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Formulation and Evaluation of Baclofen Tablet for Alcohol Withdrawal Syndrome

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Abstract: *Alcohol withdrawal syndrome is a hazardous neurological condition that arises when long-term alcohol usage is abruptly halted. Symptoms include anxiety, tremors, insomnia, hallucinations, and seizures. The current study's objective was to create and evaluate direct compression rapid release. Alcohol withdrawal symptoms can be effectively treated with Baclofen pills. Because of its potential to reduce alcohol desire, withdrawal symptoms, and neural excitability, the selective GABA receptor agonist baclofen was selected. Among the suitable pharmaceutical excipients employed to create the formulation were talc, lactose monohydrate, sodium starch glycolate, HPMC E5, magnesium stearate, and microcrystalline cellulose. The produced powder mixture was examined for pre-compression parameters such angle of repose, bulk density, tapped density, Carr's index, and Hausner ratio in order to examine flow characteristics and compressibility. Further evaluation was done on the compressed tablets' post-compression properties, including weight variation, hardness, and friability. It was determined that the tablet quality measurements and flow characteristics were sufficient. The tablets' friability was below pharmacopeial limits, and their mechanical strength, consistency, and stability were all good. The study concluded that direct compression Baclofen immediate release tablets exhibited suitable pharmacological characteristics and might be an effective oral dosage form for treating alcohol withdrawal syndrome.*

Keywords: Alcohol Withdrawal Syndrome, Baclofen, Immediate Release Tablets, Direct Compression, GABA Receptor Agonist, Tablet Formulation, Pharmaceutical Evaluation, Precompression Parameters

I. INTRODUCTION

Alcohol use disorder (AUD) is a chronic relapsing disorder characterized by excessive alcohol intake, dependence, and withdrawal symptoms following abrupt cessation of alcohol consumption. Long-term alcohol exposure affects several neurotransmitter systems in the brain, particularly the gamma-aminobutyric acid (GABA) system, which is the primary inhibitory neurotransmitter pathway of the central nervous system. Chronic alcohol consumption enhances GABAergic activity and suppresses excitatory neurotransmission. However, sudden discontinuation of alcohol leads to neurochemical imbalance, resulting in central nervous system hyperexcitability. Alcohol withdrawal syndrome includes symptoms such as anxiety, insomnia, sweating, tremors, irritability, hallucinations, and seizures. Severe withdrawal conditions may progress to delirium tremens, which can become life-threatening if not properly managed. Pharmacological management of alcohol withdrawal mainly focuses on restoring inhibitory neurotransmission and reducing neuronal excitability. Baclofen is a selective GABAB receptor agonist widely used as a centrally acting skeletal muscle relaxant. In recent years, it has gained attention for its role in reducing alcohol craving, withdrawal symptoms, and relapse rates. Baclofen acts by inhibiting the release of excitatory neurotransmitters and restoring inhibitory balance within the brain. Due to its favourable pharmacological profile and lower risk of dependence, Baclofen is considered a promising therapeutic option in alcohol withdrawal management. Among various dosage forms, tablets remain the most preferred oral drug delivery system because of their convenience, stability, accurate

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dosing, ease of administration, and cost-effective manufacturing. Immediate release tablets are designed to disintegrate rapidly after administration and provide quick onset of therapeutic action. The present study focuses on the formulation and evaluation of immediate release Baclofen tablets using suitable pharmaceutical excipients and the direct compression method. The prepared formulation was evaluated for both pre-compression and post-compression parameters to assess its quality, performance, and suitability for therapeutic application.

II. METHOD OF PREPARATION:

Direct compression is one of the simplest and most widely used methods for tablet manufacturing in the pharmaceutical industry. In this method, powdered drug and excipients are blended uniformly and directly compressed into tablets without any granulation step. The method is preferred because it requires fewer processing steps, less equipment, reduced manufacturing time, and lower production cost compared to wet granulation and dry granulation techniques. Direct compression is especially suitable for drugs and excipients possessing good flowability and compressibility. Excipients such as microcrystalline cellulose (MCC), spray-dried lactose, and super disintegrants are commonly used to improve powder flow and tablet strength during direct compression. Since the method avoids the use of heat and moisture, it is highly beneficial for moisture-sensitive and heat-sensitive drugs. The direct compression process generally involves weighing, sieving, blending, lubrication, and compression of the powder blend. Uniform mixing of ingredients is essential to ensure content uniformity and consistent tablet quality. Lubricants and glidants are added in the final stage to improve powder flow and prevent sticking during compression. Advantages of direct compression include simplicity, reduced processing time, fewer stability problems, improved dissolution profile, and lower chances of drug degradation. However, the method requires powders with excellent flow and compressibility characteristics for successful tablet production. In the present study, Baclofen tablets were prepared using the direct compression method because of its simplicity, cost-effectiveness, and suitability for immediate release tablet formulation.

Procedure:

1. All the ingredients were weighed accurately by using an analytical balance.
2. Baclofen, MCC, Lactose and SSG were passed through a #60 mesh sieve.
3. Magnesium stearate and talc were passed through a # sieves 80 mesh sieve.
4. The sieved powders were mixed together properly in motar pestle.
5. HPMCE50 was added and mixed in it.
6. Lubricants were added and mixed gently for 2 -3 minutes.
7. The final blend was compressed by single punch tablet machine to obtain the tablets.

Baclofen:

Baclofen is a centrally acting skeletal muscle relaxant and a selective GABAB receptor agonist widely used in the treatment of muscle spasticity and neurological disorders. In recent years, Baclofen has gained significant attention for its role in the management of alcohol withdrawal syndrome and alcohol dependence. Chronic alcohol consumption alters inhibitory and excitatory neurotransmission within the brain, particularly affecting the gamma-aminobutyric acid (GABA) system. Sudden cessation of alcohol intake results in reduced inhibitory activity and increased neuronal excitability, leading to withdrawal symptoms such as anxiety, tremors, agitation, insomnia, and seizures. Baclofen acts by stimulating GABAB receptors present in the brain and spinal cord, thereby reducing the release of excitatory neurotransmitters and restoring inhibitory balance within the central nervous system. Due to this mechanism, Baclofen helps reduce alcohol craving, withdrawal severity, and relapse risk. Compared to conventional therapies, Baclofen has shown good tolerability and lower risk of dependence, making it a promising therapeutic option for alcohol withdrawal management (Addolorato et al., 2007). Chemically, Baclofen is a derivative of gamma-aminobutyric acid and is generally administered orally in tablet form. Immediate release tablets are commonly preferred because of their rapid onset of action, accurate dosing, patient compliance, ease of administration, and cost-effective manufacturing. The formulation of Baclofen tablets requires suitable pharmaceutical excipients to achieve adequate hardness, rapid

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disintegration, and effective dissolution profile. Therefore, the present research focuses on the formulation and evaluation of Baclofen immediate release tablets using the direct compression method for improved therapeutic effectiveness in alcohol withdrawal syndrome.

Microcrystalline Cellulose:

Microcrystalline Cellulose (MCC) is one of the most widely used pharmaceutical excipients in tablet formulation because of its excellent compressibility, flow property, and binding ability. It is a purified, partially depolymerized cellulose prepared from alpha-cellulose obtained from plant fibres. MCC is commonly used as a diluent and dry binder in tablet manufacturing, especially in direct compression formulations.

In immediate release tablet formulations, MCC improves powder flow and produces tablets with good mechanical strength and uniformity. Due to its porous nature and high surface area, MCC also promotes rapid water penetration into tablets, thereby supporting faster disintegration and dissolution. Among different grades, MCC PH102 is preferred for direct compression because of its larger particle size and improved flow characteristics.

MCC is chemically inert, non-toxic, and compatible with a wide range of active pharmaceutical ingredients. It also exhibits low moisture sensitivity, making it suitable for stable oral solid dosage forms. Because of these advantages, MCC was selected as a diluent in the present study for the formulation of Baclofen immediate release tablets.

Lactose Monohydrate:

Lactose monohydrate is one of the most commonly used pharmaceutical excipients in tablet and capsule formulations. It is a crystalline form of lactose containing one molecule of water and is widely used as a diluent or filler in oral solid dosage forms. Lactose monohydrate is preferred because of its good stability, compatibility with many active pharmaceutical ingredients, pleasant taste, and ease of processing.

In tablet formulation, lactose monohydrate increases the bulk of the tablet and helps achieve uniform tablet weight and content uniformity. It also improves powder flow and contributes to the overall compressibility of the formulation. Due to its water-soluble nature, lactose promotes rapid disintegration and dissolution of immediate release tablets, making it highly suitable for formulations requiring quick drug release.

Lactose monohydrate is chemically inert, non-toxic, and widely accepted for pharmaceutical use. It is commonly used in direct compression and wet granulation techniques because of its good blending properties and low cost.

Sodium Strach Glycolate:

Sodium Starch Glycolate (SSG) is a widely used pharmaceutical excipient employed as a super disintegrant in tablet formulations. It is a modified starch derived mainly from potato, wheat, or maize starch and is commonly used in immediate release tablets because of its rapid swelling property. SSG enhances tablet disintegration by absorbing water quickly and swelling extensively, which causes the tablet to break apart rapidly after administration.

SSG is highly effective at low concentrations, generally ranging from 2–8% of the total tablet weight. Due to its excellent swelling capacity and water uptake ability, it significantly improves the dissolution rate and bioavailability of drugs in immediate release formulations. SSG is compatible with a wide range of active pharmaceutical ingredients and is extensively used in direct compression and wet granulation methods.

In Baclofen tablet formulation, Sodium Starch Glycolate was used as a super disintegrant to promote rapid tablet disintegration and ensure faster drug release. Its inclusion in the formulation helps achieve immediate therapeutic action and improves the overall performance of the tablet dosage form.

HPMCE50:

Hydroxypropyl Methylcellulose (HPMC E5) is a semi-synthetic, non-ionic cellulose ether widely used in pharmaceutical formulations as a binder, film-forming agent, and release-modifying polymer. HPMC E5 belongs to the low-viscosity grade of HPMC and is particularly suitable for immediate release tablet formulations because it provides

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effective binding without significantly delaying drug release. HPMC E5 possesses excellent compressibility, compatibility, and stability, making it suitable for direct compression and wet granulation methods. It improves tablet cohesion and mechanical strength while maintaining rapid disintegration and dissolution characteristics. Due to its hydrophilic nature, HPMC absorbs water and forms a gel-like structure that supports uniform tablet integrity during manufacturing. In immediate release Baclofen tablet formulation, HPMC E5 was used as a binder to improve granule cohesion and tablet hardness while maintaining acceptable disintegration time and dissolution profile. The polymer is chemically inert, non-toxic, and widely accepted in oral solid dosage forms because of its safety and formulation versatility.

Magnesium Stearate:

Magnesium stearate is one of the most commonly used pharmaceutical excipients in tablet and capsule formulations. It is a fine white powder composed of magnesium salt of stearic acid and is mainly used as a lubricant during tablet manufacturing. Magnesium stearate reduces friction between the tablet material and the surfaces of punches and dies during compression, thereby preventing sticking, picking, and damage to tablets.

In tablet formulations, magnesium stearate improves powder flow and facilitates smooth ejection of tablets from the compression machine. It is generally used in low concentrations, usually between 0.25–5% of the total tablet weight, because excessive amounts may decrease tablet hardness and delay drug dissolution due to its hydrophobic nature.

Magnesium stearate is chemically inert, non-toxic, and compatible with most pharmaceutical ingredients, making it a widely accepted lubricant in oral solid dosage forms. In the present study, magnesium stearate was incorporated as a lubricant in Baclofen tablet formulation to improve flow characteristics and ensure efficient tablet compression without sticking or mechanical damage.

Talc:

Talc is a naturally occurring hydrated magnesium silicate widely used in pharmaceutical formulations as a glidant and anti-adherent. It is a fine, soft, white powder with excellent lubricating and flow-improving properties. In tablet manufacturing, talc helps reduce friction between powder particles and prevents sticking of granules to punches and dies during compression. Talc improves the flowability of powder blends, ensuring uniform die filling and consistent tablet weight. It also acts as an anti-adherent by preventing tablets from sticking to the surfaces of compression equipment. Due to its chemical inertness, non-toxicity, and compatibility with most active pharmaceutical ingredients, talc is commonly incorporated into oral solid dosage forms. In the present study, talc was used as a glidant in the formulation of Baclofen tablets to improve powder flow characteristics and facilitate smooth tablet compression. The use of talc contributed to uniform tablet formation and reduced manufacturing defects during compression.

Evaluation of Tablet:

Pre compression test:

Angle of Repose:

Angle of repose is an important pre-compression parameter used to evaluate the flow property of powder blends in tablet formulation. It is defined as the maximum angle formed between the surface of a pile of powder and the horizontal plane when the powder is allowed to flow freely through a funnel. The angle of repose provides information about interparticle friction and flow characteristics of powders. A lower angle of repose indicates excellent flowability, while a higher angle suggests poor flow property due to increased friction between particles. Good flowability is essential in tablet manufacturing to ensure uniform die filling, consistent tablet weight, and efficient compression. The angle of repose is commonly determined by the fixed funnel method. In the present study, the angle of repose was measured to assess the flow behaviour of the Baclofen powder blend before compression. The obtained value indicated satisfactory flow characteristics suitable for direct compression method.

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Interpretation Of Angle of Repose

Angle of repose	Flow property
<25°	*Excellent*
25-30°	*good*
30-40°	*Passable*
>40°	*Poor*

Table 1: *Angle of Repose.*

Bulk Density:

Bulk density is an important pre-compression parameter used to evaluate the flow characteristics and packing ability of powder blends in tablet formulation. It is defined as the ratio of the mass of powder to the bulk volume occupied by the powder before tapping. Bulk density provides information regarding the packing arrangement of particles and helps in determining the compressibility and flow behaviour of powders. A powder with good bulk density generally exhibits better flow properties, which is essential for uniform die filling and consistent tablet weight during compression. Bulk density is affected by particle size, shape, moisture content, and cohesiveness of the powder blend. It is commonly determined by pouring a known quantity of powder into a graduated measuring cylinder and measuring the volume occupied without tapping. In the present study, bulk density was evaluated to assess the flow behaviour of the Baclofen powder blend prior to compression. The obtained value indicated satisfactory flow property suitable for direct compression method.

Formula:

Bulk density=M/V

Where:

M=Mass of powder

V=Bulk volume of powder

Tapped Density:

Bulk density is an important pre-compression parameter used to evaluate the flow characteristics and packing ability of powder blends in tablet formulation. It is defined as the ratio of the mass of powder to the bulk volume occupied by the powder before tapping. Bulk density provides information regarding the packing arrangement of particles and helps in determining the compressibility and flow behaviour of powders. A powder with good bulk density generally exhibits better flow properties, which is essential for uniform die filling and consistent tablet weight during compression. Bulk density is affected by particle size, shape, moisture content, and cohesiveness of the powder blend. It is commonly determined by pouring a known quantity of powder into a graduated measuring cylinder and measuring the volume occupied without tapping.

In the present study, bulk density was evaluated to assess the flow behaviour of the Baclofen powder blend prior to compression. The obtained value indicated satisfactory flow property suitable for direct compression method.

Formula:

Tapped Density=M/V

Where:

M=Mass of powder

V=Tapped volume of powder

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Carr's Index:

Carr's Index, also known as Compressibility Index, is an important pre-compression parameter used to evaluate the flowability and compressibility of powder blends in tablet formulation. It is calculated using bulk density and tapped density values. Carr's Index provides information about the interparticle interactions and packing ability of powder particles. A lower Carr's Index value indicates good flow property and lower compressibility, whereas a higher value suggests poor flowability due to increased friction between particles. Powder blends with good flow properties ensure uniform die filling, consistent tablet weight, and efficient compression during tablet manufacturing. Carr's Index is widely used in pharmaceutical industries to assess the suitability of powders for direct compression method. In the present study, Carr's Index was determined to evaluate the compressibility and flow behaviour of the Baclofen powder blend before tablet compression.

FORMULA:

Carr's Index=Tapped density – bulk density/tapped density X 100

Interpretation of carr's index:

Carr's index (%)	Flow Property
5-15%	*Excellent*
16-20%	*Good*
21-25%	*Fair*
>25%	*Poor*

Table 2: *Carr's Index.*

Hausner Ratio:

Hausner Ratio is an important pre-compression parameter used to evaluate the flowability of powder blends in pharmaceutical formulations. It is calculated using the values of tapped density and bulk density. Hausner Ratio provides information about interparticle friction and powder cohesiveness, which directly influence powder flow during tablet manufacturing. A lower Hausner Ratio indicates better flow property, whereas a higher value suggests poor flowability due to increased friction between powder particles. Powder blends with good flow properties are essential for achieving uniform die filling, consistent tablet weight, and efficient compression during tablet production. Hausner Ratio is widely used in pharmaceutical industries along with Carr's Index to assess the suitability of powder blends for direct compression method. In the present study, Hausner Ratio was determined to evaluate the flow characteristics of the Baclofen powder blend prior to tablet compression.

Formula:

Hausner Ratio= Tapped density/Bulk density

Interpretation Of Hausner Ratio:

HAUSNER RATIO	FLOW PROPERTY
1.00 – 1.11	*Excellent*
1.12 – 1.18	*Good*
1.19 – 1.25	*Fair*
>1.25	*Poor*

Table 3: *Hausner Ratio.*

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Post Compression Test:

Weight Variation:

Weight variation test is an important quality control test performed to ensure uniformity of tablet weight within a batch. The test determines whether each tablet contains a uniform amount of active pharmaceutical ingredient and excipients. Uniform tablet weight is essential to maintain dose accuracy, therapeutic effectiveness, and patient safety. In this test, a specified number of tablets are individually weighed and the average tablet weight is calculated. The individual tablet weights are then compared with the average weight to determine the percentage deviation. Tablets that fall within the official pharmacopoeia limits are considered acceptable. Weight variation mainly depends on factors such as powder flow property, die filling efficiency, granule size, and compression process. Good flowability and uniform mixing of powder blends help achieve consistent tablet weight during manufacturing. In the present went study, the weight variation test was performed to evaluate the uniformity of Baclofen tablets prepared by direct compression method. The obtained results were found within acceptable pharmacopoeia limits, indicating proper mixing and compression of the formulation.

Pharmacopeial Limits:

Average Tablet Weight	Percentage Deviation Allowed
80mg or less	±10
80 – 250mg	±7.5%
More than 250 mg	±5%

Table 4: *Weight Variation.*

Procedure:

1. Select 20 tablets randomly from the batch.
2. Weight each tablet individually using the analytical balance.
3. Calculate the average weight of tablets'
4. Determine the percentage deviation of individual tablets from the average weight.
5. Compare the values with official pharmacopeia limits.

Formula:

Percentage Deviation = Individual weight – average weight/average weight X 100

Hardness test:

Hardness test is an important post-compression evaluation parameter used to determine the mechanical strength of tablets. It measures the ability of a tablet to withstand handling, packaging, transportation, and storage without breaking or cracking. Adequate tablet hardness is essential to maintain the integrity of the dosage form while ensuring proper disintegration and dissolution after administration. Tablet hardness is determined by applying force to a tablet until it breaks. The force required to break the tablet is recorded as the hardness value, usually expressed in kg/cm². The hardness of tablets depends on factors such as compression force, binder concentration, particle size, and formulation composition. In pharmaceutical industries and laboratories, hardness testing is commonly performed using instruments such as Monsanto hardness tester, Pfizer hardness tester, or digital hardness testers. For immediate release tablets, excessive hardness may delay disintegration and drug release, whereas very low hardness may result in tablet breakage during handling. In the present study, the hardness of Baclofen tablets was evaluated using a Monsanto hardness tester. The obtained hardness values were found within acceptable limits, indicating good mechanical strength and proper compression of the formulation.

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Procedure:

1. Randomly select 3–5 tablets from the batch.
2. Place one tablet between the jaws of the hardness tester.
3. Apply pressure gradually until the tablet breaks.
4. Record the hardness value shown on the scale.
5. Repeat the procedure for all selected tablets.
6. Calculate the average hardness value.

Formula:

Average Hardness = Sum of hardness values/number of tablets.

Friability Test:

Friability test is an important post-compression evaluation parameter used to determine the mechanical strength and resistance of tablets to abrasion, shock, and breakage during handling, packaging, transportation, and storage. The test measures the tendency of tablets to chip, crumble, or break under mechanical stress. Friability is usually expressed as the percentage weight loss of tablets after a specified number of rotations in a friabilator. Roche Friabilator is the most commonly used apparatus for this test. Tablets are rotated at a fixed speed, causing them to fall repeatedly from a certain height, which subjects them to mechanical stress. After completion of the test, tablets are reweighed and the percentage weight loss is calculated. A low friability value indicates good mechanical strength and durability of tablets. According to pharmacopoeia standards, friability of conventional tablets should generally be less than 1%. Excessive friability may result from insufficient binder concentration, low compression force, or poor formulation properties. In the present study, friability testing was performed to evaluate the mechanical resistance of Baclofen tablets prepared by direct compression method. The obtained friability value was found within acceptable pharmacopoeia limits, indicating satisfactory tablet strength and stability.

Procedure:

1. Select and weigh 10 tablets accurately (Initial weight = W1).
2. Place the tablets in Roche Friabilator.
3. Rotate the apparatus at 25 rpm for 4 minutes (100 revolutions).
4. Remove tablets, dedust them, and weigh again (Final weight = W2).
5. Calculate percentage friability.

Formula:

Friability (%) = W1 – W2/W1 X 100

Results Of Evaluation Parameters:

Evaluation Parameters	Results
Angle of repose	*26.5°*
Bulk density	*0.50g/ml*
Tapped density	*0.625g/ml*
Carr's index	*20%*
Hausner ratio	*1.25*
Weight variation	*200mg*
Friability	*0.46%*
Hardness	*5.04kg/cm2*

Table 5: *Result of Evaluation Parameter.*

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III. CONCLUSION

This study successfully created and evaluated quick release Baclofen tablets using the direct compression method. The generated formulation showed satisfactory pre-compression and post-compression qualities, including good flowability, compressibility, mechanical strength, and tablet uniformity. The results obtained for angle of repose, Carr's index, Hausner ratio, hardness, friability, and weight fluctuation were found to be within acceptable pharmacopeial standards, confirming the formulation's quality and stability. The addition of suitable excipients such MCC, lactose monohydrate, sodium starch glycolate, and HPMC E5 significantly improved tablet performance and rapid disintegration. Baclofen is a potentially useful therapy for alcohol withdrawal syndrome because of its $GABA_B$ receptor agonistic activity, which reduces neuronal hyperexcitability and withdrawal symptoms. Overall, the study demonstrates that direct compression fast release Baclofen tablets can provide a reliable, effective, and patient-friendly dosage form for treating alcohol withdrawal.

Ethics:

This study was a secondary analysis based on the currently existing data and did not directly involve with human participants or experimental animals. Therefore, the ethics approval was not required in this paper.

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Conflict of interest:

The author declares that there is no conflict of interest.

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Data Access:

The data that supports the finding of this study are available from the corresponding author upon reasonable individual request.

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