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FOMULATION AND DEVELOPMENT OF BACLOFEN FAST DISSOLVING TABLETS BY DIFFERENT TECHNIQUES.

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Abstract: Baclofen is a centrally acting muscle relaxant. It relieves the spasm, cramping and tightness of muscles from multiple sclerosis, spinal cord injuries or other spinal cord diseases. In the present research work fast dissolving tablets of Baclofen were prepared by solid dispersion and direct compression methods. The concept of formulating fast dissolving tablets containing Baclofen offer a suitable and practical approach in serving the desired objective of faster disintegration and dissolution characteristic with increase bioavailability. Fast dissolving tablets of Baclofen were prepared by using various techniques like solid dispersion and direct compression. Prepared tablets were subjected to different evaluation parameters such as hardness, friability, weight variation, drug content uniformity, wetting time, water absorption ratio, in vitro disintegration time, in vitro dissolution studies and stability studies. Results revealed that all formulations have acceptable physical parameters.

Index Terms - **Fast dissolving tablet, Baclofen, Super disintegrants, In vitro dissolution.**

I. INTRODUCTION

The Oral route of administration continues to be the most preferred route due to its manifold advantages including ease of ingestion, pain avoidance, versatility, and most importantly patient compliance. Therefore, oral solid dosage forms are popular because of ease of administration, accurate dosage, self-medication, pain avoidance and most importantly patient compliance. Among the pharmaceutical dosage forms, conventional tablets are most popular, because of their ease of transportability and comparatively lower manufacturing cost.

Topical route is recently developed and is employed for only few drugs like nitroglycerine, scopolamine for systemic effect. Topical route has limitations in its ability to allow effective drug absorption for systemic drug action. Nevertheless, it is possible that at least 90% of all drugs used to produce systemic effect are administered by oral route [1].

During the past four decades, the pharmaceutical industry has invested vast amounts of time and money in the study of tablet compaction. The expenditure is quite reasonable when one considers how valuable tablets, as a dosage form, are to the industry. Because oral dosage forms can be self-administered by the patient, they are obviously more profitable to manufacture than parenteral dosage forms that must be administered, in most cases, by trained personnel [2].

There are several factors other than physicochemical properties of the drug that may influence the dissolution rate and hence, bioavailability of the drugs from the solid dosage forms. It has shown that, the dissolution rate o Tablets are popular for several reasons: [3]

1.The oral route represents a convenient and safe way of drug administration.
2.The preparation procedure enables accurate dosing of the drug.
3.Tablets are convenient to handle and can be prepared in a versatile way With respect to their use and to the delivery of the drug.
4.Tablets can be mass produced with robust and quality-controlled production.

Fast dissolving tablets are defined as the tablets, which are meant to disintegrate immediately upon contact with the saliva leading to faster release of the drugs in the oral cavity and disintegrate rapidly within 15 seconds to 3 minutes. The faster the drug goes into solution, faster the absorption and onset of clinical effect is. For the drug attaining the therapeutic level by the gastric wall and elicit therapeutic effect, both rate and extent of absorption is important. The conventional tablet shows the delay in absorption and fast dissolving tablets disintegrate and dissolve rapidly and absorption takes place quickly, thus bioavailability increases [4].

Some factors like GI disturbances and blood supply to GI differ with age as the elderly are considered as separate unique Medicare population [4]

Ideal characteristics of fast dissolving tablets [5] [6]**:**

- They should not require water or other liquid at the time of administration.
- Should easily disintegrate and dissolve.
- Mask or overcome unacceptable taste of drug.
- They should have high drug loading.
- They should have a pleasant feel in the mouth.
- They should have negligible or no residue in oral cavity after administration.
- They should have low sensitivity against environmental conditions like moisture, temperature, etc.
- Ease of administration for patients who are mentally ill, disabled, and uncooperative.
- Should be portable without fragility concern.

Advantages of fast dissolving tablets [6] [7]**:**

- Ease of administration to patients who refuse to swallow a tablet such as paediatrics, geriatric patients, and psychiatric patients.
- No need or little water is required to swallow the dosage form which is a highly convenient feature for patients who are traveling and do not have access to water.
- Free of risk of suffocation due to physical obstruction when swallowed, thus offering improved safety.
- Rapid disintegration and absorption of drug, which will produce quick onset of action.
- Quick absorption from the gastro intestinal tract improves bioavailability and reduces unwanted effects caused by the drugs and improves patient compliance.
- Drug and dosage form stability.
- New business opportunities like product differentiation, line extension and life cycle management. Exclusivity of product promotion.

Disadvantages of FDT [8]**:**

- Most fast-dissolving tablets lack the mechanical strength common to traditional tablets. Many products are very lightweight and fragile requiring them to be individually packaged. Patients should be advised not to push these tablets through the foil film, but instead peel the film back to release the fast-dissolving tablet.
- Due to the formulation of fast dissolving tablets which are also more susceptible to degradation via temperature and humidity, some of the newest fast dissolving tablet formulations are dispensed in a conventional stock bottle. Pharmacists are advised to take care when dispensing such formulations to ensure they are not exposed to high levels of moisture or humidity. Excess handling of tablets can introduce enough moisture to initiate dissolution of the tablet matrix.

Developmental challenges in fast dissolving drug delivery.

Taste of the active ingredient [9]**:**

Some drugs have relatively no taste, and simply adding a suitable flavor can hide any slight unpleasant sensation. However, most drugs do require taste masking if they are to be incorporated into fast dissolving formulations. Numerous methods exist to achieve this, including simple wet granulation or roller compression with other excipients to minimize the presented surface area of the drug. Spray drying can also be employed to shroud the drug.

Hygroscopy [10]**:**

Several fast-dissolving dosage forms are hygroscopic and cannot maintain physical integrity under normal conditions of temperature and humidity. Hence, they need protection from humidity that calls for specialized product package.

Friability [6]**:**

In order to allow fast dissolving tablets to disintegrating rapidly in the mouth, they are made of either very porous or soft molded matrices or compressed into tablets with low compression force, which makes the tablet friable and/or brittle which are difficult to handle, often require specialized peel-off blister packing.

RESEARCH METHODOLOGY

METHODS OF PREPARATION OF BACLOFEN FAST DISSOLVING TABLETS:

Solid dispersion method.

Method: Solid dispersion of Baclofen was prepared by solvent evaporation method using various carriers such as (Mannitol, PEG-6000 and Cros povidone in different ratio 1:1, 1:2, 1:4, and 1:9). The weighed quantity of drug and mannitol (1:1) was taken in China dish; to which methanol was added. The solvent evaporated at room temperature and dried in a hot air oven at 50 0C for 4 hrs. The resultant mass was passed through sieve no.60 and stored in desiccators. The procedure was repeated with other carriers.

Direct compression method [11]**:**

Method: All the ingredients were passed through 60 mesh sieves separately. The drug and mannitol were mixed by small portion of both each time and blending it to get a uniform mixture kept aside. Then the ingredients were weighed and mixed in geometrical order and tablets were compressed of 6mm sizes flat round punch to get tablet using Rimek Compression Machine The methodology section outline the plan and method that how the study is conducted. This includes Universe of the study, sample of the study, Data and Sources of Data, study's variables, and analytical framework. The details are as follows;

3.1Population and Sample

KSE-100 index is an index of 100 companies selected from 580 companies based on sector leading and market capitalization. It represents almost 80% weight of the total market capitalization of KSE. It reflects different sector company's performance and productivity. It is the performance indicator or benchmark of all listed companies of KSE. So, it can be regarded as universe of the study. On-financial firms listed at KSE-100 Index (74 companies according to the page of KSE visited on 20.5.2015) are treated as universe of the study and the study have selected sample from these companies.

The study comprised of non-financial companies listed at KSE-100 Index and 30 actively traded companies are selected on the bases of market capitalization. And 2015 is taken as base year for KSE-100 index.

3.2 Data and Sources of Data

Materials

Sr. No.	Materials	Source
1.	Baclofen	Gift sample from Natco Pharma Ltd. Hyderabad.
2.	Croscarmellose sodium	Gift sample from Lobo chemicals, Mumbai.
3.	Cross povidone	Gift sample from Merck Limited, Mumbai.
4.	Sodium starch glycolate	Gift sample from Merck Limited, Mumbai.
5.	Microcrystalline cellulose	SD Fine Chem. Ltd, Mumbai
6.	Mannitol	SD Fine Chem. Ltd, Mumbai.
7.	Camphor	SD Fine Chem. Ltd., Mumbai
8.	Kyron -T134	Gift sample from Corel Pharma Chem., Ahmadabad
9.	Magnesium stearate	SD Fine Chem. Ltd., Mumbai
10.	Talc	SD Fine Chem. Ltd., Mumbai

IV. RESULTS AND DISCUSSION

4.1 Results of Descriptive Statics of Study Variables

The tablet prepared by solid dispersion method passes weight variation was found in the range 99 to 101 mg which is below ±7.5%, hardness 3 to 3.5 Kg/cm2, percentage friability of 0.42 to 0.77 %, in vitro disintegration time of 13 to 89 sec, drug content uniformity was in between 98.23 to 101.19%, water absorption ratio was found between 28 to 52% and wetting time between 54 to 107 sec. and shows maximum drug release within 5 min.

The tablets prepared by direct compression method passes weight variation was found in the range 98 to 102 mg which is below ±7.5%, hardness 3 to 3.5 kg/cm², percentage friability of 0.41 to 0.74, in vitro disintegration time of 12 to 50 sec, drug content uniformity was in between 98.91 to 100.80%, water absorption ration was found between 45 to 60% and wetting time between 54 to 98 sec. and shows maximum drug release within 4 min.

The FTIR studies of formulation show that no interaction between drug and excipient.

In the present research work fast dissolving tablets of Baclofen were prepared by solid dispersion and direct compression methods. All the tablets of Baclofen were subjected to weight variation, hardness, friability, in-vitro disintegration time, drug polymer interaction, drug content uniformity, water absorption ratio, wetting time, and in vitro drug release.

Based on the above studies the following conclusions can be drawn: Tablets prepared by solid dispersion and direct compression methods were found to be good, were free from chipping and capping. The low values of the standard deviation of average weight of the prepared tablets indicate weight uniformity within the batches prepared. The hardness of the prepared tablets was found to

be in the range of 2.5 to 3.5 Kg/cm².The friability values of the prepared tablets were found to be less than 1%. FTIR study indicated that the drug is compatible with all the excipients.

The in-vitro disintegration time of Baclofen tablets prepared by solid dispersion and direct compression methods were found to be in the range of 12 to 89 sec fulfilling the official requirements.

The drug content of tablets was uniform in all the batches and was between 98.17 to 101.48%.

The drug release from fast dissolving tablets of Baclofen prepared by solid dispersion method were found to be in the range of 49.05% to 99.99% within 5 min. The direct compression method showed 39.14% to 99.15% within 4 min.

The stability study shows that no significant changes in tablets after Three months study.

RESULTS:

DRUG-POLYMER INTERACTION STUDIES BY

FTIR: - There is always a possibility of drug-polymer interaction in any formulation due to their intimate contact. Compatibility studies were carried out to know the possible interactions between Baclofen and excipients used in the formulation.

The prominent peaks of Baclofen pure drug were shown at 1100cm-1 (due to –C-Cl), 1530 cm-1 (due to -COOH), and 1610 cm-1 (due to –NH2). These prominent peaks of Drug were also present in the IR spectrum of formulation BM4 (Drug +Mannitol), BC8 (Drug+ Cross povidone). This is clearly indicating that drug has retained its identity without changing its character.

DISSOLUTION STUDY:

***In-vitro* dissolution studies:**

Dissolution rate was studied by using USP type-II apparatus (USP XXIII Dissolution Test Apparatus at 50 rpm) using 900 ml of phosphate buffer pH (7.4) as dissolution medium. Temperature of the dissolution medium was maintained at 37□0.50C, aliquot of dissolution medium was withdrawn at every 1 min interval and filtered. The absorbance of filtered solution was measured by UV spectrophotometric method at 266 nm and concentration of the drug was determined from standard calibration curve.

The dissolution of Baclofen from the tablets is shown in (Table 7,8 ,9, 10) shows the t50% and t90% of the release profiles. These values changed with the change of method of preparation of tablets.

Table 7: Release profile of Baclofen fast dissolving tablets prepared by solid dispersion method

Formulation Code	BM_1	BM_2	BM_3	BM_4	BC_5	BC_6	BC_7	BC_8
$t_{50\%}$ (min)	5.60 ±1.42	5.57 ± 1.08	4.02 ±0.67	3.53 ±0.54	4.00 ± 1.97	3.00 ± 0.89	2.44 ±1.08	2.50 ± 0.65
$t_{90\%}$ (min)	10.08 ±0.65	10.03±1.11	9.95 ±1.84	6.35±0.56	7.20 ±0.75	5.40 ±0.71	4.47 ±1.21	4.50 ±1.08

Table 8: Release profile of the Baclofen fast dissolving tablets prepared by direct compression method

Formulation Code	BD_1	BD_2	BD_3	BD_4	BD_5	BD_6
$t_{50\%}$ (min)	4.00 ± 0.12	3.00 ± 0.21	2.01 ± 0.39	4.58 ± 0.51	4.06 ± 0.54	3.00 ± 0.45
$t_{90\%}$ (min)	7.21 ± 0.29	5.40 ± 0.32	3.63 ± 0.56	8.02 ± 0.18	7.32 ± 0.27	5.04 ± 0.34

RESULT OF STABILITY STUDY:

The promising formulations were subjected to short term stability study by storing the formulations at 20 ± 2^0C and 45 ± 2^0C up to three months. After stability Period time the tablets Prepared by solid dispersion method, the formulations are BM_4 BC_8, and direct compression method $BD_{3, BD6}$ were showed no major change in result in disintegration time, wetting time and drug content.

Table 9: Result of stability study at 40^0C/75%±5% RH

Formulation code	In vitro disintegration time (sec) ± SD	Wetting time(sec) ± SD	Drug content
BM_4	53 ± 1.00	66 ± 1.10	100.36 ± 0.31
BC_8	17 ± 1.75	60 ± 1.81	100.39 ± 1.81
BD_3	21 ± 1.34	57 ± 2.56	100.37 ± 0.56
BD_6	35 ± 1.23	82 ± 1.63	100.08 ± 0.06

Table 10: Result of stability study at 25^0C75%±5% RH

Formulation code	In vitro disintegration time (sec) ± SD	Wetting time(sec) ± SD	Drug content
BM_4	51 ± 1.22	69 ± 1.21	100.32 ± 0.21
BC_8	12 ± 1.12	72 ± 1.42	100.30 ± 1.64
BD_3	20 ± 1.65	51 ± 1.52	100.33 ± 0.53
BD_6	28 ± 1.45	87 ± 1.25	100.03 ± 0.33

Table 4.1 displayed mean, standard deviation, maximum minimum and jarque-bera test and its p value of the macroeconomic variables of the study. The descriptive statistics indicated that the mean values of variables (index, INF, EX, OilP and INT) were 0.020, 0.007, 0.003, 0.041 and 0.047 respectively. The maximum values of the variables between the study periods were 0.14, 0.02, 0.04, 0.41, 0.11 and 0.05 for the KSE- 100 Index, inflation, exchange rate, oil prices and interest rate.

The standard deviations for each variable indicated that data were widely spread around their respective means.

Column 6 in table 4.1 shows jarque bera test which is used to check the normality of data. The hypotheses of the normal distribution are given;

$H_{0:}$ The data is normally distributed.

$H_{1:\,The}$ data is not normally distributed.

Table 4.1 shows that at 5 % level of confidence, the null hypothesis of normality cannot be rejected. KSE-100 index and macroeconomic variables inflation, exchange rate, oil prices and interest rate are normally distributed.

The descriptive statistics from Table 4.1 showed that the values were normally distributed about their mean and variance. This indicated that aggregate stock prices on the KSE and the macroeconomic factors, inflation rate, oil prices, exchange rate, and interest rate are all not too much sensitive to periodic changes and speculation. To interpret, this study found that an individual investor could not earn higher rate of profit from the KSE. Additionally, individual investors and corporations could not earn higher profits and interest rates from the economy and foreign companies could not earn considerably higher returns in terms of exchange rate. The investor could only earn a normal profit from KSE.

Figure sand Tables

Table 1: Formula of Baclofen fast dissolving tablets prepared by solid dispersion method (1-tablet)

Ingredients(mg)	Formulations code							
	BM_1	**BM_2**	**BM_3**	**BM_4**	**BC_5**	**BC_6**	**BC_7**	**BC_8**
Solid dispersion of drug and polymer	10.10	15.29	25.69	50.00	10.13	15.22	25.00	50.10
Crosprovidone	6	6	6	6	-	-	-	-
Sodium starch glycolate	-	-	-	-	6	6	6	6
Lactose	76.90	71.71	61.31	37.00	76.87	71.78	62.00	36.90
Kyron-T-134	5	5	5	5	5	5	5	5
Mg stearate	1	1	1	1	1	1	1	1
Talc	1	1	1	1	1	1	1	1
Total Weight	100	100	100	100	100	100	100	100

Table 2: Formula of Baclofen fast dissolving tablets prepared by direct compression method (1-tablet)

Ingredients(mg)	Formulations code					
	BD_1	BD_2	BD_3	BD_4	BD_5	BD_6
Baclofen	5	5	5	5	5	5
Crosprovidone	3	6	9	-	-	-
Sodium starch glycolate	-	-	-	3	6	9
Croscarmellose Sodium	-	-	-	-	-	-
Mannitol	85	82	79	85	82	79
Kyron-T-134	5	5	5	5	5	5
Mg stearate	1	1	1	1	1	1
Talc	1	1	1	1	1	1
Total Weight	100	100	100	100	100	100

Table 3: Pre-compression parameters of power blend used for solid dispersion method

Formulation code	Bulk density* (g/cc) ± SD, n=3	Tapped density*(g/cc) ± SD, n=3	Angle of repose*(degree) ± SD, n=3	Carr's index* (%) ± SD, n=3	Hausner's ratio* ± SD, n=3
BM_1	0.392 ± 0.10	0.510 ± 0.02	24.22 ± 1.23	20.00 ± 1.58	1.275 ± 0.01
BM_2	0.400 ± 0.02	0.500 ± 0.01	24.44 ± 1.41	21.75 ± 1.22	1.250 ± 0.09
BM_3	0.384 ± 0.07	0.555 ± 0.01	24.22 ± 0.57	16.98 ± 0.63	1.200 ± 0.05
BM_4	0.392 ± 0.01	0.576 ± 0.02	21.52 ± 0.69	19.73 ± 0.58	1.242 ± 0.01
BM_5	0.401 ± 0.09	0. 425± 0.02	24.14 ± 1.20	21.66 ± 0.60	1.270 ± 0.02
BM_6	0.401 ± 0.15	0.327 ± 0.03	24.98 ± 1.55	23.24 ± 0.75	1.311 ± 0.04
BM_7	0.396 ± 0.02	0.556 ± 0.02	23.12 ± 1.42	16.98 ± 1.23	1.200 ± 0.01
BM_8	0.350 ± 0.13	0.659 ± 0.01	21.56 ± 1.35	19.73 ± 0.67	1.240 ± 0.07

Table 4: Pre-compression parameters blend used for direct compression method

Formulation code	Bulk density* (g/cc) ± SD, n=3	Tapped density*(g/cc) ± SD, n=3	Angle of repose*(degree) ± SD, n=3	Carr's index* (%) ± SD, n=3	Hausner's ratio* ± SD, n=3
BD_1	0.40 ± 0.06	0.512 ± 0.01	23.19 ± 1.27	22.00 ± 1.23	1.28 ± 0.03
BD_2	0.398 ± 0.06	0.51 ± 0.01	25.28 ± 1.19	21.95 ± 1.02	1.28 ± 0.02
BD_3	0.401± 0.06	0.513 ± 0.01	27.20 ± 1.30	21.82 ± 1.03	1.27 ± 0.03
BD_4	0.392 ± 0.06	0.504 ± 0.02	25.14 ± 1.01	22.21 ± 1.25	1.29 ± 0.03
BD_5	0.402 ± 0.06	0.498 ± 0.01	28.56 ± 1.45	19.49 ± 1.36	1.24 ± 0.03
BD_6	0.443 ± 0.06	0.508 ± 0.02	26.41 ± 1.56	19.49 ± 1.29	1.23 ± 0.03

Table 5: Post compression parameters of tablets prepared by solid dispersion method

Formulations code	Parameters							
	Hardness ($kg/cm^{2)}$ ± SD	Friability (%)	Thickness* (mm) ± SD	Weight variation* (mg) ± SD	*In vitro* disintegration time* (sec)± SD	Wetting time* (sec)± SD	Water absorption ratio* ± S. D	Drug Content* (%) ± SD
BM_1	3.0 ± 0.11	0.55	3.01 ± 0.09	99 ± 0.61	89±1.50	92 ± 1.0	51 ± 1.24	98.23 ± 0.22
BM_2	3.5 ± 0.10	0.65	3.03 ± 0.10	101 ± 0.13	76 ±1.0	87 ± 1.42	52 ± 1.0	101.19 ± 0.34
BM_3	3.0 ± 0.15	0.61	3.10 ± 0.20	99 ± 0.47	65 ±1.7	69 ± 1.89	33 ± 1.12	100.80± 1.63
BM_4	3.5 ± 0.20	0.42	3.00 ± 0.21	100 ± 0.25	51± 1.0	61 ± 2.10	28 ± 1.34	100.48 ± 1.21
BM_5	3.0 ± 0.10	0.61	3.12 ± 0.28	99 ± 0.37	56±1.4	92 ± 1.12	51 ± 1.31	99.98 ± 1.41
BM_6	3.0 ± 0.21	0.52	3.00 ± 0.12	101 ± 0.61	48±1.2	73 ± 1.35	49 ± 1.73	99.99 ± 0.55
BM_7	3.0 ± 0.05	0.42	3.08 ± 0.17	99 ± 0.42	36±2.1	64 ± 1.79	33 ± 1.54	99.99 ± 1.53
BM_8	3.0 ± 0.18	0.47	3.04 ± 0.10	101 ± 0.49	13±1.5	54 ± 1.41	42 ± 1.37	100.48 ± 1.51

Table 6: Post compression parameters of tablets prepared by direct compression method

Formulations code	Parameters							
	Hardness ($kg/cm^{2)}$ ± SD	Friability (%)	Thickness* (mm) ± SD	Weight variation* (mg) ± SD	*In vitro* disintegration time* (sec)± SD	Wetting time* (sec)± SD	Water absorption ratio* ± S. D	Drug Content* (%) ± SD
BD_1	3.0 ± 0.12	0.61	3.12 ± 0.10	100 ± 0.11	25 ± 1.56	87 ± 1.25	51 ± 1.22	99.20 ±0.7
BD_2	3.5 ± 0.17	0.65	3.08 ± 0.02	101 ± 0.23	19 ± 2.36	69 ± 1.37	52 ± 1.52	100.80 ± 0.40
BD_3	3.5 ± 0.23	0.74	3.14 ± 0.10	98± 0.56	12 ± 1.36	54 ± 1.53	60 ± 1.33	100.47± 0.53
BD_4	3.5 ± 0.27	0.69	3.14 ± 0.20	99 ± 0.45	50 ± 1.59	98 ± 1.54	52 ± 1.95	99.85 ± 1.02
BD_5	3.5 ± 0.14	0.41	3.13 ± 0.14	100 ± 0.55	35 ± 1.28	87 ± 1.35	54± 1.66	99.93 ± 1.90
BD_6	3.0 ± 0.15	0.52	3.13 ± 0.14	101 ± 0.34	30 ± 1.53	76 ± 1.23	45 ± 1.30	100.10 ± 1.20

Table 7: Release profile of Baclofen fast dissolving tablets prepared by solid dispersion method

Formulation Code	BM_1	BM_2	BM_3	BM_4	BC_5	BC_6	BC_7	BC_8
$t_{50\%}$ (min)	5.60 ±1.42	5.57 ± 1.08	4.02 ±0.67	3.53 ±0.54	4.00 ± 1.97	3.00 ± 0.89	2.44 ±1.08	2.50 ± 0.65
$t_{90\%}$ (min)	10.08 ±0.65	10.03±1.11	9.95 ±1.84	6.35±0.56	7.20 ±0.75	5.40 ±0.71	4.47 ±1.21	4.50 ±1.08

Table 8: Release profile of the Baclofen fast dissolving tablets prepared by direct compression method

Formulation Code	BD_1	BD_2	BD_3	BD_4	BD_5	BD_6
$t_{50\%}$ (min)	4.00 ± 0.12	3.00 ± 0.21	2.01 ± 0.39	4.58 ± 0.51	4.06 ± 0.54	3.00 ± 0.45
$t_{90\%}$ (min)	7.21 ± 0.29	5.40 ± 0.32	3.63 ± 0.56	8.02 ± 0.18	7.32 ± 0.27	5.04 ± 0.34

Table 9: Result of stability study at 40^0C/75%±5% RH

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BD_6	35 ± 1.23	82 ± 1.63	100.08 ± 0.06

Table 10: Result of stability study at 25^0C75%±5% RH

Formulation code	In vitro disintegration time (sec) ± SD	Wetting time(sec) ± SD	Drug content
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BD_3	20 ± 1.65	51 ± 1.52	100.33 ± 0.53
BD_6	28 ± 1.45	87 ± 1.25	100.03 ± 0.33

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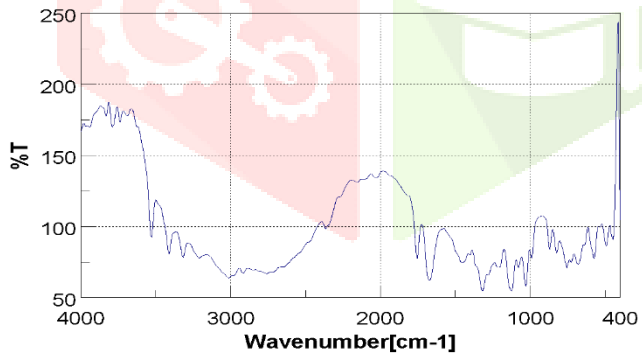

FIG 1: IR image of Baclofen with Mannitol.

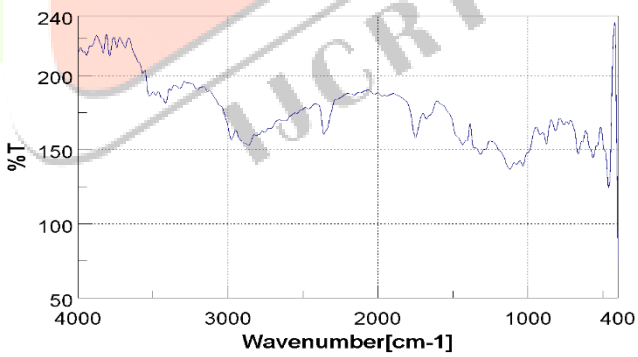

FIG 2: IR image of Baclofen with Cross povidone.

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