EJPMR, 2026, 13(7), 95-106 **Research Article** **Impact Factor: 8.158**

EUROPEAN JOURNAL OF PHARMACEUTICAL AND MEDICAL RESEARCH

www.ejpmr.com

ISSN (O): 2394-3211
ISSN (P): 3051-2573
Coden USA: EJPMAG

FOMULATION AND EVALUATON OF IMMEDIATE RELEASE TABLETS OF HIBISCUS ROSA –SINENSIS AND ACMELLA OLERACEA FOR DIURETIC ACTIVITY

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DOI: https://doi.org/10.5281/zenodo.21026637

How to cite this Article: Moikar Snehal Vishwanath*[1], Khaladkar Shraddha Madan[2]. (2026). Fomulation and Evaluaton of Immediate Release Tablets of Hibiscus Rosa -Sinensis And Acmella Oleracea For Diuretic Activity. European Journal of Pharmaceutical and Medical Research, 13(7), 95-106.

Article Received on 04/06/2026 **Article Revised on 25/06/2026** **Article Published on 01/07/2026**

ABSTRACT

The present study focuses on the formulation and evaluation of immediate release tablets containing extracts of Hibiscus rosa-sinensis and Acmella oleracea for assessing diuretic activity. Herbal extracts were selected based on their reported pharmacological potential, particularly the diuretic effect of Hibiscus rosa-sinensis, which has been shown to significantly increase urine output and electrolyte excretion in experimental models , and the diverse therapeutic properties of Acmella oleracea, including bioactive phytoconstituents with potential renal and systemic effects.Innovare Academics Journals. The prepared tablets were evaluated for physicochemical parameters including weight variation, hardness, friability, thickness, and disintegration time, ensuring compliance with pharmacopeial standards. In vitro dissolution studies confirmed rapid release of active constituents, indicating suitability of the formulation for immediate therapeutic action.The diuretic activity of the formulated tablets was evaluated using standard experimental models (e.g., Lipschitz test) by measuring urine volume and electrolyte excretion (Na^+, K^+, Cl^-) in treated groups compared to control and standard diuretics. The formulation exhibited significant, dose-dependent enhancement in urine output and electrolyte excretion, demonstrating comparable efficacy to standard drugs.

KEYWORDS: Immediate release tablets, Herbal formulation, Diuretic activity,Polyherbal tablets,Tablet formulation.

INTODUCTION

The use of medicinal plants for the treatment of various ailments has been an integral part of traditional healthcare systems worldwide. In recent years, there has been a growing interest in herbal medicines due to their perceived safety, effectiveness, and minimal side effects compared to synthetic drugs. Among these, plant-based diuretics have gained attention for their role in managing conditions such as hypertension, edema, and renal disorders. Diuretics are substances that promote the increased production of urine, thereby facilitating the removal of excess fluids and electrolytes from the body. Although synthetic diuretics are widely used, their prolonged use is often associated with adverse effects such as electrolyte imbalance and dehydration. This has led to a renewed focus on natural alternatives derived from medicinal plants. Hibiscus rosa-sinensis is a widely distributed ornamental plant known for its various pharmacological properties, including anti-inflammatory, antioxidant, and potential diuretic effects.

WHAT ARE DIUETICS?

Diuretics are a class of therapeutic agents that increase the rate of urine formation and promote the excretion of water and electrolytes, particularly sodium and chloride, from the body. They are commonly used in the treatment of conditions associated with fluid retention and elevated blood pressure, such as Hypertension, Heart Failure, edema, and renal disorders.

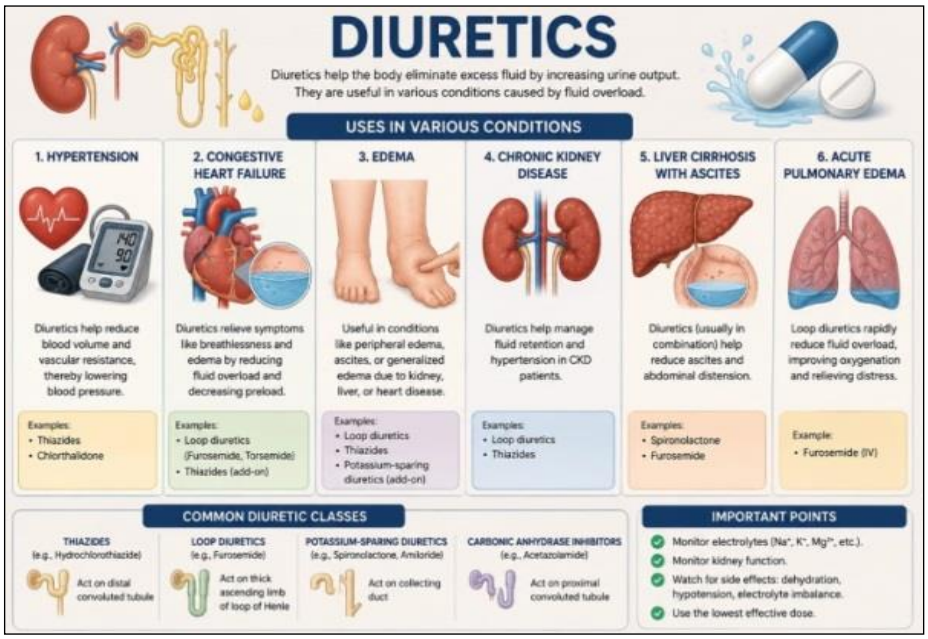


Figure 1: Diuretics in different conditions.

WHY SHOULD CHOOSE HERBAL OVER SYNTHETIC?

Synthetic diuretic drugs are widely used for the management of hypertension, edema, and renal disorders, but their prolonged use may produce adverse effects such as electrolyte imbalance, dehydration, and kidney dysfunction. Herbal medicines are gaining importance due to their comparatively safer profile and traditional therapeutic value. Although *Hibiscus rosa-sinensis* and *Acmella oleracea* have been traditionally reported to possess medicinal properties, limited scientific work has been carried out on the formulation of these herbal extracts into stable and effective immediate release tablet dosage forms for diuretic activity.

There is a need to develop a standardized herbal immediate release tablet containing extracts of *Hibiscus rosa-sinensis* and *Acmella oleracea* and to evaluate its physicochemical characteristics, drug release behavior, and diuretic potential. Therefore, the present research aims to formulate and evaluate immediate release tablets of these herbal extracts to establish their effectiveness and suitability as a natural diuretic formulation.

Pathophysiology Related to Immediate Release Diuretic Tablets

Diuretics are agents that increase the excretion of water and electrolytes such as sodium and chloride through the kidneys. Immediate release diuretic tablets are designed to disintegrate and release the active ingredient rapidly after oral administration, producing a quick onset of action.

Normal Physiology of Urine Formation

The kidneys regulate body fluid balance through filtration, reabsorption, and secretion in the nephron. Sodium and water are normally reabsorbed in different segments of the nephron to maintain electrolyte and fluid homeostasis.

Pathophysiology of Fluid Retention

Fluid retention occurs due to excessive reabsorption of sodium and water or impaired renal excretion. This condition is commonly associated with:

- Hypertension
- Congestive heart failure
- Renal disorders
- Liver cirrhosis
- Edema

In these conditions, increased sodium retention leads to water accumulation in tissues and blood vessels, causing swelling and elevated blood pressure.

Mechanism of Diuretic Action

Diuretics act by inhibiting sodium and water reabsorption in the nephron, resulting in increased urine output. Immediate release formulations rapidly dissolve in gastrointestinal fluids, allowing faster absorption and onset of pharmacological action.

For herbal formulations containing Hibiscus rosa-sinensis and Acmella oleracea, phytoconstituents such as flavonoids, alkaloids, tannins, and phenolic compounds may contribute to:

- Increased renal blood flow
- Inhibition of tubular sodium reabsorption
- Enhanced glomerular filtration
- Increased excretion of sodium and water

PLANT PROFILE

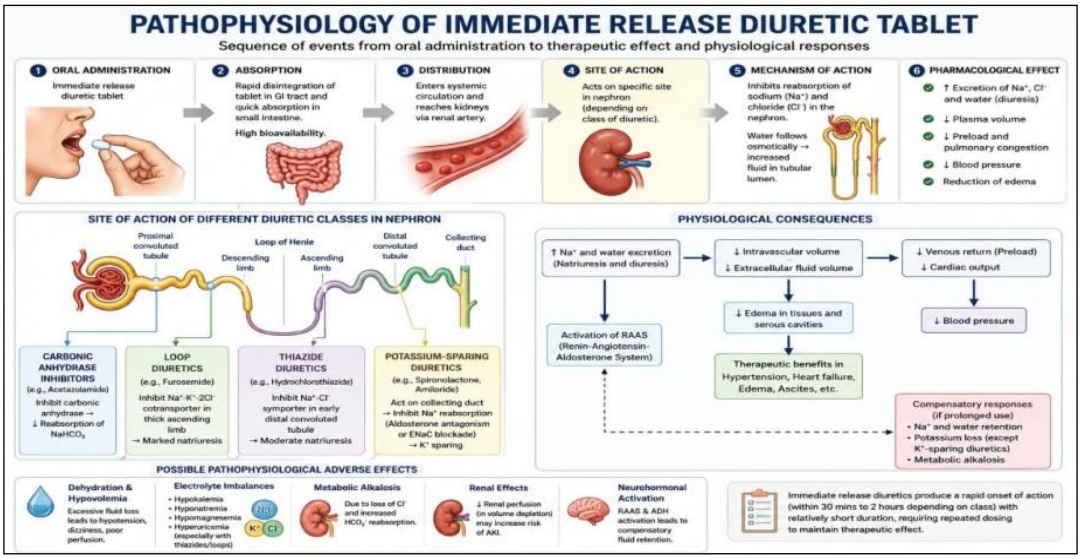


Figure 2: Pathophysiology of Immediate Release Tab.

1. HIBISCUS ROSA SINESIS

INTRODUCTION

Hibiscus rosa-sinensis is a flowering medicinal plant belonging to the family **Malvaceae**. It is commonly known as **Chinese hibiscus** or **shoe flower**. The plant is widely distributed in tropical and subtropical regions and is traditionally used in herbal medicine for various therapeutic purposes.

Figure 3: Hibiscus rosa sinesis.

Table 1: Biological Profile Of Hibiscus Rosa Sinesis.

SR.NO	CHARACTERISTICS	INFORMATION
1.	Common name	Rosella, Jamaican sorrel, florida cranberry, red sorrel karkde, gongura, zobo bissap
2.	Family	Malvaceae(mallow family)
3.	Major active compound	Orgaic acids, anthocyanins, flavonoid and polyphenols, polysaccharides, vitamins, other component.
4.	Growth rate	Fast
5.	Medicinal uses	High in vitamin c, antioxidents, used to lower blood pressure support liver health And act as a diuretic.
6.	Diuretic mechanism	Act as diuretic primarily by inhibiting the reabsorption of

2. ACMELLA OLEARACEA

INTODUCTION

Acmella oleracea is a medicinal herb belonging to the family **Asteraceae**. It is commonly known as the **toothache plant** or **paracress** because of its traditional use in relieving toothache and oral discomfort. The plant is widely used in traditional medicine due to its diverse pharmacological properties.

Figure 2: Acmella Oleracea.

Table 2: Biological Profile of Hibiscus Rosa Sinesis.

SR.NO	CHARACTERISTICS	INFORMATION
1.	Common name	Toothache Plant, Spilanthes, Para Cress
2.	Family	Asteraceae
3.	Part used	Flower heads, Leaves, Aerial parts
4.	Major active compound	Spilanthol (an alkylamide)
5.	Other constituent	Flavonoids, Tannins, Sterols
6.	Diuretic mechanism	Increases excretion of Sodium (Na^+) and Chloride (Cl^-)

CHEMICAL CONSTITUENT

1. HIBISCUS ROSA SINESIS

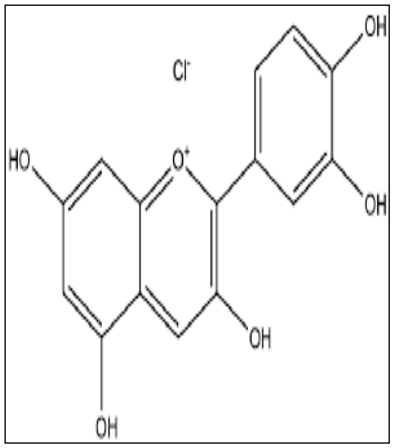


Figure 5: Quercetin.

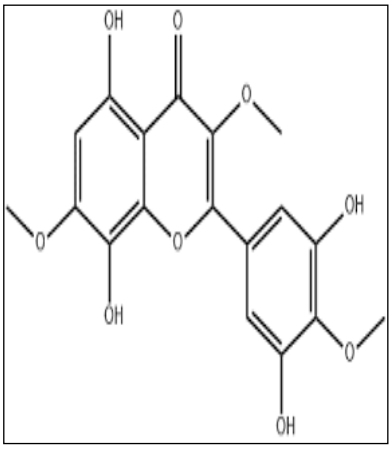


Figure 5: Anthocyanin.

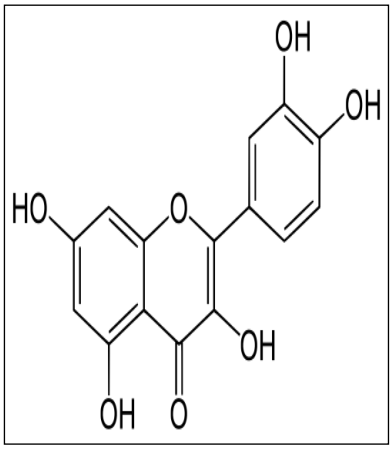


Figure 7: Hibiscetin.

EVIDENCE SUPPORTING DIURETIC ACTIVITY

Rats were adrenalectomized (ADX) under surgical anesthesia with sodium pentobarbital (55 mg/kg). A 2-cm incision was made at the costoventral angle, and the left and right adrenal glands were removed without exposing the kidney. The complete gland was excised together with the adjacent fat and the mesenteric junction. The rats were placed on a normal diet and 1% saline solution

FORMULATION CONSIDERATION OF HIBISCUS ROSA SINESIS AND ACMELLA OLERACEA IMMEDIATE RELEASE TAB

- Extaction of plant material
- Physiochemical screening of extract
- Fomula fo batches
- Wet granulation process

- The standardized solid powder extracts of Hibiscus rosa-sinensis and Acmella oleracea employed in the formulation study were procured online from Sai Herbs.(KR Impex Enterprises (Sai Herbs) Gulmarg Avenue, Amritsar Punjab India

- **PHYSIOCHEMICAL SCREENING OF EXTACT**

Requirements	
Chemicals	**Aparatus**
Ethanol, magnesium turning, concentrated HCL, NAOH, Dil.HCL, Fecl3, lead acetate solution, distilled water conc.H2SO4.	Test tubes, test tube stand, beaker, burner, spatula, weighing balance

TEST FO ACMELLA OLEACEA EXTACT

Table 3: Preliminay Test.

Sr.No.	Test	Procedure	Positive result
1.	SHINODA TEST	Add small quantity of extact to ethanol and then add mg turning and few dop of conc. Hcl	Pink, cimson or reddish color appears
2.	DRAGONDROFF TEST	2ml of extract add few drops of reagent	Orange or reddish brown ppt
3.	FECL3TEST	Add 2-3 drops of 5%Fecl3 solution to extract	Deep blue green or black coloration
4.	LEAD ACETATE TEST	Add few dop of 10%lead acetate solution	Formation of bulky white ppt

Figure 6: Shinoda Test.

Figure 7: Dagondroff Test.

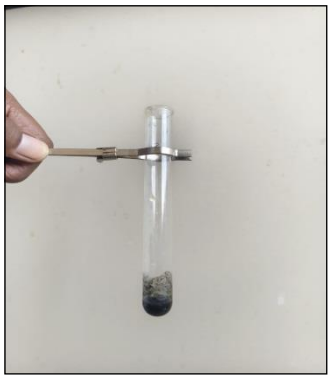


Figure 8: Fecl3 Test.

Figure 9: Lead Acetate Test.

TEST FO HIBISCUS EXTRACT

Table 4: Preliminay test of acmella oleracea extract.

sr.no.	Test	Procedure	Positive result
1)	SHINODA TEST	Add small quantity of extact to ethanol and then add mg turning and few dop of conc. Hcl	Pink, cimson or reddish color appears
2)	NAOH TEST	Add 2ml NAOH to the extract	Blue green coloration develops
3)	FECL3TEST	Add 2-3 drops of 5% Fecl3 solution to extract	Deep blue green or black coloration
4)	LEAD ACETATE TEST	Add few dop of 10% lead acetate solution	Formation of bulky white ppt

Figure 10: SHINODA TEST.

Figure 11: NAOH TEST.

Figure 12: FECL3 TEST.

Figure 13: LEAD ACETATE TEST

OBSERVATION

TEST	CHEMICAL CONSTITUENT IDENTIFIED	HIBISCUS EXTACT	ACMELLA EXTRACT
Dragondroff Test	Alkaloid	Present (+)	Present (+)
NAOH Test	Flavanoid	Present (+)	Present (+)
Fecl3Test	Phenol and Tannin	Present (+)	Present (+)
Lead acetate test	Flavonoid and Tannin	Present (+)	Present (+)

FOMULA FOR BATCHES

Table 5: FORMULA TABLE.

Sr.no	Ingredient	Role of ingredient	Batch 1(in gram)	Batch 2(in gram)	Batch 3(in gram)
1)	Hibiscus extract	Active ingredient	15g	20g	25g
2)	Acmella oleracea extract	Active ingredient	15g	10g	5g
3)	Guar gum	Binder	16g	16g	16g
4)	Starch	Diluent ,disintegant	2.5g	2.5g	2.5g
5)	Acacia gum	Binder	1g	1g	1g
6)	Talc	Glident	0.3g	0.3g	0.3g
7)	kaolin	Adsobants	0.2g	0.2g	0.2g
8)	Total		50g	50g	50g

WET GRANULATION PROCESS

Requirements	
Chemicals	**Aparatus**
Hibiscus extract	Beaker,
Acmella oleracea extract	Petry plate, hot air oven,
Guar gum	Sieve no.60,80,22
Starch	Mortor pastle
Acacia gum	Tablet compression machine
Talc	Stirrer
kaolin	weighing balance

Figure 16: SOLID EXTRACT.

Figure 17: INGREDIENTS.

Step 1: Pass all the ingredient form the sieve number #60and talc from #80.

Figure 14: SIEVING.

Step 2: Transfer the following ingredient into the mortor or blender.

- Hibiscus extract
- Acmella oleacea extract
- Guar gum
- Starch
- Kaolin

Blend for 10-15 min to obtain unifom mixture.

Figure 15: MIXING ALL INGREDIENT.

Step 3

- Preparation of binder – 1gram of acacia gum in approximately 10ml purified water .(granulating fluid)
- Add above binder solution slowly to the mixture .

Step 4

- Produce wet granules passing through sieve number #16 0r #20.

Figure 16: Peperation Wet Granules.

Step5: Drying granules in hot air oven at 40-50 degree celcius for 2-4 hrs or until the moisture content is 3-5%

Figure 17 DRYING GRANULES.

Step 6

- Pass the ganules though the sieve no 20 and 22 and break lumps and obtain uniform granule size.

Figure 18 RECIEVING PROCESS.

Step 7: after the sieving mix uniformly in mortor fo 10-15 min and add the talc and blend gently for the 3-5 min

Figure 19: MIXING.

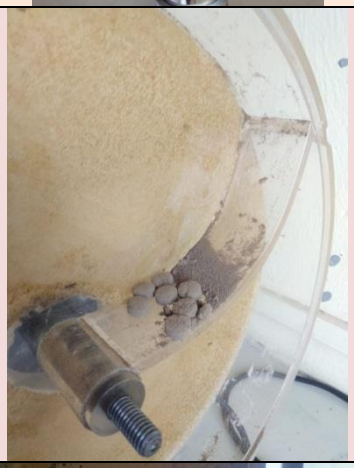
Step 8: Compression of above mixture to make immediate release tab in tablet compression machine

Figure 20: Tablet Compression.

EVALUATION PARAMETE OF IMMEDIATE RELEASE TAB

Table 6: Evaluation Paameters.

Sr.no.	Test	Procedure	Performed test
1.	**Appearance**	Color, shape, odor, surface texture, defects.	
2.	**Thickness**	• Randomly select **3 to 10 tablets** from each batch. • Clean the tablet surface to remove any dust particles. • Measure the thickness of each tablet using a **Vernier caliper** or **digital thickness gauge**. • Place the tablet between the two jaws of the instrument carefully without applying excessive pressure. • Record the thickness reading in **millimeters (mm)**. • Repeat the procedure for all selected tablets. • Calculate the average thickness and standard deviation.	
3.	**Weight Variation Test**	• Randomly select **20 tablets** from each batch. • Clean the tablets to remove dust particles. • Weigh all 20 tablets together using a digital weighing balance and calculate the average weight. • Weigh each tablet individually and record the weights. • Compare the individual tablet weights with the average tablet weight. • Calculate the percentage weight variation for each tablet.	

4.	**Hardness Test**	Select 3–6 tablets randomly. Place one tablet in the hardness tester. Apply pressure until the tablet breaks. Record the hardness value. Repeat for all tablets and calculate the average hardness.	
5.	**Friability Test**	Weigh 10 tablets accurately (Initial weight = W_1). Place the tablets in a Roche friabilator. Rotate the friabilator at 25 rpm for 4 minutes (100 rotations). Remove tablets, dedust, and weigh again (Final weight = W_2). Calculate percentage friability.	
6.	**Disintegration Test**	Place one tablet in each tube of the **disintegration apparatus**. Fill the vessel with distilled water maintained at **37 ± 0.5°C**. Start the apparatus and allow the basket to move up and down. Observe the time taken for complete disintegration of tablets. Record the disintegration time for each tablet.	
7.	**Diameter**	Take 3–10 tablets randomly. Measure diameter using Vernier caliper. Record readings in mm. Calculate average.	

OBSERVATION

Table 7: Evaluation Paameter Result.

Sr.no	Test	Standard ranges	Batch 1	Batch 2	Batch3
1.	Appearence	Uniform and defectfree	Smooth,uniform reddish brown tablet	Smooth and uniform	Minor roughness
2.	Thickness	4.5-5.5mm	4.5-5.5mm	4.5-5.5mm	4.5-5.5mm
3.	Diameter	10mm	10mm	10mm	10mm
4.	Hardness	5-7Kg/cm2	5.8+/-0.2	5.2+/-0.3	4.4+/-0.4
5.	Weight variation	475-525(+/-5%)	498+/-3	501+/-2	505+/-4
6.	Friability	NMT 1%	0.42%	0.58%	0.86%
7.	disintegration	NMT 15 min	5.2min	6.8min	9.5min

According to above table, All formulations exhibited acceptable post-compression characteristics within pharmacopeial limits. Among the prepared batches, F2 demonstrated optimum tablet properties with satisfactory hardness, low friability, uniform appearance, and rapid disintegration behavior.

RESULT

The present study was carried out to formulate and evaluate immediate-release polyherbal tablets containing extracts of Hibiscus rosa-sinensis and Acmella oleracea. Different formulations were prepared by varying the concentration of the herbal extracts while maintaining a constant tablet weight of 500 mg.

Preformulation studies confirmed acceptable physicochemical properties of the extracts. Phytochemical screening revealed the presence of flavonoids, alkaloids, tannins, saponins, glycosides, and phenolic compounds, which are reported to possess diuretic potential. Compatibility studies indicated that the extracts were compatible with the selected herbal excipients.

The prepared tablets were evaluated for post-compression parameters including appearance, weight variation, hardness, friability, and disintegration time. All formulations complied with acceptable pharmacopeial limits for immediate-release tablets. The formulations showed satisfactory mechasnical strength, acceptable friability, uniform weight variation, and rapid disintegration characteristics.SSS

Among all formulations, F2 showed optimum tablet characteristics with acceptable hardness, low friability, and satisfactory disintegration time. The formulation also exhibited good immediate-release properties.

CONCLUSION

The present study successfully formulated immediate-release polyherbal tablets containing Hibiscus rosa-sinensis and Acmella oleracea extracts using herbal excipients. The prepared formulations showed satisfactory physicochemical and post-compression evaluation parameters within acceptable limits for immediate-release tablets.

Phytochemical screening confirmed the presence of bioactive constituents associated with diuretic potential. Among the formulations, F2 demonstrated optimum tablet properties and was considered the optimized formulation.

The study suggests that the formulated polyherbal tablets may possess potential diuretic activity due to the presence of phytoconstituents reported in the selected medicinal plants. However, further pharmacological studies are required to confirm the diuretic activity experimentally.

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