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Oral Medication- Infused Jelly as A Developing Platform

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Abstract

A developing medicine administration method called oral medicated jelly was created to increase patient compliance, particularly in groups like juvenile, elderly, and dysphagic patients who have trouble swallowing pills or capsules. This innovative formulation can improve patient adherence and therapeutic efficacy by providing a tasty, easily swallowed substitute. Medicated jelly formulations allow for the inclusion of a variety of active pharmaceutical ingredients (APIs), including those with limited water solubility, can conceal disagreeable medication tastes, and offer flexibility in dose administration. In order to guarantee controlled release, enhance bioavailability, and stable APIs inside a semi-solid matrix, recent developments have concentrated on refining the jelly composition. Innovative processing methods combined with the use of natural and synthetic polymers allow for the customization of jelly qualities to satisfy therapeutic requirements. This analysis examines the benefits, difficulties, and prospects. Oral medicated jellies are a flexible drug delivery method that can be used in a variety of therapeutic contexts.

Keywords – Oral medicated jelly, gelling agent, paediatric formulation, dysphagia, hypertension.

INTRODUCTION

The tasty oral medicated jellies are a solid type that is given in the mouth and is meant to dissolve either in throat or mouth for a local or systemic effect. Because oral drug delivery is noninvasive and typically provides inexpensive treatment costs, patients are generally at ease using it. Additionally, the oral drug delivery system's cost-efficiency, safety, and effectiveness improve patient compliance. Natural gums like tragacanth, pectin, and sodium alginate, as well as synthetic derivatives like methyl cellulose and sodium carboxy methyl cellulose, can be used to make jellies. Everyone loves jelly over oral fluids or tablets because they are visually appealing, taste well, and are simple to manage.

The need for the creation of oral medicated jellies (OMJs) has grown dramatically over the past ten years due to its substantial influence on patient compliance. Many members of the population, particularly those who have swallowing difficulties like oral medicinal jellies. It has been noted that dysphasia, or trouble swallowing, is prevalent in people of all ages and groups, but it is more prevalent in young people, the elderly, institutionalized patients, and those who have motion sickness, discomfort, or feeling queasy. Across all age groups, dysphasia is prevalent and affects over up to 60% of the senior population and 35% of the general population living in institutions, and 18–22% of all individuals in extended care institutions. Several demographic groups find bitter drugs more acceptable when OMJs have a pleasant taste and flavour. As a medicine delivery method, medicated jelly has grown in popularity over the years. "Jelly can be defined as transparent or translucent non-greasy, semisolid preparation meant for external as well as internal applications." Today, medicinal jelly contains a number of other ingredients. For instance, a medication that needs to start working quickly and whose main sites of absorption both the stomach and small intestine.

Natural gums such as tragacanth, pectin, and alginate of sodium can be used to make them, or synthetic versions of natural substances like sodium carboxymethylcellulose and methylcellulose can be used. Compared to oral medicine administration, children may prefer jelly as a drug delivery route as opposed to oral fluid or pill administration. The application of medicinal jelly is viable for both systematically and locally therapy of the mouth diseases. Jellies have enough water in them jelly with water provides an effect of local cooling after evaporation, and the leftover film offers protection. To stop nose bleeding, for instance, the usage of ephedrine sulphate jelly as a vasoconstrictor. To set oral medicated jellies apart from more typical dose forms, they should have certain desired qualities. Among the key benefits of these dosage forms is that they don't need water to swallow, however after just a few seconds, they melt or disintegrate in the mouth. [1,2,3,4]

Figure 1: *Jellies*

Goal of oral medicated jellies

To create a preparation with a local or systemic impact that dissolves in the pharynx's mouth.
In order to improve patient compliance.
Medicated jelly that contains a poorly soluble medication.
Designing a chipper dose form instead of a traditional one.[5]

Types of Jelly

Oral medicated jellies (OMJs)

It has been discovered that oral medication jelly is the best option for patients with psychiatric conditions as well as those with motion sickness, nausea, vomiting, Parkinson's disease, thyroid disorders, strokes, and multiple sclerosis. OMJs are now the only FDA-approved, quickly- dissolving dosage form that is included in Approved Drug Products with Therapeutic Equivalency Evaluations, often known as the Orange Book. Chewable pills are not the same as the new OMJs, despite being on the market for a while. Patients who experience difficulty or pain when chewing can easily take these innovative tablets.

OMJs release the medication as well as pregastric (the mouth, throat and esophagus) gastric (the stomach) and post-gastric. (The small and large intestines) portions of the gastrointestinal system. In the mouth and are absorbed through local oral mucosal tissues. Children who have lost their primary teeth yet are still unable to fully utilize their permanent teeth will find OMJ's especially helpful. [6,7,8]

History of OMJs

More than half of patients prefer OMJs over other dosage forms, and most consumers would ask their doctors for them (70%) purchase them (70%) prefer OMJs over regular tablets or liquids. According to current market research. These responses may be partially explained by well-known advantages of OMJs, namely it's ease of use in benefits such simplicity in dosage, simplicity in ingesting, flavour variety, and pleasant taste.

OMJs also provide expanded indications and other clinical benefits such increased safety and, occasionally, effectiveness. The commercialization of new goods and the development of new technologies at OMJ are also motivated by a number of business requirements, including the need for prolonged patent life, enhanced life-cycle management, expanded product lines, and competitive marketing. [9,10]

Kinds of medicated jelly

Three varieties of jellies are available.

Topical / Therapeutic jelly

Because of their spermicidal, local anaesthetic, and antiseptic qualities, they are applied to skin and mucous membranes. There is plenty of water in these jelly beans. After the water evaporates, the leftover layer offers protection and jelly beans offer a localized cooling effect. This Medicinal film typically sticks firmly and provides protection, but when the treatment is over, it can be simply washed off. As an illustration, ephedrine sulphate jelly stops nose bleeding by acting as a vasoconstrictor.

One spermicidal contraceptive option is phenyl mercuric nitrate.[11]

Lubricating jelly

Before use, lubrication is necessary for catheters, electrodiagnostic devices like cystoscopes, finger barriers and rubber gloves for rectal and other exams. When inserting items into the body's sterile regions, like the bladder the lubricants used need to required sterilized. A local anaesthetic such as lignocaine gel B. P. C., may be used for uncomfortable tests.[12]

Miscellaneous jelly

Patch testing

These are meant for use in a number of applications, such as ECG and patch testing.

Patch testing: In this instance, allergens are administered to the skin using jelly to measure sensitivity. One individual may be exposed to multiple allergies. The testing aids in maintaining the particle separation.

Electro cardiography: An electrode jelly may be administered in order to reduce the electrical resistance that exist between patients' skin or the cardiac monitor electrodes. This contains pumice powder, when applied to topically eliminates portions of the epidermis horny layer, the major layer of electrical resistance, and sodium chloride (NaCl) to ensure good conductivity. [13,14,15]

Ideal characteristics of OMJs

OMJS should have a few desirable qualities to set them apart from more conventional dose forms. Among these dosage types' important and desired qualities are in just few seconds, it should melt in mouth, but swallowing does not require water.

After oral administration, ODT should leave the mouth with minimal to no residue or have a pleasant mouthfeel. Work well with flavour masking.

Work well with flavour masking.

Drugs with a bitter taste should use efficient taste masking technology.

Be movable without worrying about fragility.

When taken orally, leave very little to no residue in the mouth.

Show minimal response to changes in temperature and humidity during the day

Permit heavy drug loading.

Flexible and compatible with standard processing and packaging machinery at a reasonable cost.

The oral disintegrating tablet shouldn't be impacted by the properties of the medicine or excipient. [16,17]

Advantages of OMJs

Faster onset of action.

Convenience and portability.

Ease of absorption.

Taste masking.
OMJs pleasant mouthfeel contributes to altering how people view medicine.
Lower chance of choking.
Accuracy of dosage.
Ideal for trips where there might not be access to water.
Traditional manufacturing machinery.
If necessary, the course of treatment may be stopped at any moment.
Economical. [18,19]

Disadvantages of OMJs

Problems with stability.
It could result in an unpleasant flavour if not properly prepared.
The property of fragile, effervescent granules is also demonstrated.
Standard blister packets don't provide any physical resistance.
Oral medicated jelly must be kept in a dry place because it is hygroscopic.
Unique packing is necessary to ensure the stability and safety of the stable product.[20]

Oral mucosa

It refers to the mucosa, epithelium, lamina propria, and submucosa, which are the soft tissue linings of the mouth. The oral cavity's entire area is approximately 100 cm^2, and saliva continuously washes the oral mucosal surface (around 0.5–2 L per day).Salivary pH varies with flow rate, ranging from 5.6 to 7.9.

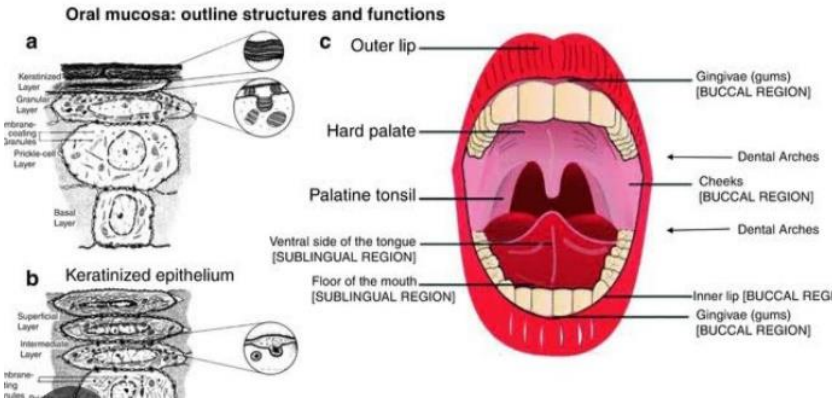

Figure 2*: *Oral cavity

Function of mucosa of mouth

Segregation of permeability.
Sensation
Temperature regulation.
Absorption.
Safety.[21]

Criteria for choosing drugs for formulation

Capacity to penetrate the mucosal of the mouth.
The molecular rate is small to moderate.
At the partially non-ionized oral cavity pH.
Drugs are administered at low doses, ideally less than mg.
The medication should be stable in both water and saliva.
Medicated jellies shouldn't contain medications with short half-lives or frequent dosages.
Drugs with extremely unpleasant or bitter tastes and odours are not appropriate for these preparations.

Be able to permeate and divide into the upper gastrointestinal tract's epithelium.[22]

Patient Factors

For patients who locate it difficult to ingest conventional pills and capsules with eight ounces of water, oral disintegrating dose forms are especially appropriate. These consist of the following:

A patient who has ongoing nausea who could be traveling or who doesn't have easy access to water

Children and elderly individuals who have trouble chewing or swallowing solid dose forms.

Older adults' people who might not being able to ingest an antidepressant on a daily basis.

An eight-year-old allergic child who wants a dosage form that is easier to take than antihistamine syrup.

Patients who are afraid of choking and refuse to consume solid preparation.[23]

Challenging in formulating OMJs

Palatability

For formulation specialist, hiding the bitterness of the drugs used to make oral medicated jellies is a difficult task. Dissolving oral medication delivery method often contain the drug in a flavor -masked form due to the fact most medications are not appetizing. As a result, patient compliance depends on the medications' ability to disguise taste.

Hygroscopicity/Moisture sensitivity

A number of oral jelly dose they are hygroscopic, meaning they Become less physically stable in typically humidity and temperature ranges. As a result, they, therefore need to be protected from dampness. necessitating the use of specific product packaging.[24]

Dosage / Quantity of drug

The quantity of medication that can be incorporated into every dosage unit. restricts the use of OMJ technology. The creation of fast dissolving dosage forms is hampered by molecules that require high doses mostly because of three factors: a) the active ingredient's flavor is masking; b) mouth sensation; and c) jelly size. [25]

Water solubility

Water-soluble medications present a variety of formulation difficulties because of production of eutectic mixtures, which lower the freezing temperatures and produce a opaque substances that may crumble when dried because of sublimation process loss of structure that support it. Occasionally, this kind of collapse can be avoided by employing different jelly-forming excipients, like almond gum, which can cause crystallinity and give the amorphous composite stiffness.

The size of jelly's

The jelly's size determines how easy it is to take. According to reports, jelly larger than 8 mm was the simplest to manage, while 78 mm was the simplest to swallow. It is therefore difficult to get a jelly that is both manageable and simple to take.[26]

The medication characteristics

The performance of jellies might impact by a variety of pharmacological features. For instance, a medication solubility, crystal structure, particle size, and bulk density can all have an impact on the final jelly's power and dissolve ability.

Mouth Sensation

In mouth, the OMJs shouldn't break up into bigger pieces. The particles produced following the OMJ's disintegration ought to be as small as practical. After oral administration OMJ should leave little to no residue in the mouth. Additionally, the mouthfeel is enhanced by the addition of tastes and cooling substances like menthol.[27]

Environmental Sensitivity

When assessing the sensitivity of jelly (such as fruit or Gelatin-based jelly) to environmental conditions, the goal is to understand how factors like temperature, humidity, and light impact its texture, flavour, colour, and shelf stability.

Formulation parameters

Name of ingredients	Examples
Gelling agent	Tragacanth, Gelatin, sodium alginate, agar
Sweeteners	Sucrose, Dextrose, Saccharin
Colouring agent	Beta carotene, Lyeopene
Flavouring agent	Cherry, Lemon, Vanilla, Orange.
Preservative	Citric acid, Methylparaben, Benzoic acid.
Stabilizer	Sorbitol, Propylene Glycol

Table1: *Ingredients used in the preparation of jelly*

Medication group	Examples
Anti-helminthic	Albendazole and mebendazole.
Anti-histamine	Citrizine and cinnarizine.
Analgesic	Ibuprofen and paracetamol.
Anti-emetic	Domperidone and ondansetron.
Anti-diabetic	Metformin and glibenclamide.
Leukotriene antagonist	Montelukast

Table 2: *Active ingredients in oral jellies*

Preparation method of jellies

All Ingredients will be weighed accurately.

Jellies were made using the congealing and heating process.

Add with distilled water that has been freshly boiled and chilled accordance with the prescribed composition.

Water is heated with stirring for approximately 90 minutes at 80 degrees Celsius to prepare sucrose syrup.

Throughout the preparation ,10 millilitres water containing weighed polymer powder was kept at 90 degrees Celsius

Kept for 20 minutes, a mixture was agitated using a stirrer that is magnetic to help the gelling agent hydrate.

The drug was transferred to different beaker and dissolved with alcoholic beverages.

It was included on simple syrup while being continuously stirred.

Add Preservatives and citric acid were continuously added at 60 degrees Celsius.

To create a jelly-like texture, purified water was used to modify the final weight, combined, moved to after being sealed, the molds cool to ambient temperature (250 ± 50 c).

Once the jelly has solidified, it is finally wrapped with paper made of gelatine and kept for dry.[28]

Evaluation Test for Jelly

Physical Appearance

Physical characteristics of a mediational jelly, such as its texture, transparency, consistency, gumminess, and grittiness, will be assessed. Rub the jelly between your fingers to judge its grittiness. The oral jelly was also tested for things like color, odour, and clarity.[29]

Viscosity

The Brookfield viscometer was used to test viscosity. Since the system is not Newtonian, spindle number four was employed. The viscosity formula is as follows

Viscosity in centipoise = Dial reading x factor.[30]

pH measurement

A pH determination test for oral medicated jelly is essential to assess the product's acidity or alkalinity, which can affect its stability, taste, and compatibility with the body.

Spreadability

To measure how easily the jelly spreads, affecting usability and consumer experience. Apply a standard weight or force to a known amount of jelly on a smooth plate and measure the spread diameter. A larger diameter indicates higher spreadability.[31]

Drug content

The primary goal of a drug content test is to ensure that each dose of a pharmaceutical product contains the specified amount of the active ingredient, as stated on the product label. This test is essential for quality control, consistency, safety, and efficacy.[32]

Stickiness and Grittiness

The jelly is rubbed between two fingers to determine its stickiness and grittiness, which are then visually assessed.

Weight variation

It is calculated by weighing ten jellies on average after they are removed from molds, weighed separately, then combined in a beaker.

Syneresis

Syneresis refers to the expulsion of liquid from a gel or jelly, which occurs when the gel structure contracts, leading to separation of the liquid phase. In the case of oral medicated jelly, syneresis can affect the product's appearance, texture, and the uniformity of the active ingredient, potentially impacting patient acceptance and the correct dosage. The goal of the syneresis test is to determine the extent of liquid separation from the jelly, which could indicate instability or poor formulation quality.

Microbial studies

The microbiological profile of jellies can be ascertained with the help of these research. Because jellies include water, they are more vulnerable to microbial development. The jellies' ability to cultivate pathogens on particular media for P. aeruginosa, S. aureus, and E. coli was examined.

In-vitro dissolution study

Using an appropriate dissolution medium and USP basket apparatus, an in-vitro dissolution investigation will be conducted. The goal of in-vitro study to evaluate the release profile of the active ingredient from the oral medicated jelly to ensure consistent and predictable drug delivery in vivo, allowing for appropriate dosing and therapeutic effectiveness.

Stability studies

The prepared jelly can be used to assess stability studies, which are determined in accordance with ICH recommendations. For 90 days, the jelly formulations are kept in polyethylene containers at 0°C, 25°C, and 60% relative humidity after being wrapped in aluminium foil.[33]

CONCLUSION

The development of oral medication-infused jelly provides a promising alternative to traditional oral dosage forms. Its distinct features, such as ease of use, improved taste, and suitability for individuals with swallowing difficulties (e.g., children and the elderly), make it a versatile option in modern medicine. The jelly's soft texture and ability to mask unpleasant tastes and odours enhance its appeal over tablets or capsules. From a formulation standpoint, incorporating hydrophilic polymers and gelling agents ensures uniform drug distribution and controlled release, leading to better bioavailability and therapeutic outcomes. The jelly's viscosity, flavour, and nutritional profile can be customized to meet specific patient needs, including those with dietary restrictions.

Additionally, this platform can accommodate various drug types, from water-soluble to fat-soluble compounds, and supports both immediate and sustained release options. Evidence from clinical studies and market trends highlights the potential of medication-infused jelly to improve patient compliance by addressing challenges such as swallowing difficulties, bad taste, and complicated dosing routines. Its convenience and portability also make it suitable for outpatient care and on-the-go use.

REFERENCES

1. Darade A.D, Mundada A.S, Oral Medicated Jellies as An Emerging Platform for Oral Drug Delivery in Paediatrics, World Journal of Pharmacy, 2021:10(6):1628- 1647.
2. Bhalerao K, Gambhire S., SinghS, Taste Masking to Improve Compliance, International Research Journal of Pharmaceutical and Applied Sciences, 2013:3(5): 224-237.
3. Sarojini S, Anusha K, ManeeshaC, Mufaquam M.A, Deepika B., Krishna Y, Oral Medicated Jellies, World Journal of Pharmacy, 2018:7(6): 352-365.
4. Raja Manali M., Dhiren P, Oral Medicated Jelly a Recent Advancement in Formulation, International Journal of Pharmaceutical Sciences, 2016: 7(2):13- 20.
5. Yadav C Tangri S., Yadav R, A Review Recent Advancement in Formulation of Oral Medicated Jelly, World Journal of Pharmaceutical Science,2018:7(7): 417- 426.
6. Pophalkar P.B, Wakade R.B, Hole S.U, Kadam C.Y, Suroshe R.S., Panchale W.A, Development and Evaluation of Ondansetron Medicated Jelly, World Journal of Pharmaceutical Research, 2018:7(19): 1252-1263.
7. Anitha M, GowthamR, HarishkumarS, Raksha C.R, Vineesh D, Nidamanuri B.S.S., Jawahar N, Pharmaceutical Oral Jellies-An Overview, Journal of Pharmaceutical Sciences and Research,2022: 14(6):763-768.
8. Prabhu S., Betageri G.V, Semisolid Preparations in Encyclopedia of Pharmaceutical Science and Technology,2013: 5(6): 3144-3159
9. Rathod H.J., Mehta D.P, A Review on Pharmaceutical Gel, International Journal of Pharmaceutical Sciences, 2015 :1(1):33-47.
10. Taranum R., Mittapally S, Soft Chewable Drug Delivery System, Oral Medicated Jelly and Soft Chewable, Journal of Drug Delivery and Therapeutics, 2018 :8(4):65-72.
11. Smola M, Vandamme T, Taste Masking of Unpleasant Oral Drugs, Drug Delivery Research Advances, Nova Science Publishers, New York, 2018 :10(4)117- 152.
12. Kim K.H, Jun M, Lee M.K, Bioavailability of the Common Cold Medicines in Jellies for Oral Administration Journal of Pharmaceutics,2020: 12(11):1073-1075.
13. Doolaanea A.A., Bahari A.Z.B.S, Advantages of Jelly Over Liquid Formulations for Pediatrics, Journal of Formulation Science & Bioavailability, 2017:1(6):102-103.
14. Cardoz M.R., Ravikumar P, Design Development and Evaluation of Novel Oral Medicated Jellies, American Journal of Pharmaceutical Sciences,2017: 4(6):1746-1754.
15. Godhwani T, Chhajed M, Chajed A, Tiwari D, Formulation Development and Evaluation of Unit MouldedSemisolid Jelly for Oral Administration as a Calcium Supplement, World Journal of Pharmaceutical Research, 2017: 1(3): 629-635.
16. Gade S, A Review Article on Oral Jellies for PediatricsAsian, Journal of Pharmacy and Technology,2020: 10(3):207-212.
17. Kaur G, Gananarajan G, A Review Article on Oral Jellies for Pediatrics Indo, American Journal of Pharmaceuticals Sciences, 2018: 5(1):444-452.
18. Kulkarni S, Londhe V, Oral Jelly of Metformin Hydrochloride Formulation Development Using Design of Experiments and Characterization, Journal of Drug Delivery Science and Technology, 2021:63:1025-1028.

19. Sharma D, Kumar, D, Singh G, Recent Developments in Medicated Lozenges, A Promising Dosage Form for the Effective Delivery of Therapeutic Agents Drug Delivery Letters, 2021:11(2): 97-109.
20. Dosani M.A, Sakarkar D.M, Kosalge, S.B, Sheikh Shafiq, S.S, Formulation Development and Evaluation of Unit Moulded Herbal Semisolid Jelly Useful in Treatment of Mouth Ulcer,2011:1(6):230-235.
21. A Satyanarayana D, K Kulkarni P, G Shivakumar, H, Gels and Jellies as A Dosage Form for Dysphagia Patients A Review Current Drug Therapy, A Journal of Current Drug Therapy, 2011:6(2):79-86.
22. Singla A.K, Chawla, M, Singh, A Potential Applications of Carbomer in Oral Mucoadhesive Controlled Drug Delivery System Journal of Drug Development and Industrial Pharmacy, 2000:26(9): 913-924.
23. Hooda R, Tripathi M, Kapoor K, A Review on Oral Mucosal Drug Delivery System the Pharma Innovation, Journal of Drug Development and Industrial Pharmacy, 2012:1(1):250-255.
24. Singla A.K, Chawla., Singh, A Potential Applications of Carbomer in Oral Mucoadhesive Controlled Drug Delivery System a Journal of Drug Development and Industrial pharmacy, 2000:26(9):913-924.
25. Smart J.D, Lectin-mediated Drug Delivery in the Oral Cavity Journal of Advanced Drug Delivery,2004: 56(4):481-489.
26. Sunil S, Sharma K., Arathy S.A, Pharmaceutical Jellies A novel way of Drug Delivery, Journal of Pharmaceutical Sciences and Research, 2020:12(7):904- 909.
27. Salunke T, Mayee R, Formulation and Evaluation of Medicated Jelly of Bitter Drugs, Internatinal Journal of Pharmacy Innovation ,2013:3(5): 1-4.
28. Islam M.S, Mojumder, T. J, Nawrin F, Development and Characterization of Palonosetron Hydrochloride Jellies, Universal Journal of Pharmaceutical Research, 2023:1(5):232-245.
29. Harshada A. Gavali, Nida N. Mulla, Sanjay K. Bais, Formulation and Evolution of Anti-Acne Herbal Face Pack by Using Red Lentils and Bael Leaves, International Journal of Pharmacy and Herbal Technology,2024:2(3): 1973-1974.
30. Yashraj D. Ghadage, Shubhada S. Pawar, Sanjay K. Bais, Formulation and Evaluation of Herbal Cough Syrup, International Journal of Pharmacy and Herbal Technology, 2024:2(3):2153-2154.
31. Pratiksha P. Shinde, Nida N. Mulla, Sanjay K. Bais, Formulation and Evaluation of Polyherbal Cold Cream by Using Turmeric, Aloe Vera and Vitamin E Capsule, International Journal of Pharmacy and Herbal Technology, 2024: 2(3):2271-2285.
32. Begum S.A, Sree, V. P, Anusha, V, Veronica Z.K, Sree, P.V, Prameela, K, Nazeema, M.D, Padmalatha, K, Formulation and Evaluation of Pediatric Oral Soft Jellies of Salbutamol Sulphate, Research Journal of Pharmacy and Technology,2018 :11(11): 4939-4945.
33. Sankar V, Hearnden V. Hull K, Juras DV, Greenberg M, Kerr AR, Lockhart PB,Sastry SV, Atenolol Gastrointestinal Therapeutic System Screening of Formulation Variables Journal of Drug Development Industrial Pharmacy,1997:23: 157–165.