Research Article
CODEN (USA): IJPLCP

ISSN: 0976-7126
Sharma *et al.*, 11(12):7148-7152, 2020

International Journal of Pharmacy & Life Sciences
Open Access to Researcher

Formulation and Evaluation of Medicated Jelly of Niacin

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Article info

Received: 06/11/2020

Revised: 26/11/2020

Accepted: 24/12/2020

www.ijplsjournal.com

Abstract

In pharmaceutical technologists have developed a novel oral dosage form known as Oral medicated jellies which disintegrate rapidly in saliva, usually in a matter of seconds, without the need of water. Drug dissolution and absorption as well as onset of clinical effect and drug conventional dosage forms bioavailability may be significantly greater than those observed from. The present investigation is focused to develop the elegant, acceptable, stable oral medicated jelly. Oral medicated jellies have widely accepted by patient as it has significant impact on the patient compliance. Oral medicated jellies are appreciated by a significant segment of populations particularly who have difficulty in swallowing. It has been reported that Dysphasia (difficulty in swallowing) is common among all age groups and more specific with pediatric, geriatric population along with institutionalized patients, psychiatric patients and patients with nausea, vomiting, and motion sickness complications. Dysphasia is observed in the general population, as well the elderly patient. Oral medicated jelly provide a better acceptability among the population with less side effect and provide good taste and flavor increase the acceptability of bitter drugs by various groups of population.

Keywords: Medicated jelly, Dysphasia, Niacin, Bioavailability, Oral Route, Patient Compliance, Gelling agents

Introduction

Development of novel drug delivery techniques that minimize toxicity and improve efficacy offers prospective benefits to patients and opens new avenues for pharmaceutical companies. Patient compliant dosage forms show beneficial over conventional ones, especially if the drug delivery problems of pediatric, geriatric and dysphagic patients are addressed. Although the spectrum of dosage forms available to these patients; such as syrups, suspensions, chewable tablets, dispersible tablets and powders for reconstitution; many questions and expectations are still to be addressed such as stability, dosage wastage, improper measurement, reconstitution, dose dumping, ease of administration, patient non acceptance and so on. Therefore, there is a scope for more patient-friendly delivery systems which involve easy administrative methods, especially by oral route. Pediatrics patient compliance with convenient administration and more palatable and elegant dosage forms are gaining significant importance in the design of novel drug delivery systems. [1-3]

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The oral route of drug administration is the most common and preferred route for drug delivery due to convenience and ease of ingestion Oral medicated jelly are tasteful strong dose shapes managed in the oral pit, intended to be broken down in mouth or pharynx for its nearby or fundamental impact. Oral medicated jelly gives a few points of interest as pharmaceutical details anyway with certain detriments. Oral cured jelly as a dose structure can be received for medication conveyance crosswise over buccal course, labial course, gingival course and sublingual course. Numerous medications can likewise be fused in them for incessant disease medicines.

Jellies are semisolid to thick viscous fluids which is easily taken by patients of advanced age and patients with dysphasia. Moreover jelly formulation with solidity appropriate for swallowing and with good texture which is suitable for improvement of patient compliance. The jelly dosage form can be swallowed easily without water and are soft and smooth. Inconvenience of administration and patient compliance are gaining significant importance in the design of dosage forms. So the present investigation is focused to develop the elegant, acceptable, stable oral medicated jelly

Medicated Jelly has been very well received by the parents for their use in children with full dentition. Children in particular may consider chewing gum as a more preferred method of drug administration compared with oral liquids and tablets. The use of Medicated Jelly is feasible in local treatment of diseases of oral cavity as well as treatment of systemic conditions. Jellies are transparent or translucent, non-greasy, semisolid preparation generally applied internally as well as externally. They are used for medication, lubrication and some miscellaneous applications. [5-7]

A number of jelly products have been developed that aim to improve compliance by aiding swallowing. Gelling agents usually employed are tragacanth, sodium alginate, pectin, starch, gelatin; cellulose derivative such as hydroxypropyl methyl cellulose, methylcellulose, carbomers, polyvinyl pyrrolidone and polyvinyl alcohol at different concentrations using various additives. Commercial oral jelly formulations of calcium gluconate, amlodipine, acyclovir, alendronate, donepezil hydrochloride, sildenafil and tadalafil are available in some countries, but scarcely any products found in those patients who really need them.

Classification of Jelly [8]

Medicated jelly: These types of jellies contain sufficient water which are mostly used on skin and mucous membrane for their local anaesthetics, and antiseptic properties.

Lubricating jelly: These types of jellies are used for lubrication of diagnostic equipment such as surgical gloves, cystoscopes, catheters, etc.

Miscellaneous jelly: These are meant for different purposes like- electrocardiography, patch testing, etc.

Niacin drug is very useful in treatment of various forms of hyperlipidemia. It is belonging to the vitamin B category which full fill the daily requirement of vitamin supplement. Many therapeutic agents are absorbed in the oral cavity. For the drugs having significant buccal absorption, dosage forms such as Medicated Jelly and Chewing Gums permit more rapid therapeutic action as compared to oral dosage forms. [9]

Materials and Methods

Materials

Niacin was a gift from modern laboratories Pvt Ltd. Pectin, guar gum Peg 400, and cremophore rh-400 citric acid methyl paraben provided by the institution. All solvents used in the experiment are of analytical grade.

Preparation of medicated jelly [10]

Oral medicated jelly is prepared by heating and congealing method**.**

Evaluation Parameters [13-15]

Physical appearance: Physical examinations are important regarding patient compliance and acceptance. The prepared jellies were examined visually for color, texture, clarity and consistency.

Stickiness and grittiness: Stickiness and grittiness should be examined by visual inspections of the formulations by slowly rubbing the jelly sample by two fingers.

pH: The pH of the jellies were examined using digital pH meter at room temperature. For this, 0.5 g of jelly should mix in 50 ml of distilled water to make 1% solution and the pH was noted.

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Pourability of the mixture: The jelly formulation mixture should be easily pourable in the moulds.

Viscosity study: Viscosity of jelly was carried out using Brookfield viscometer in which the system is non-Newtonian spindle should be used. It was measured for fixed time 5 min at 50 rpm at 25C°±5C.

Content uniformity

At first, jelly from the each formulation were taken, crushed and mixed. Drug equivalent of mixture was extracted by suitable media from the mixture. The absorbance of each solution should measure by UV-visible spectrophotometer at suitable wavelength or the quantity of drug contain in each extract was examined using suitable analytical method. This test is to ensure that each dosage forms contains equal amount of drug substances i.e. active pharmaceutical ingredients within the batch.

In- Spreadability

Jelly (1.5 g) was placed between 2 glass slides and compressed to proper thickness by keeping 1000 gm weight for 5 minutes for the determination of Spreadability. The time in second needed to separate 2 slides were taken for the measure of Spreadability. Less time interval is required to cover the distance of 7.5 cm shown better Spreadability.

$$S = W \times L/T$$

Where, S = Spreadability, W = weight tide to upper slide, L= length of glass slide (7.5cm), T= time required to separate 2 slides.

Syneresis

It is the separation of water from the gel and contraction of the gel upon storage. If limited concentration of gelling agent should employed then it is more prominent in the gels. All the jellies were observed for signs of syneresis at room temp (25°C ± 5°C) and 8°C ± 1°C. The formulations showing signs of syneresis were refused and not selected for further studies.

In *Vitro* dissolution study:

The USP paddle type apparatus used for in-vitro dissolution study by using dissolution medium (900ml) was kept at 37°C ± 0.5C and 50 rpm. 10 ml of sample should withdrawn and diluted up to 10 ml in volumetric flask with same and 10 ml sample withdrawn after 10, 20, 30, 40, 50, 60 min and sink condition is maintained by replacing with fresh media. The sample was determined for the drug content using UV-spectrophotometer or by suitable analytical method. Then % drug release was calculated after absorbance was taken.

Results and Discussion

Evaluation Parameter of Medicated Jelly [16-18]

Physical Examination

The medicated jelly examined physically for appearance like texture, transparency and consistency.

Table 1: Evaluation parameters of Prepared Jellies

Batch No.	Appearance	Consistency	Texture
F1	Light yellowish	Slightly thick	Slightly Sticky
F2	Yellow	Slightly thick	Slightly Sticky
F3	Light yellowish	Acceptable	Non Sticky
F4	Light yellowish	Acceptable	Non Sticky
F5	Yellow	Thick	Slightly Sticky

Stickiness and Grittiness

Grittiness is determined by rubbing the jelly between fingers.

Determination of pH

The pH of jelly was measured using Digital pH meter at room temperature. For this purpose, 0.5 gm of jelly was dispersed in 50 mL of distilled water to make 1% solution, and the pH was noted. The standard pH of the jelly was 6.8±0.05.

Table 2: Determination of pH of medicated Jelly

Batch No.	pH of jelly Observed
F1	6.6±0.05
F2	6.4±0.05
F3	6.7±0.05
F4	6.5±0.05
F5	6.8±0.05

Viscosity

Viscosity of jelly was measured by Brookfield viscometer using spindle DV-E-64.It was measured for the fixed time 5 minutes at the rotation of 50 RPM at room temperature (25ºC ± 5ºC).Viscosity observed in(dyne sec/cm^2)

ISSN: 0976-7126
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Table 3: Determination of Viscosity

Batch No.	Viscosity of jelly Observed (CPS)
F1	5831±40
F2	8047±40
F3	6844±40
F4	8219±40
F5	7809±40

Syneresis

Syneresis is defined as contraction & separation of water from the gel upon storage. One of the major causes for it is using lesser concentration of gelling agent. Low acylated guar gum gels are mostly prone to syneresis. It was observed after 24 h of jelly preparation. Syneresis was not noticed at room temperature probably due to binding of free water by co solute. In the preformulation studies, jellies containing guar gum and pectin combination did not show syneresis. Hence, in order to reduce syneresis of guar gum jellies, pectin was used as co solute.

Table 4: Evaluation of Syneresis of jelly

Batch No.	Room temperature	Cool Temperature
	25±5°C	**8±1°C**
F1	-	-
F2	-	-
F3	-	-
F4	-	+
F5	-	-

Weight Variation

Twenty Medicated jelly were selected and weighed individually. Average weight was calculated and the individual weights were compared with the average weight.

Table 5: Determination of wt. Variation of medicated Jelly

Batch No.	Average wt. of Jelly	Individual wt. of jelly
F1	1.5gm	1.536 gm
F2		1.556 gm
F3		1.526 gm
F4		1.556 gm
F5		1.566 gm

Drug Content

Ten medicated jelly are selected & crushed in a mortar & then mixture equivalent to that of drug was taken & dissolved in 100 ml of volumetric flask containing 6.8 pH buffer & the final volume was made up to the mark. Then the solution was filtered & diluted appropriately, and analyzed at λ max 254 by spectrophotometrically technique using UV-visible double-beam spectrophotometer.

Table 6: Determination of drug Content

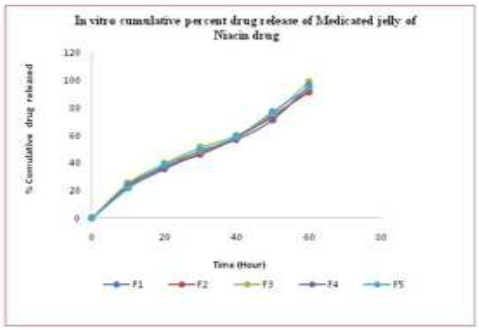
Batch No.	Result of jelly Observed
F1	95.2%±0.5
F2	96.5%±0.5
F3	98.4%±0.5
F4	97.2%±0.5
F5	94.7%±0.5

In-vitro Dissolution study of jelly

The USP paddle type apparatus used for in-vitro dissolution study by using dissolution medium (900ml) was kept at 37.0 C ± 0.5°C and 50 rpm. 10 ml of sample should withdrawn and replace with same media and sample withdrawn after 10, 20, 30, 40, 50, 60 min and sink condition is maintained by replacing with fresh media. The sample was determined for the drug content using UV-spectrophotometer or by suitable analytical method. Then % drug release was calculated after absorbance was taken.

Table 6: Determination of drug Content

Time (mins)	F1	F2	F3	F4	F5
0	0	0	0	0	0
10	22.6± 0.33	24.1± 0.82	25.3± 0.36	23.2± 0.33	21.8± 0.75
20	35.7± 0.29	37.3± 0.62	39.5± 0.14	36.3± 0.47	38.5± 0.30
30	47.5± 0.29	46.1± 0.64	51.3± 0.68	49.2± 0.01	48.8± 0.31
40	59.0± 0.13	58.1± 0.21	60.0± 0.25	57.0± 0.22	58.9± 0.29
50	73.0± 0.11	74.4± 0.24	75.9± 2.05	71.2± 0.63	76.9± 0.28
60	93±0. 71	91.0± 0.14	98.9± 0.96	95.8± 0.48	94.6± 0.21



Conclusion

Niacin or nicotinic acid in low concentrations is used to treat B3 vitamin deficiency and in higher concentrations used in the treatment of hyperlipidemia. In the present study, the jellies with Niacin were successfully formulated using pectin, guar gum as gelling agents. The optimized formulations showed acceptable physico-chemical properties and stability. Formulations F3 could be effectively employed for oral delivery for pediatric, geriatric and dysphasic patients as alternatives to solid oral dosage forms

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Cite this article as:
Sharma M.., Joshi A., Koshta A., Malviya S. and Kharia A. (2020). Formulation and Evaluation of Medicated Jelly of Niacin, *Int. J. of Pharm. & Life Sci.*, 11(12): 7148-7152.
Source of Support: Nil
Conflict of Interest: Not declared
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