International Journal of Pharmaceutical Research and Applications
Volume 10, Issue 3 May-June 2025, pp: 1535-1542 www.ijprajournal.com SSN: 2456-4494

Formulation and Evaluation of Voglibose Mouth Dissolving Tablets

P. Samba Siva Rao[1*], Dr. G. Nagaraju[1], A. Sanjay[2], B. Navya[3], I. Manasa[4], K. Pavani[5], M. Rajesh kumar[6]

[1]Associated professor Dhanvanthari institute of pharmaceutical sciences,[1]Principal of Dhanvanthari institute of pharmaceutical sciences, Sujatha Nagar, Kothagudem.*

2,3,4,5,6. 4thYear 2 semester Pharmacy Students of Dhanvanthari institute of pharmaceutical sciences, Sujatha Nagar, Kothagudem, Telangana, India, 507120.

Date of Submission: 10-06-2025 Date of Acceptance: 20-06-2025

ABSTRACT: Mouth dissolving tablets are solid dosage forms which break down in the oral cavity less than one minute without using of water. These dosage forms are placed in the mouth, allowable to diffuse or melt in the saliva.Mouth dissolving Voglibose tablets offer a convenient and patient-friendly alternative to traditional tablets for the management of type 2 diabetes mellitus. With their rapid disintegration and absorption, these tablets provide a quick and effective way to control postprandial blood glucose levels**.**

Voglibose is alpha glycosidase inhibitor, drug which is used in a treatment of type 2 diabetes mellitus.The study was aimed at development of voglibose mouth dissolving tablets which can disintegrate or dissolve rapidly once place in the oral cavity. The tablets were prepared with different super disintegrant like crospovidone, sodium starch glycolate and lactose at different concentrations. The blend was evaluated for angle of repose, bulk density, tapped density, carr's index, Hausner's ratio. The tablets were evaluated for hardness, friability, weight variation, content uniformity test, disintegration test, wetting time. The optimized formulation exhibited excellent disintegration time and dissolution profile, meeting the pharmacopoeia requirements for MDTs. Furthermore, sensory evaluation revealed improved palatability compared to conventional tablets. Thus, the developed MDT of Voglibose offers a promising alternative for enhancing patient compliance and convenience in the management of diabetes mellitus.

The tablets were evaluated for hardness, friability, weight variation, content uniformity test, disintegration test, wetting time.

Key words: voglibose, Mouth dissolving tablets, alpha glucosidase inhibitors, super disintegrants.

I. INTRODUCTION:

More than 50% of pharmaceutical products are orally administered for several reasons. This route of administration is considered as the most widely used route as it offers advantages like ease of administration, versatility, patient compliance and accurate dosing. Undesirable taste is one of the important formulation problems that are encountered with such oral product.

Mouth dissolving tablets offer several benefits, making them particularly useful for individuals who have difficulty swallowing traditional pills or require rapid drug absorption. These tablets dissolve quickly in saliva, eliminating the need for water and facilitating easy administration, especially for children, the elderly, or those with swallowing difficulties.

Diabetes mellitus

Diabetes mellitus is a metabolic disorder, in which glucose levels in the blood is much higher than normal [hyperglycaemia] and hence this condition is also commonly referred to as sugar disease. The defect in these conditions is that either the pancreas does not produce enough insulin or it produce sufficient insulin, but the ells of the body are unable to use the insulin properly. Insulin, a hormone released from the pancreas, control the amount of glucose in the body. Glucose in the bloodstream stimulates the pancreas to produce insulin. Insulin allows glucose to move from the blood into the cells. Once insides the cell, glucose is converted to the energy, which is used immediately, or the glucose is stored as fat or glycogen until it is needed. The level of glucose in the blood varies normally throughout the day. They rise after a meal and return to normal within about 2hours after eating. Once the levels of glucose in the blood return normally, insulin production

International Journal of Pharmaceutical Research and Applications
Volume 10, Issue 3 May-June 2025, pp: 1535-1542 www.ijprajournal.com SSN: 2456-4494

decreases. The variation in blood glucose levels is useful within a narrow range about 70 to 110mg per decilitre [mg/dl] from blood in healthy peoples. If people eat a large amount of carbohydrates, the levels may increase more. People older than 65 years tend to have slightly higher levels, especially after eating. [1,3]
There are 2 types of diabetes mellitus There are…,
Type one diabetes [Insulin dependent]
Type two diabetes mellitus [non-insulin]

Voglibose Voglibose is an oral medication used primarily for managing type 2 diabetes.

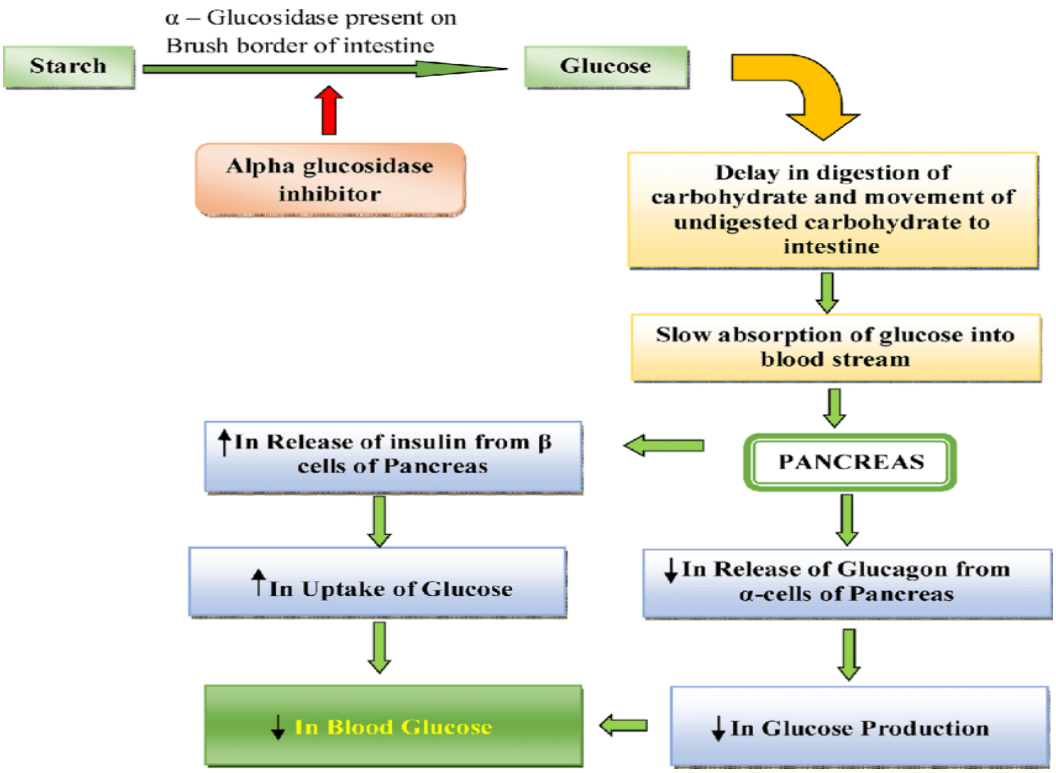
It slows down the digestion and absorption of sugar. Common side effects include abdominal pain, diarrhoea and flatulence.

Voglibose is an alpha-glucosidase inhibitor indicated in the management of postprandial blood glucose in patients with type II diabetes.

Mechanism of Action of Voglibose:

The anti-hypoglycaemic action of voglibose results from a reversible inhibition of membrane bound intestines α glycosidase hydrolyse enzymes which hydrolyseoligosaccharides anddisaccharides to glucose and other monosaccharides in the brush border of the small intestine [6,9].

Alpha-glucosidase inhibitors are saccharides that act as competitive inhibitors of enzymes needed to digest carbohydrates: specifically alpha-glucosidase enzymes in the brush border of the small intestines. The membrane-bound intestinal alpha-glucosidaseshydrolyse oligosaccharides, trisaccharide's, and disaccharides to glucose and other monosaccharides in the small intestine. also blocks pancreatic alpha-amylase in addition to inhibiting membrane-bound alpha-glucosidases. Pancreatic alpha-amylase hydrolys complex starches to oligosaccharides in the lumen of the small intestine. Inhibition of these enzyme systems reduces the rate of digestion of complex carbohydrates. Less glucose is absorbed because the carbohydrates are not broken down into glucose molecules.[6,9]



II. MATERIALS AND METHODS:

In the direct compression method of tablet production, dry ingredients are thoroughly mixed and then compressed into tablets. This eliminates the drying steps associated with the wet granulation method. It also reduces the higher costs involved in wet granulation including increased equipment,

International Journal of Pharmaceutical Research and Applications
Volume 10, Issue 3 May-June 2025, pp: 1535-1542 www.ijprajournal.com SSN: 2456-4494

labour, time, process validation and energy expenditure. As a result, direct compression is both efficient and economical, well suited to the production of high-quality tablets, which exhibit hardness, low friability and excellent dissolution rates. As an added benefit, direct compression can improve the physical and chemical stability of tablets as compared to wet granulation. [11,13]

Preparation of Mouth Dissolving voglibose tablet

Weigh the ingredients according to the formulation. Mix the ingredients in a suitable container to ensure uniform distribution. Granulate the mixture using a suitablemethod (e.g., wet granulation or dry granulation). Ensure the granules are uniform in size and shape.Dry the granules using a suitable method (e.g., tray drying or fluid bed drying).Ensure the granules are dry and free-flowing.Mill the dried granules into a fine powder using a suitable mill (e.g., hammer mill or pin mill).Mix the powdered granules with magnesium stearate (lubricant) to ensure uniform distribution.Compress the mixture into tablets using a suitable tablet press.Ensure the tablets are uniform in size, shape, and weight. Apply a coating to the tablets if desired (e.g., to improve appearance or mask taste).[15,16]

Formulation detail of each Formulation: [TABLE-01]

INGREDIENTS	F1	F2	F3	F4	F5	F6	F7	F8	F9
Voglibose	0.3	0.3	0.3	0.3	0.3	0.3	0.3	0.3	0.3
mannitol	132	122	122	132	122	122	132	122	122
Crospovidone	58.2	68.2	78.2	_	_	_	_	_	_
Croscarmellose	_	_	_	58.2	68.2	78.2	_	_	_
Sodium Starch glycolate IP	_	_	_	_	_	_	58.2	68.2	78.2
starch	14	14	14	14	14	14	14	14	14
FerricOxide yellow	0.5	0.5	0.5	0,5	0.5	0.5	0.5	0.5	0.5
Aspartame	4	4	4	4	4	4	4	4	4
Flavour	2	2	2	2	2	2	2	2	2
Colloidal Anhydrous Silica IP	2	2	2	2	2	2	2	2	2
Magnesium Stearate	2	2	2	2	2	2	2	2	2
Avg. wt.(mg)	125	125	125	125	125	125	125	125	1252

Pre formulating studies: The Pre-formulation studies are the first step in the rational development of dosage form of a drug substance. The objective of pre-formulation studies is to develop a portfolio of information about the drug substance, so that this information is useful to develop formulation.

Pre-formulation can be defined as investigation of physical and chemical properties of drug substance alone and when combined with excipients.

The powder blends were evaluated for angle of repose, bulk density, tapped density,

International Journal of Pharmaceutical Research and Applications
Volume 10, Issue 3 May-June 2025, pp: 1535-1542 www.ijprajournal.com SSN: 2456-4494

compressibility index, Hausner's ratio etc. as following

Bulk Density:

Bulk density is defined as the ratio of total mass of powder to the bulk volume of powder. Bulk density is calculated according to the formula which is mentioned below.

Bulk Density = Mass of powder/Volume of powder

Tapped Density:

It is the ratio of total mass of the powder to the tapped volume of the powder

Tapped Density = Mass of powder(mg)/Volume of tapped power(ml)

Angle of Repose: It is defined as the maximum angle possible between the surface of a pile of powder and the horizontal plane.

It can be expressed as fallows

tan (è) = h/r

Where, (è) = angle of repose

h = height in CMS,

r = radius in CMS.

Carr's Index & Hausner's Ratio:

Carr's index and Hausner's ratio measure the propensity of powder to be compressed and the flow ability of powder. Carr's index and Hausner's ratio can be calculated from the bulk and tapped density.

Carr's Index = Tapped density–Bulk density / Tapped density × 100

Hausner's Ratio = Tapped density / Bulk density

Sieving, Mixing & Lubrication:

Voglibose was sieved through mesh 100 (#100); mannitol, microcrystalline cellulose PH 102, croscarmellose sodium and orange DC 100 PH were sieved through mesh 40 (#40). Voglibose was first mixed geometrically with mannitol and then with all other excipients manually in a polybag for 5 minutes.

Magnesium Stearate and Aerosol were sieved through mesh 60 (#60) and lubrication was done with the above mixed powder manually in a polybag for 45 seconds. The moisture content of the lubricated powder was observed in Denever digital moisture analyser at 105°C. The pre-compression parameters of the bulk lubricated powder were performed using Electro lab Tapped Density Tester USP.

The pre compression parameters revealed good flow property of powder for both 0.2 and 0.3 mg of voglibose tablets.

Compression: After performing the pre-compression parameters, the lubricated powder was subjected for punching using tablet punching machine. The hardness, thickness, weight variation and friability of the punched tablets were maintained in the desired range. [18,15]

Evaluation detail of Physical properties of each Formulation: [TABLE-2]

Formulation	Angleof Repose	Loosebulk density (gm\ml)	Tapped Bulk density (gm\ml)	Compressibility Index (%)	Hausner's ratio
F1	28°.30'	0.46	0.56	16.36	1.19
F2	25°.77'	0.46	0.56	17.85	1.21
F3	25°.28'	0.47	0.56	16.07	1.19
F4	24°.56'	0.32	0.38	15.78	1.18
F5	23°.88'	0.38	0.46	17.39	1.21
F6	21°.36'	0.45	0.54	16.66	1.20
F7	25°.22'	0.45	0.52	13.46	1.15
F8	28°.29'	0.45	0.54	16.66	1.20
F9	26°.54'	0.45	0.56	19.64	1.24

International Journal of Pharmaceutical Research and Applications
Volume 10, Issue 3 May-June 2025, pp: 1535-1542 www.ijprajournal.com SSN: 2456-4494

III. RESULT:

The powder blends of proposed formulations (F-1 to F 9) were evaluated for BD, TD, compressibility index, Hausner's ratio and angle of repose (Table-2). The results of BD and TD ranged from 0.32 to 0.47 and 0.38 to 0.56 respectively and the compressibility index (%) ranged from 13.46 to 19.64. The results of angle of repose ranged from 21.36 to 28.3. The Hausner's ratio ranged from 1.15 to 1.24 which ultimately indicates good flow of powder blend. The thickness of the tablets ranged from 3.12 ± 0.06 to 3.18 ± 0.012mm. The hardness and percentage friability ranged from 3.3 ± 0.42 to 3.5 ± 0.57 kg/cm2 and 0.42 to 0.61% respectively. The weight variation and drug content uniformity ranged from 213.55 ± 1.19 to 316.55 ± 1.19 and 98.00 ± 0.05 to 99.45 ± 0.02 respectively. Disintegration time was found to be in the range 30 to 36 sec. (Table-2). The cumulative % drug release of prepared tablet using different concentration of different super disintegrating agents is shown in table01.

IV. DISCUSSION:

The results of angle of repose (< 30) indicated good flow properties of the powder blends which was further supported by lower compressibility index values. It was found that all the formulations showed uniform thickness and the average percentage deviation of all tablet formulations were found to be within the limit (Cooper et al., 1986). Uniformity in drug content was found among different batches of the tablets and the percentage of drug content was more than 98%. In this study the percentage friability for all the formulations was below 1% which was within the prescribed limits

Weight Variation:

Twenty tablets were selected at random and average weight was determined then individual tablets were weighted and the individual weighted was compared with an average weight

Hardness:

The resistance of tablet for shipping or breakage, under condition of storage, transportation and handling, before usage, depends on its hardness, before usage, depends on its hardness. The hardness of tablet of each formulation was measured by Monsanto hardness tester. Six tablets from each formulation were randomly selected and evaluated, and the average values were calculated.

Friability:

Friability is the measurement of tablets strength. Friability is the loss in weight of tablet in the container due to removal of fine particle from their surface. 10 tablets were initially weighed (initial weight) and transferred into the friabilator. The Friabilator was operated at 25 rpm for 4 min. The tablets were weighed again (final weight) and the percentage loss in weight was determined% Friability = Initial Weight-Final Weight-Initial weight × 100

Content Uniformity Test:

Ten Tablets accurately weighted and powdered a quantity of the powder equivalent to 10 mg of voglibose was weighted accurately and dissolved in buffer solution. After filtration and sufficient dilution with phosphate buffer solution, sample were analysed UV spectrophotometrically at 282 nm against buffer solution as a blank

Disintegration Test: The test was carried out on 6 tablets using the apparatus specified in I.P./1996, Purified water at 37˚C ± 2˚C was used as a disintegration media and record the time taken for complete disintegration of the tablet.[23,20

EVALUATION OF POST COMPRESSION PARAMETERS: [TABLE-3]

Batch	Thickness (mm)	Hardness (Kg/cm2)	Friability (%)	Weight variation (mg	Drug content Uniformity (%)	Disintegration time (Sec.)
F1	3.16±0.010	3.5±0.47	0.42	215.65 ±1.29	99.45±0.02	34

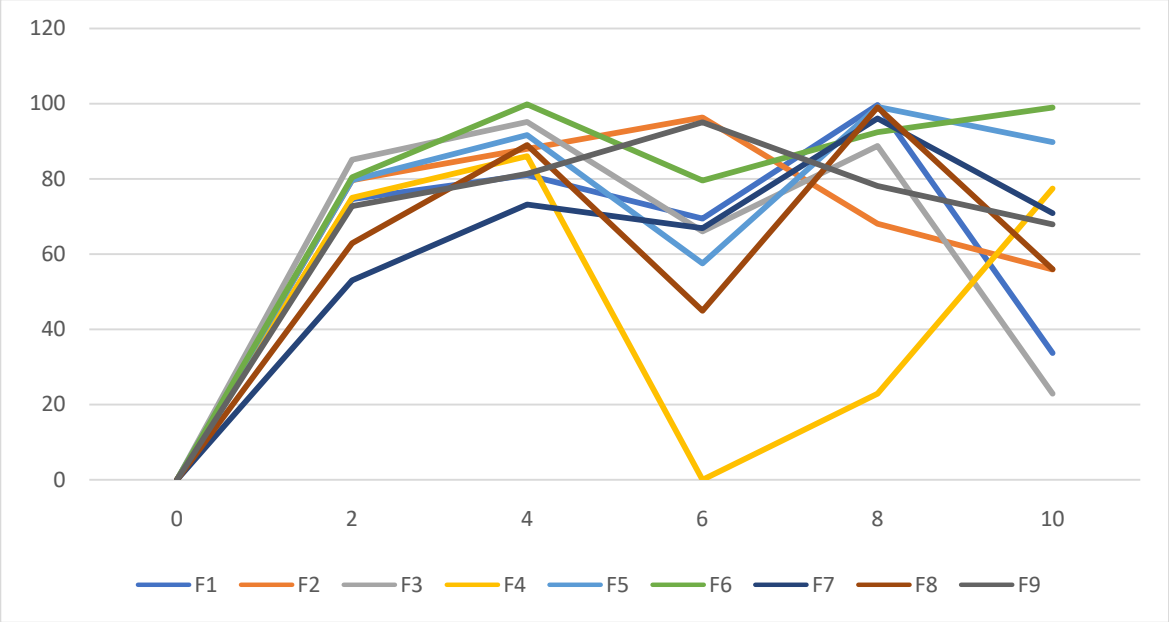
International Journal of Pharmaceutical Research and Applications
Volume 10, Issue 3 May-June 2025, pp: 1535-1542 www.ijprajournal.com SSN: 2456-4494

F2	3.14±0.012	3..4±0.32	0.56	215.65 ±1.71	98.37±0.02	32
F3	3.12±0.06	3..4±0.54	0.49	214.55 ±1.18	98.55±0.02	35
F4	3.16±0.012	3.3±0.42	0.60	214.05 ±1.37	98.03±0.03	30
F5	3.18±0.011	3.5±0.35	0.55	216.65 ±1.49	98.45±0.05	32
F6	3.16±0.010	3.5±0.54	0.42	215.55 ±1.19	99.45±0.01	30
F7	3.14±0.012	3..5±0.57	0.61	214.55 ±1.19	98.21±0.06	36
F8	3.12±0.06	3.3±0.45	0.48	216.55 ±1.19	98.00±0.05	34
F9	3.18±0.012	3..4±0.32	0.51	213.55 ±1.19	99.00±0.03	32

DISSOLUTION ROFILE OF FORMULATION COMPARED WITH INNOVATOR: [TABLE-4]

SL.NO	Time (min)	F1	F2	F3	F4	F5	F6	F7	F8	F9
1	0	0	0	0	0	0	0	0	0	0
2	2	74.6	79.63	85.11	75.1	79.59	80.43	53.1	62.89	72.76
3	4	81.06	87.96	95.16	86.03	91.58	99.85	73.17	75.36	81.35
4	6	95.41	96.32	66.03	91.54	57.47	79.63	84.15	91.52	95.01
5	8	99.66	68.09	88.75	22.86	99.09	92.46	96.03	99.05	78.09
6	10	85.04	55.87	22.86	77.43	89.77	98.99	99.89	55.99	67.90

International Journal of Pharmaceutical Research and Applications
Volume 10, Issue 3 May-June 2025, pp: 1535-1542 www.ijprajournal.com SSN: 2456-4494



V. CONCLUSION:

Voglibose is an alpha glucosidase inhibitor used in the treatment of diabetes mellitus type II.Nine formulation of mouth dissolving tablets were prepared by direct compression technique by using of super disintegrant like crospovidone, sodium starch glycolate and lactose.Developed mouth dissolving tablets gave satisfactory results for various Physicochemical parameters like hardness, friability, weight variation, drug content, in-vitro Disintegration time, in-vitro drug release study and wetting time.

From all the 9 batches evaluation, Formulation F6 showed desired drug release profile. Batch F6 also pass all the official and non-official tests of tablets and give the maximum release in the shortest time (4 min). Therefore, Formulation F6 was considered as optimized formula for preparation of Voglibose Potassium Mouth Dissolving Tablet.

ACKNOWLEDGEMENT: I am grateful and thankful to my project guide and principal for giving intense support and assistance throughout the research work.

REFERENCES:

[1]. Pathophysiology [a essential guide for pharmacy and other para medical courses]:Authors Dr.C.M JANGAME , R.D. WADULKAR , SHIVAKUMAR S.LADDE , Dr.B.N.POUL.

[2]. Jayesh R. Tundlayat , Abhay kumar, D.Sakhare and Kailash, R.Biyani: DEVELOPMENT AND CHARACTERIZATION OF MOUTH DISSOLVING TABLET IF VOGLIBOSE.

[3]. B.D Vaishnav, A. K. Sharma and B.K. Bansal: FORMULATION AND EVALUATION OF MOUTH DISSOLVING TABLET.

[4]. Prabhat S, Ranjan S and Sahana S: Formulation and Evaluation of Orally disintegrating tablet containing taste masked miratazapine.6. Nagashree K: Soliddosage forms: tablets. Research & Review. Journal of Pharmaceutical Analysis 2015.

[5]. https://my.clevelandclinic.org/health/body/22601-insulin

[6]. https://www.cdc.gov/diabetes/about/how-to-use-insulin.html

[7]. Deshmukh VN, Mouth Dissolving Drug Delivery System: A Review, Int. J. Pharm. Tech. Res., 4(1) (2012).

[8]. https://go.drugbank.com/drugs/DB04878

[9]. Deshmukh VN, Mouth Dissolving Drug Delivery System: A Review, Int. J. Pharm. Tech. Res., 4(1) (2012).

[10]. Seager H. Drug-delivery products and the Zydis fast-dissolving dosage form. Journal of Pharmacy and Pharmacology. 1998; 50(4):375-8

[11]. M. E. Aulton, T. I. Wells. Pharmaceutics: The Science of Dosage Form Design, 2nd

Ed., Churchill Livingstone, London, England, pp 397.
[12]. Gupta DK, Maurya A and Varshney MM: Orodispersible Tablets: An Overview of formulation and technology. World J Pharm Pharm Sci 2020; 9(10): 1406 1418.16.
[13]. Keyur S: "Formulation and Evaluation of Gastroprotective Floating tablets of Quetiapine Fumarate". Journal of Drug Delivery and therapeutics.
[14]. Delivery and Therapeutics 2021; 11(3 5): 65-73.MehetreG: "Quetiapine Fumarate Bucco adhesive Tablet Formulation and In-vitro Evaluation", Research J Pharma and Tech 2020; 13(11): 5095-102.
[15]. Abdelmonem R, Abdellatif MM, Al Samadi IEI and EL Nabarawi MA: Formulation and Evaluation of baclofen – meloxicam orally disintegrating tablets using co-processed excipients and improvement of ODTs Performance using six sigma method. Drugs Des Devel Ther 2021; 15: 4383 402.
[16]. Note for guidance on stability testing. Stability testing of new drug substances and products [cited 2008 Aug 02].
[17]. K. R. Deshmukh, V. Patel, S. Verma, A. Pandey, P. Dewangan. Review on mouth dissolving tablet techniques, Int. J. Research Ayu & Pharm (2011).
[18]. H. Shihora and S. Panda. Super disintegrants, Utility in Dosage Forms: A Quick Review, Journal of Pharmaceutical Science and Bioscientific Research 1, (2011).
[19]. R. Pahwa and N. Gupta. Super disintegrants in the Development of Orally Disintegrating Tablets: A Review, International Journal of Pharmaceutical Science and Research. Vol. 2 (2011).
[20]. H. Shihora and S. Panda. Super disintegrants, Utility in Dosage Forms: A Quick Review, Journal of Pharmaceutical Science and Bioscientific Research 1, (2011).M. E. Aulton, T. I. Wells. Pharmaceutics: The Science of Dosage Form Design, 2nd Ed., Churchill Livingstone, London, England, pp 397.
[21]. G. Abdelbary, C. Eouani, P. Prinderre, J. Joachim, J. Reynier and P. Piccerelle. Determination of the in vitro disintegration profile of rapidly disintegrating tablets and correlation with oral disintegration, Int.J Pharm 292: 29 41(2005).
[22]. J. Cooper, C. Gunn. Powder flow and compaction. In: Carter SJ. Eds. Tutorial Pharmacy, CBS Publishers and Distributors, New Delhi, India, 1986, pp 211 233.
[23]. drugbank.com/drugs/DB04878.
[24]. Kacso I, Rus LM, Martin F, Miclaus M, Filip X and Dan M: Solid State Compatibility studies of Ketoconazole fumaric acid co-crystal with tablet excipients. J Therm Anal Calorium 2021.
[25]. Khan A, Nasir S, Alyami HS and Ullah A: Sedem-ODT Expert System A Solution to Challenges in characterization of pharmaceutical. Powder and powdered material. Adv Funch Mater 2020.
[26]. Seager H. Drug-delivery products and the Zydis fast-dissolving dosage form. Journal of Pharmacy and Pharmacology. 1998; 50(4):375-82.
[27]. Nagashree K: Solid dosage forms: tablets. Research & Review. Journal of Pharmaceutical Analysis 2015.
[28]. Gupta A et al. Recent Trends of Fast Dissolving Tablet - An Overview of Formulation.
[29]. Mohd Yasir et al. Orally disintegrating tablets: formulation, preparation techniques and evaluation. Journal of Applied Pharmaceutical Science. 2011; 01(04): 35-45.
[30]. Ghosh T, Ghosh A, Prasad D. A review on new generationorodispersible tablets and its future prospective. Int j pharm pharmacy. 2011; 3(1): 1-7.