4.46
4.	3.10	-0.26	-7.73
5.	3.49	0.13	3.86
6.	3.78	0.42	12.5
7.	3.11	-0.25	-7.44
8.	3.24	-0.12	-3.57
9.	3.13	-0.23	-6.84

10.	3.31	-0.05	-1.48
11.	3.25	-0.11	-3.27
12.	3.55	0.19	5.65
13.	3.45	0.09	2.67
14.	3.16	-0.20	-5.95
15.	3.24	-0.12	3.57
16.	3.44	0.08	2.38

17.	3.97	0.61	18.15
18.	3.82	0.46	13.69
19.	3.43	0.07	2.08
20.	3.22	-0.14	-4.16

Weightvariation=+5%

TABLE6:Friability

CONTENT	INITIALWEIGHT(gm)	FINALWEIGHT(gm)
lozenges	32.8	31.98

Friabilityof10tablet=differenceininitialweight andfinalweight

=initialweight–finalweight

32.8-31.98=0.82

%friability=differenceinweight/initialweightX100

=0.82/32.8

0.025X100=2.5%W/W

TABLE7:Hardness

SL.NO	HARDNESS(g)		AVG(g)
	INITIAL	FINAL	
1	0	4.4	
2.	0	4.2	
3.	0	4.1	
4.	0	3.9	
5.	0	4.3	4.15
6.	0	4.0	
7.	0	4.3	

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8.	0	4.2
9.	0	4.1
10.	4.0	4.0

Averagehardness=4.15g/cm^3

TABLE8:Surveyreport:Averagescore

SLNO	PARAMETERS	AVERAGE SCORE
1	Colourandacceptability	3
2	Tasteandpalatability	4
3	Easeofdissolution	5
4	Durationofactionandsatisfaction	4
5	Safetyandsterility	4
6	Comparisonwithothermarketedlozenges	4
7	Recommendationtoothermotionsickness patients	3

DISCUSSION

Traditionallytheplants*KaempferiagalangaL, Zingiberofficinalis*hasgotawideapplicationitcan beusedtotreatemesis[motionsickness,morning sickness].
glycosides,tannins,saponins,flavonoids

Theplantswerecollected, identified andextracted usingwaterandthetwoextractweresubjectedto preliminary phytochemicalstudies ofalkaloids, carbohydrates,steroids,proteins

Thephysiochemicalparameterof theherbal lozenges wasalsostudied,andtheresultwas obtained.Asurvey wasalsoconductedvia questionnaireamong10volunteersforcheckingthe anti-emeticproperty oflozenges.Hencethe traditionaluseoftheplantsforantiemeticactivity wasjustifiedbyformulatingitintoanherballozenge

CONCLUSIONS

Thelozengesweredeveloped bythoroughstudyof herbs,followedbyoptimizationof formulation dosageandevaluationofqualitativeandquantitative analysisbyprécisedadvanced analytical instrumentalmethodsforassessment.

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