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Formulation and Evaluation of Buccal Disintegrating Tablet Containing Anticonvulsant Drug

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ABSTRACT

The oral and buccal routes are widely recognized as the most convenient and patient-friendly methods of drug administration, offering ease of use, safety, and improved compliance. Buccal disintegrating tablets provide an advantage over conventional dosage forms, especially for patients who experience difficulty in swallowing, such as those with dysphagia, motion sickness, or neurological conditions. These tablets dissolve rapidly in saliva without the need for water, ensuring quick onset of action and ease of administration.

The present study focuses on the formulation and evaluation of buccal disintegrating tablets of Gabapentin, an anticonvulsant drug, using β-Cyclodextrin to enhance its solubility and stability. β-Cyclodextrin is a well-established pharmaceutical excipient known for improving the solubility of poorly water-soluble drugs through complexation. Various formulations were prepared using the direct compression method, and the tablets were evaluated for physicochemical parameters including disintegration time, drug release profile, and mechanical properties.

Among the different formulations tested, formulation F5 exhibited the most promising results, with rapid disintegration and a high drug release rate of 99.99%. The study concludes that β-Cyclodextrin-based buccal disintegrating tablets of Gabapentin are a viable alternative for enhancing bioavailability and improving patient compliance..

Keywords: *gabapentine buccal tablet, treatment convulsant disease with B Cyclodextrin*

1. INTRODUCTION

The pharmaceutical industry has engendered considerable interest making it a major participant in the healthcare industry. The advances and progress made by pharmaceutical industry have greatly contributed in terms of treatment of disease, thereby enhancing the quality of life. Buccal drug delivery involves the administration of the desired drug through the buccal mucosal membrane lining of the oral cavity. This route is useful for mucosal (local effect) and transmucosal (systemic effect) drug administration. A buccal medicine is a medicine given between the gums and the inner lining of the mouth cheek. This area is called the buccal pouch. Medicine is usually given in the buccal area when it is needed to take effect quickly or when the child is not conscious. This delivery route extends numerous advantages over the other delivery routes such as oral, parenteral and dermal, due to its rich blood supply, rapid onset of action, avoidance of the first pass metabolism as well as enzymatic degradation, which results in enhanced bioavailability, increased patient compliance, and easy of self-medication. The buccal cavity mainly comprises the primary organ of the digestive system including the teeth, tongue and salivary glands.

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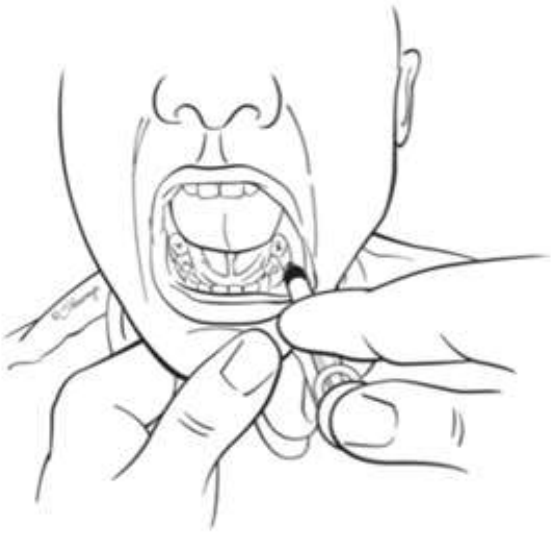

Picture 1 How to give buccal medicines.

Figure No. 1: Administration of Buccal Tablet

Cyclodextrin form inclusion complexes with appropriately sized guest molecules to improve aqueous solubility, physical chemical stability, and bioavailability of drugs. Cyclodextrin is a group of compounds made up of glucose monomers arranged in a donut form. They are non-reducing, crystalline cyclic oligosaccrides with a truncated core that produces a hydrophilic outer surface. Cyclodextrin and its derivatives have become common modalities for increasing oral bio availability and absorption rate as a result of these effects

CALIBRATION CURVE OF GABAPENTIN [10]

Sample No.	**Concentration (**µg/ml)	**Absorbance at 210 nm**
1.	0	0
2.	0.2	0.061
3.	0.4	0.124
4.	0.6	0.183
5.	0.8	0.245
6.	1	0.306

Table No.1

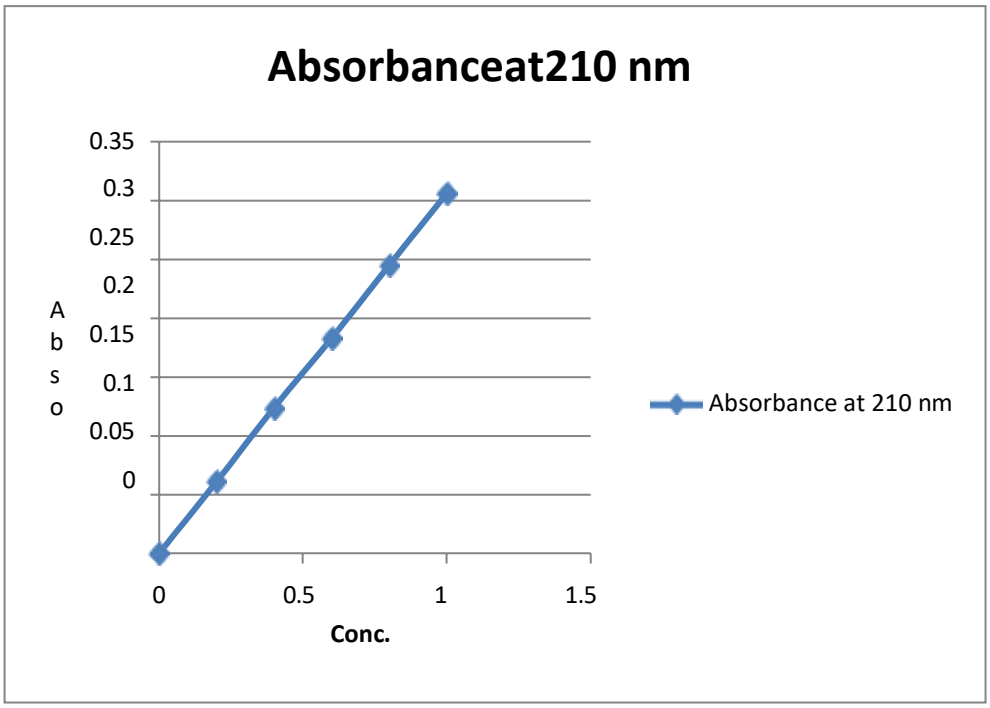

Figure No.2: Calibration curve of Gabapentin with 6.8 pH buffer at 210 nm

FTIR Studies [11]

Identification of drug and drug-polymer compatibility study Procedure:

The FTIR spectra of the pure drug, excipient and physical mixture of drug and excipient were recorded in between 400-4000 wave number (cm-1). No peaks are observed which interfere with the main drug peaks. The following spectrum and table shows IR spectrum for drug and polymer and the wave number of characteristic bands for the same.

The IR Spectrum preview pictures are as follows:

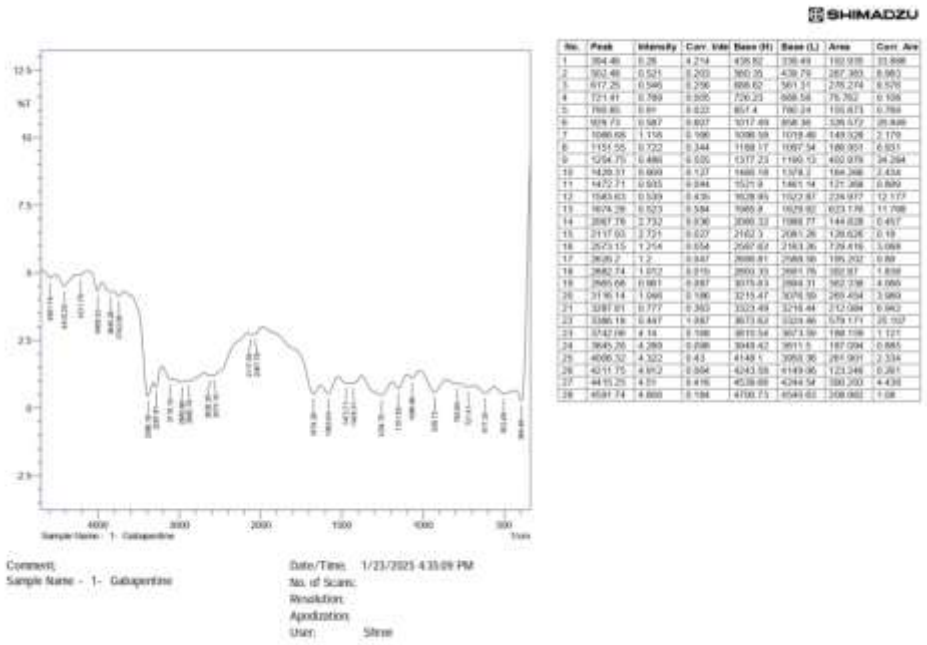

Figure No.03: Identification of Gabapentin with I.R. Spectrum

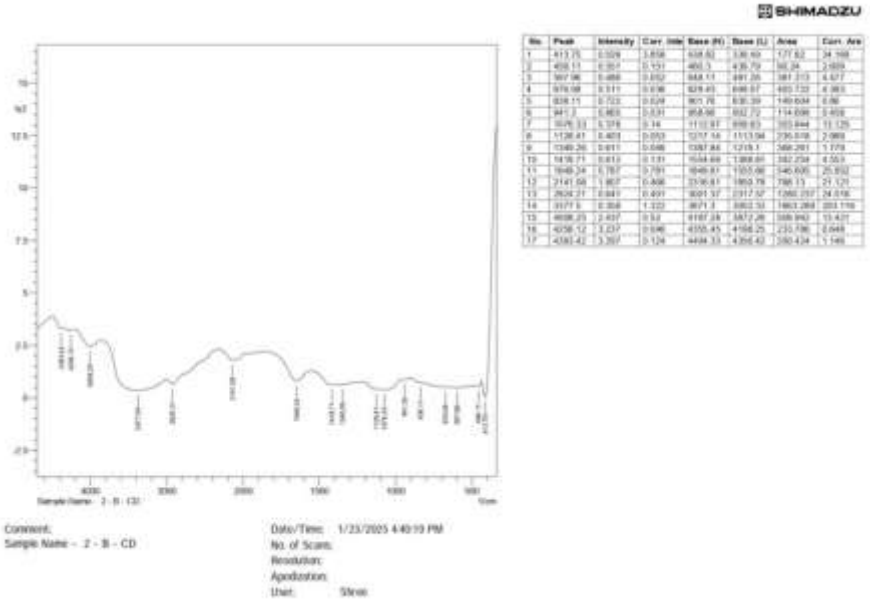

Figure No.04: Identification of with with B - Cyclodextrin I.R. Spectrum

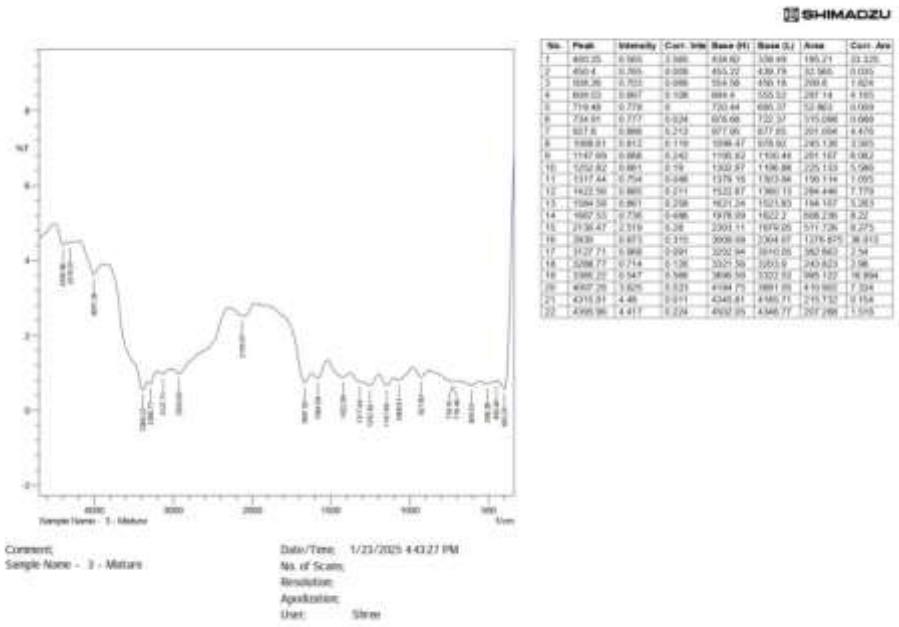

Figure No.05 Spectrum of Gabapentin with polymers

Identification of Gabapentin with I.R. Spectrum

Sr. No.	Wave number (cm-1)	Functional group
1.	3475	N-H
2.	3450	O-H
3.	2950	C-H

4.	6575	C=O

Table No.02

Experimental Work:

1. Organoleptic Characters [12]

2. Solubility Study [13]

3. Melting Point [14]

4. Micrometric Properties of Drug [15]

4.1 bulk density:

4.2 tapped density:

4.3 compressibility index:

4.4 hausner's ratio:

4.5 angle of repose:

Formulation of Buccal Disintegrating Gabapentin Tablets [16,17]

The key process in the formulation development of Gabapentin. Tablets including direct compression method to be adopted using different superdisintegrant and before weighing active ingredient. The dispensing area maintained temperature below 25ºC and humidity below 30 % RH.

Procedure:

Accurately weigh the active (Gabapentin) and every one other ingredients, were individually knowledgeable sieve no.44 then all the ingredients were mixed thoroughly by triturating upto 15 min. The mixed powder was lubricated with B-CD and also the powder was again mixed thoroughly for punching to tablets by Direct compression method. All the formulations were prepared in keeping with direct compression method were prepared as per the procedure given below and aim is to Buccal Disintegrating tablet of Gabapentin.

Composition of Buccal disintegrating tablet

Sr. No.	**Ingredients(mg/tablet)**	**F1**	**F2**	**F3**	**F4**	**F5**	**F6**	**F7**	**F8**	**F9**
1.	Gabapentin	100	100	100	100	100	100	100	100	100
2.	β-Cyclodextrin	250	260	270	275	280	290	300	310	320
3.	Mg. sterate	1	1	1	1	1	1	1	1	1
4.	Peppermint oil	q. s.	q. s.	q. s.	q. s.	q. s.	q. s.	q. s.	q. s.	q. s.

Table No.3 Composition of Buccal disintegrating tablet:

Evaluation Studies:

The formulated tablets were evaluated for the following physicochemical parameters.

1. Weight Variation Test [18]

2. Thickness Uniformity [19]

3. Hardness [20]

4. Friability [19, 21]

5. Content Uniformity [22]

6. Disintegration Test [22]

7. Swelling Studies [23]

8. In-Vitro release Study [22]

2. RESULT AND DISCUSSION

1. Organoleptic Characters

Sr. No	Characteristics	Result
1.	Color	White
2.	Order	Odorless
3.	Taste	Bitter
4.	Nature	Partially white amorphous powder

Table No.04 Organoleptic Characters

The physical appearance of sample of gabapentin is carried out as per I.P. it shows that white in colour ,odourless ,bitter and white amorphous powder.

2. Solubility Study

Sr. No.	Solvent	Solubility
1.	Water	Soluble
2.	0.1NHCL	Soluble
3.	Methanol	Slightly soluble
4.	Ethanol	Slightly soluble
5.	Toluene	Insoluble
6.	Phosphate Buffer 6.8pH	Soluble

Table No.05 Solubility Study

The solubility of given drug is soluble in water

3. Melting Point

Melting point values of gabapentin sample was found to be 165^0C, 166^0C and 164^0C. The reported melting point Average for gabapentin is 1650C. Hence, experimental values are in good agreement with official values.

4. Micrometric properties of drug

Formulation code	Bulk Density	Tapped Density	Carr's index	Hausner ratio	Angleof repose

F1	0.298	0.377	13.63	1.26	15.64
F2	0.294	0.370	11.76	1.25	14.57
F3	0.307	0.373	12.12	1.21	15.10
F4	0.312	0.357	10.76	1.14	15.10
F5	0.312	0.350	15.15	1.12	15.64
F6	0.307	0.363	16.41	1.18	15.10
F7	0.296	0.357	12.12	1.20	15.10
F8	0.305	0.338	17.64	1.10	14.57
F9	0.303	0.344	13.4	1.13	15.10

Table No.06

5. Physical Evaluation of formulated tablets

Formulation code	Weight Variation(mg)	Thickness	Hardness	Friability	Content uniformity	Disintegration test (sec)	Swelling studies
F1	498	6.7	5.7	0.69	98.12	56	56.23
F2	503	6.5	5.9	0.56	98.58	1.10	53.23
F3	508	6.1	6	0.66	97.02	58	53.22
F4	503	6.7	5.5	0.59	99.13	39	48.49
F5	505	6.8	5.3	0.62	99.33	42	42.56
F6	500	6.6	5.6	0.58	99.01	51	48.45
F7	511	6.7	5.1	0.55	97.25	1.20	45.23
F8	491	6.5	5.2	0.53	97.98	1.09	44.52
F9	510	6.6	5.3	0.50	98.91	1.11	42.23

Table No.07

6. In-vitro release study

Formulation code/Time (min)	F1	F2	F3	F4	F5	F6	F7	F8	F9
0	0	0	0	0	0	0	0	0	0

3	42.21 %	38.52 %	52.32 %	21.79 %	42.89 %	51.12 %	38.95 %	22.62 %	25.91 %
6	62%	58.66 %	59.32 %	48.98 %	55.93 %	56.32 %	43.23 %	29.31 %	55.11 %
9	89.21 %	78.01 %	63.08 %	69.51 %	69.38 %	63.23 %	66.21 %	62.25 %	67.14 %
12	91.21 %	85.02 %	84.56 %	85.14 %	98.63 %	91.23 %	76.56 %	69.21 %	79.27 %
15	94.33 %	87.00 %	89.21 %	91.25 %	99.99 %	96.96 %	87.59 %	93.20 %	81.25 %
18	94.33 %	91.32 %	95.39 %	96.52 %	99.99 %	98.97 %	91.26 %	93.20 %	91.03 %
21	97.00 %	96.54 %	97.28 %	98.23 %	99.99 %	98.85 %	95.36 %	96.31 %	95.30 %

Table No.08

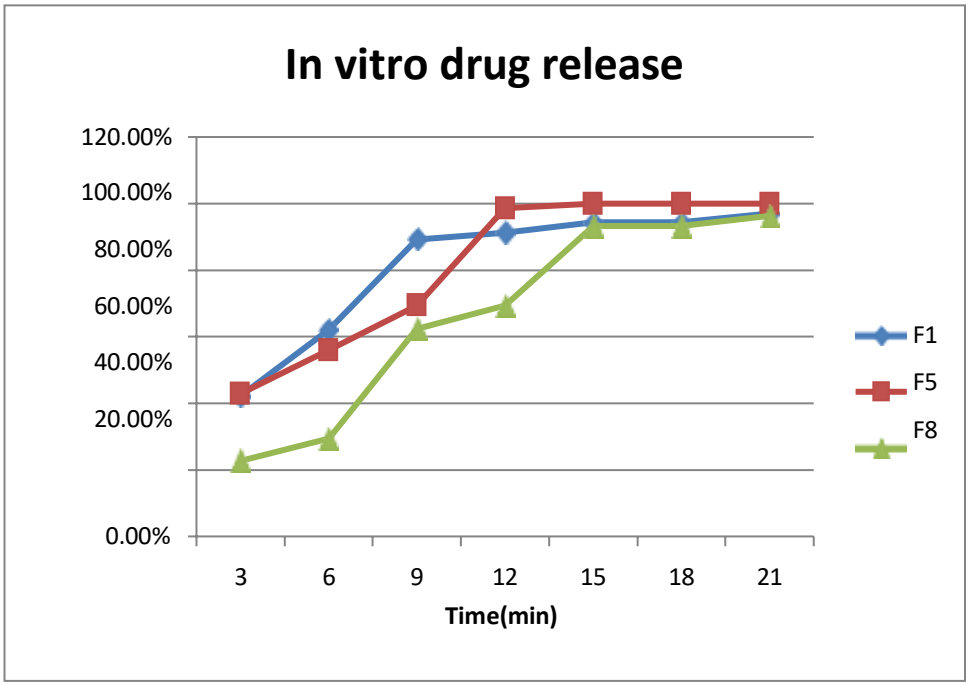

Fig. No. 6 Comparative study of In-vitro% drug release curve of formulation F1, F5 and F8.

3. CONCLUSION

The present study was designed to formulate and evaluate buccal disintegrating tablets of Gabapentin using β-Cyclodextrin as a solubility-enhancing agent. Buccal tablets offer a promising alternative for drug delivery, especially for patients who face difficulty swallowing conventional tablets or require a faster onset of therapeutic action. The use of β-Cyclodextrin

played a significant role in enhancing the solubility of Gabapentin, a drug known for its low aqueous solubility, thereby facilitating improved drug release and bioavailability.

A total of nine formulations (F1–F9) were developed using the direct compression technique, and various physicochemical parameters such as weight variation, hardness, friability, disintegration time, swelling index, and in-vitro drug release were evaluated. Among these, formulation F5 demonstrated the most favorable outcomes, including optimal mechanical strength, fast disintegration, and the highest percentage of drug release (99.99% within 15–21 minutes). These findings suggest that the composition and concentration of β-Cyclodextrin in F5 effectively enhanced drug dissolution without compromising the tablet's physical integrity.

The successful development of this buccal dosage form highlights several benefits. Firstly, it bypasses hepatic first-pass metabolism, which can significantly improve the bioavailability of Gabapentin. Secondly, the disintegrating property ensures rapid drug action, making it highly suitable for patients requiring immediate relief from neuropathic pain or seizures. Thirdly, the formulation showed excellent content uniformity and reproducibility, which are crucial for ensuring consistent therapeutic effects.

Furthermore, this buccal disintegrating tablet design may be particularly beneficial for pediatric and geriatric populations, as it eliminates the need for water and reduces the risk of choking. From an industrial perspective, such formulations are cost-effective, easy to manufacture using existing equipment, and align well with modern patient-centric drug delivery approaches.

In conclusion, formulation F5 stands out as a highly effective and patient-friendly buccal delivery system for Gabapentin. The study not only demonstrates the utility of β-Cyclodextrin in enhancing drug solubility and stability but also provides a foundation for future research on buccal drug delivery of other poorly soluble therapeutic agents. Further in-vivo studies and clinical evaluations are recommended to confirm the therapeutic potential and patient acceptability of this dosage form in real-world settings

REFERENCES

[1] Surender Verma and Mahima Kaul “AN OVERVIEW ON BUCCAL DRUG DELIVERY SYSTEM” IJPSR, 2011; Vol. 2(6): 1303-1321.

[2] Akshay. M. Akotakar , Ashwini. A. Zanke “Formulation and Evaluation of Buccal Disintegrating Tablet of Anticonvulsant Drug” Asian Journal of Research in Pharmaceutical Sciences. 12(2): April - June, 2022.

[3] Rameshwari S, Jeya Anandhi J Arulmigu Kalasalingam College Of Pharmacy, Tamilnadu Asian Journal Of Pharmaceutical And Clinical Research July-September 2009; 2(3). Issn 0974-2441.

[4] Gandhi Sd, Pandya Pr, Umbarkar R, Tambawala T And Shah Ma. Mucoadhesive Drug Delivery System- An Unusual Maneuver For Sitespecific Drug Delivery System, Inter. J. Pharm. Sci., 2011, 851- 872.

[5] K. Naga Raju, S.Velmurgan, B. Deepika, Sundar Vinushitha, Klr Pharmacy College, Poloncha, Andhra Pradesh, International Journal Of Pharmacy& Pharmaceutical Science, Volume 3,2011, Page No. 239-246.

[6] N. S. Miller, M. Chittchang, T. P. Johnston. The Use Of Mucoadhesive Polymers In Buccal Drug Delivery. Adv Drug Delivery Review.2005; 57:1666- 91.

[7] Khanna R, Agarwal Sp, Ahuja A. Mucoadhesive Buccal Drug Delivery: A Potential Alternative To Conventional Therapy. Indian Journal Of Pharmaceutical Science 1998;60(L):1-11.

[8] Khairnar Ga, Sayyad Fj. Development Of Buccal Drug Delivery System Based On Mucoadhesive Polymers. International Journal Of Pharmtech Research. 2010; 2(1): 719-735.

[9] Prof. F. R. Sheeba ,“Beta-Cyclodextrin As An Excipient In Drug Formulation” Asian Journal of Pharmaceutical Research and Development. 2021; 9(4): 122-127.

[10] Mr. K. Govindasamy Formulation And Evaluation Of Gabapentin Oral Controlled Release Matrix Tablets Submitted To The Tamil Nadu Dr. M.G.R. Medical University Chennai – 32 In The Department Of Pharmaceutics Reg. No: 26106811,Page No.54.

[11] Mr. K. Govindasamy Formulation And Evaluation Of Gabapentin Oral Controlled Release Matrix Tablets Submitted To The Tamil Nadu Dr. M.G.R. Medical University Chennai – 32 In The Department Of Pharmaceutics Reg. No: 26106811,Page No.60.

[12] Shraddha R Nagpure, Prerana B Jadhav. Formulation Development and Evaluation of Gabapentin Buccal Tablets International Journal of Innovative Pharmaceutical Sciences and Research 2018, 6 (06), 13-22 Issn (Online) 2347-2154.

[13] Http://Drugbank.Ca/Drugs/Db00996(Aprd00015)

[14] K. Govindasamy. Formulation and Evaluation of Gabapentin Oral Controlled Release Matrix Tablets Submitted to The Tamil Nadu Dr. M.G.R. Medical UniversityChennai – 32 In The Department Of Pharmaceutics Reg. No: 26106811, Page No.54.

[15] K. Govindasamy. Formulation and Evaluation of Gabapentin Oral Controlled Release Matrix Tablets Submitted to The Tamil Nadu Dr. M.G.R. Medical UniversityChennai – 32 In The Department Of PharmaceuticsReg. No: 26106811, Page No.60.

[16] K. Govindasamy. Formulation and Evaluation of Gabapentin Oral Controlled Release Matrix Tablets Submitted To The Tamil Nadu Dr. M.G.R. Medical UniversityChennai – 32 In The Department Of Pharmaceutics Reg. No: 26106811, Page No.52.

[17] Timmermans J, Moes AJ. Factors Controlling The Buoyancy And Gastric Retentioncapabilities Of Floating Matrix Capsules. New Data For Reconsidering The Controversy. J. Pharm. Sci. 1994; 83: 18-24

[18] Swetha. Koorapati. Formulation And In Vitro Evaluation of Gastroretentive Dosage Form Of Gabapentin. Submitted To The Tamil Nadu Dr. M.G.R. Medical University, Chennai Reg.No:26103014, Page No. 110.

[19] Kenneth E. Avis, Herbert A. Lieberman, And Leon Lachman. Pharmaceutical Dosage Forms, Tablets, 3 Rd Edition, Published By: Marcel Dekker, Vol-1, 42- 56.

[20] Waldwell, L.J; Gardner. C.R; Cargil, R. C; Us Patent 4, 1988; 735,804.

[21] Doddayya Hiremath Et AL. Formulation and Evaluation of Controlled Release Matrix Tablets Of Ambroxol Hydrochloride. Journal Of Pharmacy Research. 2010; 3(8),1810-1813.

[22] Pimlott SJ, Addy M. Site Dependent Absorption Study on Buccal Mucosae. Oral Surg Oral Med Oral Pathol Oral RadiolEndod 1985; 59:145-48.

[23] Robinson JR. Sustained and Controlled Release Drug Delivery System, 2nd Edition, Published By: Marcel Dekker, 138-171...