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RESEARCH ARTICLE

ORAL RECONSTITUTABLE HERBAL DRY SYRUP: FORMULATION, DEVELOPMENT AND ASSESSMENT

Anukriti Gupta[1]*, Dr. J.N. Mishra[2], Mr. D.K. Vishwakarma[2] and Mr. Chitranshu Pandey[3]

1. Student, Kailash Institute Of Pharmacy & Management, Gida, Gorakhpur.
2. Faculty, Kailash Institute Of Pharmacy & Management, Gida, Gorakhpur.
3. MRD Life Sciences Pvt. Ltd., Lucknow.

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Abstract

The ease of administration, patient comfort, and formulation stability are all advantages of the oral dose form. Tablets and capsules are the most popular oral dosage forms; nevertheless, one notable disadvantage of these solid dosage form is the trouble in ingesting them, especially when a supplement is designated for children or the elderly. The disease TB(Mycobacteriae) had antibiotics and one of those is levofloxacin that is used in the cure this Mycobacteria. Levofloxacin is a broad-spectrum antibiotic that develop Multi Drug Resistance (MDR) in our body. So, in order to modify this treatment of MDR, herbal drugs are implemented in the drug for better working of the antibiotic. Herbal medications, whether extract or decoction, will not induce drug resistance when administered against any infection. Hence an effective ad appropriate drug therapy as an anti – tuberculosis drug needs to be discovered which will solve the problem of cross resistance and drug resistanceThe goal of this research was to build and create an oral Reconstitutable Herbal Dry Syrup that can be readily dispersed in a potable water medium before usage and is chemically and microbiologically stable throughout consumption. This herbal drug is anti-infective, anti-hepatotoxic and anti-inflammatory, cholagogue etc.There was no discernible difference in particle size, fluidity, pH, or drug content after 15 days of testing. After employing Reconstitutable water with levofloxacin herbal dry syrup, the stability was effectively evaluated.

Introduction:-

Dry syrups are solid dose forms that may be reconstituted with water and administered orally. Dry syrup is used to provide antibiotics, as well as some moisture fragile and paediatric medications. Many preparations, such as Amoxicillin trihydrate, Erythromycin ethyl succinate, Dicloxacillin sodium, and others, are accessible as dry powder mixtures or granules that really should be suspended in water or perhaps another vehicle before being administered orally.When medication stability is a critical concern, the reconstitution framework is the composition of choice. The dry mixture of oral suspension comprises medicine, as well as any colourants, tastes, sweeteners, stabilising agents, suspending agents, and preservation agents that may be required to improve the formulation's stability.

Corresponding Author:- Anukriti Gupta
Address:- Student, Kailash Institute Of Pharmacy & Management, Gida, Gorakhpur.

Because the medicine is disseminated at the moment of delivery, the dry syrup form has higher bioavailability than tablets and capsules.

Despite the fact that tests have shown that the dry oral suspension be consumed straight away after the constitution in a liquid since the suspension is stable for up to 24 hours after preparation.

As a result, any medicinal formulation with a pleasant taste would be favoured over a competitor's product, resulting in higher patient compliance and therapeutic benefit, as well as increased sales and profits for the corporation. Many formulations with better performance and ical durability of the active components until reconstituted at the start of treatment have been developed in response to the quest for increased palatability in these products. By modifying the volume to swallow, the same suspension may be simply delivered to children of various ages.

Fluoroquinolone use has increased dramatically since the introduction of the first respiratory fluoroquinolone in the late 1990s. Levofloxacin, like other fluroquinolones, is a potent antibiotic due to widespread resistance among Gram-negative, atypical bacteria, and Gram-positive (including penicillin-resistant forms of Streptococcus pneumonia) . Because of its great safety, tissue penetration , and bioavailability, sufficient doses of levofloxacin can be kept at the infection site. High-dose (750 mg), short-course (5 days) therapy regimens may provide successful treatment, particularly in HAP, due to higher drug concentrations, improved adherence, and the potential to reduce resistance development. The mere thought of such medical practice conjures up an image of a medicine man with walls filled with shelves of herbal tinctures, extracts in brown bottles of various sizes, ointments, powders made with mortar and pestle, creams and lotions.

This research paper relates to dry syrup formulation. Thisparticularly relates to dry syrup formulation using ayurvedic/ herbal ingredients or extracts for the treatment of different disease conditions specifically respiratory tract infection (RTI).

Cough is a reaction that is intended to protect the respiratory system from any irritating factor.But natural products do not have harmful effects and can be an effective remedy for a variety of coughing. In this research paper, we will introduce you remedies for coughing, especially dry coughs. This will introduce a new way of looking for the introduction of natural products, Home Remedies for Dry Cough (blood cough), as well as Tuberculosis.

Process of Development of dry syrup

A) Powder mixture:

Powder mixture, also known as powder mixes, are made by powdering the dry mixture's excipients. Small amounts of excipients may necessitate two mixing steps. To help in dispersion, such excipients might be used with a little amount of a large excipient. Milled sucrose, for example, has a wide surface area that allows modest amounts of flavour oils to be absorbed. Mixing the remaining excipients is the second stage. The most important factor to consider when choosing a suitable mixer is that it must generate a homogeneous mixture quickly and consistently.

B) Granulated products:

Granulation is used to break down all excipients in granulated goods. The most common granulation method uses water or maybe a hydrophilic binder solution as the granulating fluid. Incorporating the medication can be done in two different ways. Drugs may be dry-mixed with other excipients, or they may be suspended or dissolved in the granulating fluid. Following are the steps involved in wet granulation. Non-aqueous granulating liquids can be utilised for medications that are hydrolysed. In a fluid bed drier or atray oven. To break up or eliminate granule aggregates, the desiccated granules are screened in a vibrating sieve or oscillating screen.

C) Combination products:

To alleviate the shortcomings of granular goods, granular and powdered excipients might be blended. If the majority of the dissolution medium are added post granulation, less granulation energy and apparatus may be required.Before filling the containers, part of the excipients is granulated first, then the other excipients are blended with the dry granules. The presence of diluents aids flow by reducing segregation and the production of dust.

Material & Methodology:-

Material:-

Plant Sample Collection

CIMAP, Lucknow-226015, Uttar Pradesh, India, has certified the plant material.

The authors chose Zingiber officinale (Ginger) rhizomes and Eugenia Caryophyllus (Clove) buds for antimicrobial and phytochemical examination using plant materials obtained from various locations around MRD life science laboratory Lucknow.

Chemicals

Auantor Performance Material India Limited provided Methanol, Petroleum ether, acetone, chloroform, DMSO, Sodium Carboxymethyl cellulose, and Sodium benzoate. Similarly, Kashyap Sweeteners Ltd bought Sorbitol, Sucrose, and Mannitol. Additionally, Cipla provided the Levofloxacin medication, and Titan Biotech Ltd. provided Nutrient Broth, Nutrient Agar, Agar-Agar, and Micro press a division of Tulip Diagnostic Ltd. provided Blood Agar.

Microorganism

Mycobacterium tuberculosis (MTB) pure culture is prepared in MRD Life Science Ltd.

Methodology:-

Preparation of Plant Extract

The sections of plants were separated using dried rhizomes of Zingiber officinale and dried flower buds of Eugenia caryophyllus. They were cleaned and dried in the sun, then dried in a hot air oven for 5-6 days. Finally, the dry sample was crushed and pulverised into powder form. To correctly weigh 5-grams of spice powder and macerate with the appropriate solvent (methanol, acetone, ether, chloroform (70%) and water (100%) for 72-84 hours. A 1:10 ratio was maintained between the sample and the solvent. After that, filter the extract using Whatmann No. 1 filter paper. The solvents would then be partly evaporated at 802°C to get the filtrate residue.

Phytochemical Screening

In 50 ml of methanol and water, 5 gm of extract powder was dissolved. The water filtrate was maintained on a warm liquid bath at 75°C to concentrate the product, which was then filtered to eliminate waste and stored in a freezer at 4°C until use. The extract was qualitatively tested for various phytochemical compound like tableno.

Table no.1:- Photochemical Analysis.

S. No.	**Phytochemicals**	**Chemical Test**	**Inference**
1	Alkaloid	Meyer's Test	White ppt.
2	Flavonoid	Alkaline reagent Test	Colorless
3	Saponin	Froth Test	1 cm foam formation
4	Phenol	Ferric Chloride Test	Blue – green color
5	Carbohydrate	Fehling's Test	Red color ppt.
6	Tannin	Ferric Chloride Test	Blue -green color
7	Steroid	Salkowoski Test	Green/light green ppt.
8	Amino Acid	Ninhydrin Test	Blue/purple color
9	Cardiac Glycoside	Ferric Chloride Test	Reddish – brown layer
10	Terpenoid	Salkowoski Test	Reddish – brown ppt.

Inoculum Preparation

1. Take 0.65 g NB in a beaker and dissolved in 30 ml and adjusted the volume till 50 ml with distilled water
2. Transferred the NB in the test tubes and sealed them with cotton plug and wrapped with the silver foil and placed in autoclave (121^{o}C for 15 min. at 15 psi) for sterilization
3. Take the test tubes in the Laminar Air Flow and the sub culturing of the bacteria was done there
4. Again sealed the test tubes with the cotton plug and kept them in the incubator at 37^{o}C for 24 hrs.

Extract Antimicrobial Sensitivity Testing by Well Diffusion method

Bacteria (MTB) were inoculated using 20 ml spreading on agar plate with the use of sterile cotton swab after poured agar medium (20 ml) in single sterile Petri plate. In an agar plate, make a well (approximately 6mm) with the use of

micropipette tips. In the well, 45 liters of extract with concentrations of 50, 70, 60, and 100 mg/ml were poured. As controls, 45 microliters of 100% distilled water, methanol, and 10% acetone were employed. After that, the plates were incubated at 37°C for 18-24 hours.With the use of a Transilluminator, the width of the inhibition zones was measured and recorded in mm to assess the antibacterial property.

ANTIMICROBIAL SENSITIVITY TESTING			
	parts of plants	Extract	Mycobacterium Tuberculosis (ZOI)
	CLOVE(BUDS)	Ether 70%	31.24mm
		Methanol 70%	34.69mm
		Acetone 70%	31.24mm
	GINGER(RHIZOME)	Methanol 50%	25.73mm
		Acetone 70%	36.52mm
		Ether 60%	34.67mm
		distilled water 100%	15,63mm

Table no. 2:- AST of Zinger Offlicinale &Eugenia caryophyllus extract.

Formulation of Levofloxacin herbal dry syrup

Dried extract of each herb was passed through 100 mesh sized sieve. The sieved powders of all extracts are taken 1:1 (w/w) at concentrate and all extracts are mixed in a mass mixer at 25rpm for 20 minutes to uniform mixing.

The different binding and stabilizing agents like cellulose derivatives, starches and natural gum were used along with different concentration of herbal extract blend as actives, sorbitol and sucrose as base as given in table 2. The dry mixture of ingredients was dissolved in cold and warm drinking water separately. The rapid dissolving of dry powder in warm drinking water was noticed. When comparing cold water to pre-boiled warm water, the prepared syrup was shown to be more stable.

Table no. 3:- Formulation of Herbal Dry Syrup.

	EXCIPIENTS										
Formulation	Method	Herbal extract	Levofloxacin	Methanol	Sodium carboxymethyl cellulose	Mannitol	Sucrose	Potato starch	Sorbitol	Sodium benzoate	distilled water
F1	Dry granulation	0.1gm	200mg	1 ml	9.0 ml	10 ml	13 ml	-	-	-	5 ml
F2	Powder blend	0.4gm	200mg	-	0.7gm	-	2.0gm	0.6gm	2.0gm	0.1gm	-
F3	Powder blend	0.4gm	200mg	-	0.80gm	-	4.0gm	0.8gm	4.0gm	0.1gm	-
F4	Powder blend	0.4gm	200mg	-	0.8gm	-	5.0gm	0.10gm	1.0gm	0.2gm	-
F5	Powder blend	04gm	200mg	-	0.10gm	-	7.0gm	0.12gm	3.0gm	0.4gm	-
F6	Powder blend	0.5gm	200mg	-	0.11gm	-	8.0gm	o.13gm	4.0gm	0.50gm	-

Evaluationparameters

Prestudies Of Powder Blends

Bulk density-

Bulk density is the ratio of a given quantity of powder or granules to the bulk volume of the powder or granules. The granules were accurately weighed and carefully put into a 100ml measuring cylinder, where the starting quantity was determined and computed using the equation

Bulk density = Mass / Volume

Tapped density-

The ratio of a given quantity of powder or granules to the continuous or unchanging capacity of the particle following tapped is known as tapped density. A powdered cylinder with a known mass of granules is put in front of a mechanical tapper, which is operated for a predetermined number of taps until the powder bed capacity reaches a minimum volume. The tapped density can be calculated by multiplying the quantity of the grains in the cylinder by the minimal volume.

Tapped density = Weight granules / Tapped volume of granules

Angle of Repose-

The peak angle potential here between surface of the powder pile and the horizontal plane is defined as angle of repose. To investigate the flow property of the powder or granules, the angle of repose of the powder or granules was computed using the fixed funnel method. The varying angles of friction and reactivity illustrate how stresses are carried through some type of bead and how the beads respond to applied tension.Angle of repose is the most apparent example, which may be calculated analytically using a variety of methods. Pouring powder into a conical form on a straight, level surface and measuring the angle with the horizontal are used to compute the angle of repose.

$$\theta = \tan^{-1}(h/r)$$

Carr's index (CI)-

The comparative flow rate, cohesiveness, and particle sizes of the powder are all indirectly related to compressibility. Powders having compressibility values of less than 20% have been discovered to have good flow characteristics. The compressibility of a material may be estimated using tapped (pt) and apparent (pb) bulk density measurements.

$$\text{Carr's index} = (pt - pb) \times 100$$

Evaluation Of After Recostituable Oral Suspension

Organoleptic evaluation:

Visual and olfactory tests were performed on the formulation.

1) Flow properties:

The dry syrup formulation's angle of repose and Hausner's ratio were established. The dry syrup composition was reconstituted by filling the bottle with distilled water up to the 30 ml mark. The ingredients were well combined by shaking, placed into a measuring cylinder, and evaluated on days 1, 2, 3, 5, 7, and 11 after reconstitution.

2) Rheological behaviour:

The Brookfield viscometer is used to determine the rheological properties of the reconstituted solution.

3) Deposit behaviour:

a) Redispersibility:

Within a week of seven days of storage, the Redispersibility of a preparation is determined by measuring the number of strokes necessary to redisperse the created sediment. (not more than 100 strokes = Redispersibility).

b) Sedimentation Volume Ratio (SVR):

The sedimentation volume of suspension is simply the ratio of the balance capacity of the sediment, Vu, to the overall volume, Vo, of the suspension, i.e., F= Vu/Vo. For any pharmacological solution, F is usually between 0 and 1. The F value gives qualitative information regarding the suspension's physical stability.

4) Drug content:

With 100ml liquid, the required amount of medicine combination is separated and filtered through a nylon filter membrane. UV Spectroscopy is used to measure the absorbance of the solution, which is diluted to filtered water using solvent. The drug concentration is calculated using the solvent calibration graph.

5) pH values:

A pH metre was used to determine the pH of the suspension.

6) Particle size:
The average crystalline size of the Oral Reconstitutable Suspension is studied using a conventional microscopy method.We determine the average standard deviation of 100 particles.

7) Stability:
The reconstituted suspension is stored in sealed amber-colored glass vials at 45°C for 36 days before being reassembled with filtered water to a level of 60 ml with mild agitation. For 15 days, the reassembled suspension is held at 4°C, 25°C, and 45°C.

8) In-vitro drug release:
The in vitro dissolution tests were performed at 100 rpm with a USP equipment Type II. 900 mL liquid was used as the dissolving media, which was kept at 37°C + 0.50 C. A UV spectrophotometer was used to monitor drug release at various time intervals throughout a two-hour period.

Result:-

Phytochemical Screening

Phytochemical Screening of Ginger (Zingiber officinale)

Extract	Alkaloids	Flavonoids	Phenol	Carbohydrate	Tannin	Amino acid	Saponin	Cardiac glycoside	Terpenoid	
Methanolic	+	+	-	+	+	+	-	-	+	
Hot water	+	+	-	+	+	-	+	-	-	

Phytochemical Screening Clove (Eugenia caryophyllus)

Extract	Alkaloids	Flavonoids	Phenol	Carbohydrate	Tannin	Amino acid	Saponin	Cardiac glycoside	Terpenoid	
Methalolic	-	-	+	+	+	-	-	+	+	
Hot water	+	+	-	-	+	-	+	-	-	

Table no. 4:- Phytochemical Analysis of Zingiber officinale & Eugenia caryophyllus.

Organoleptic properties of formulation

Formulation	Colour	Odour	Appearance
F1	White	Herbal characteristics	powder
F2	White	Herbal characteristics	Powder
F3	White	Herbal characteristics	Powder
F4	White	Herbal characteristics	Powder
F5	White	Herbal characteristics	Powder

Table no. 5:- Formulation's organoleptic qualities.

Evaluation of taste masked oral Reconstitutable system

Formulation	Bulk density	Tapped density	Angle of repose
F1	0.324	0.470	21.09
F2	0.355	0.456	21.86
F3	0.347	0.435	21.64
F4	0.313	0.476	21.76
F5	0.367	0.433	21.44
F6	0.385	0.496	21.87

Table no. 6:- Flow characteristics of taste-masked powder mixes containing a variety of different evaluations.

Different quantities of all components were used to make dry syrup using the powder mix technique. Various experiments were conducted on formulations F1-F6, including bulk density (0.32 to 0.38), tapped density (0.43 to 0.49), and angle repose (25.67o), with all of the results indicating satisfactory flow.

Figure 1:- Flow characteristics of powder mixes of formulations F1-F6.

Parameters of taste masked oral Reconstitutable suspension

Formulation	Average particle size	viscosity	pH	Redispersibility	Sedimentation
F1	14.5	248cps	6.3	12	0.51
F2	16.2	322cps	6.1	9	0.54
F3	15.8	596cps	6.1	14	0.50
F4	17.6	789cps	6.3	8	0.53
F5	20.91	887cps	6.1	10	0.52
F6	18.1	1235cps	6.3	6	0.56

Table no. 7:- Taste masked oral Reconstitutable suspension.

The size of the particles of the flavour masked regenerated dry syrup was (14.5 to 20.91), and the viscosity of the flavor masked regenerated dry syrup was (14.5 to 20.91). (248 to 887cps). For all formulations, the sedimentation flavour concealed of the regenerated dry syrup ranged from (0.51 to 0.56). All of the formulations' pH levels were within the acceptable limit (6.1 to 6.3).

Fig. no. 2:- taste masked oral Reconstitutable suspension of formulation F1-F6.

Drug Content

Formulation	% Drug content
F1	90%
F2	92%
F3	94%
F4	97%
F5	93%
F6	95%

Table no. 8:- % drug content uniformity.

In-vitro drug release

The experiment was conducted out in 500 cc of 0.1 N HCI using a USP II equipment at 370.5oC and 100rpm. Within 30 minutes, the formulation released 92 percent of the medication. The findings of the drug's release from suspension were placed in a table.

Table no. 9:- Shows the total proportion of drugs released.

Time in min.	F1	F2	F3	F4	F5	F6
5	25.02	24.00	22.00	23.02	20.01	21.02
10	39.00	34.00	35.80	36.01	35.76	33.01
15	46.32	45.01	47.92	45.84	46.20	44.89
20	54.68	59.02	56.70	58.52	58.67	55.70
25	66.40	62.41	63.10	61.02	69.21	68.39

30	72.00	71.66	72.64	73.44	74.20	75.10
35	81.23	83.41	83.42	82.02	81.00	83.40

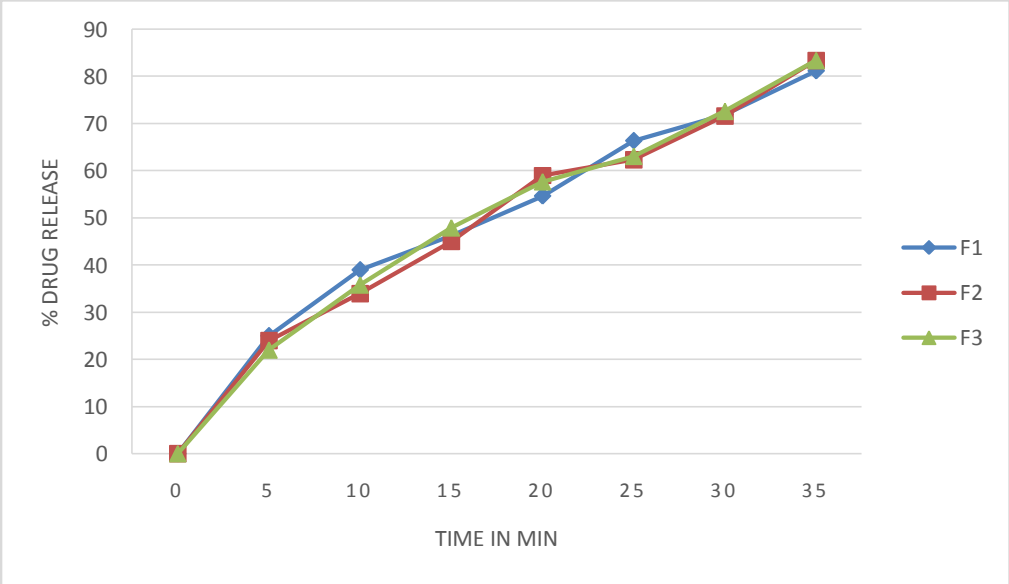

Fig no. 3:- % In 0.1N HCl, the release of drug profile of formulations F1-F3.

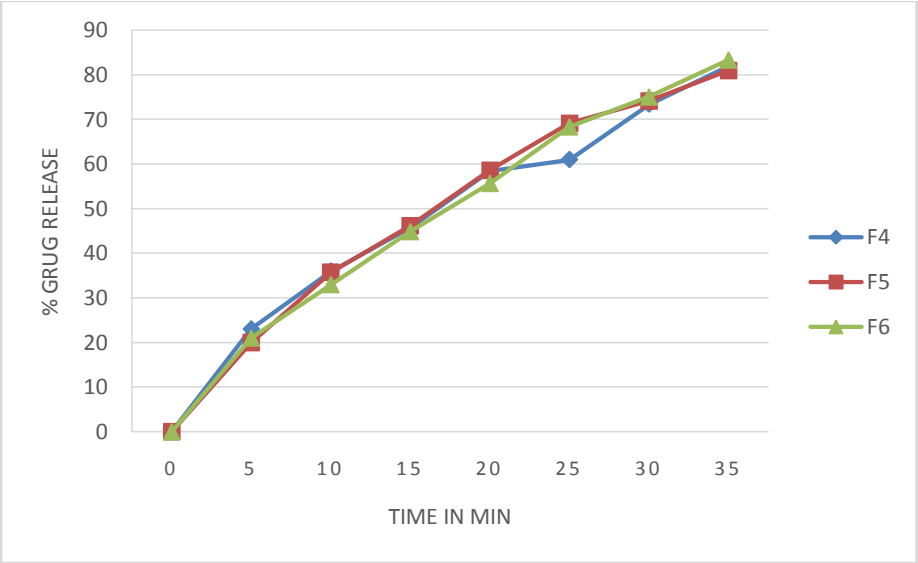

Fig no. 4:- % F4-F6 formulation medication release profile in 0.1N HCl.

Stability Study of Formulation F5

Formulation F5		
Evaluation parameter	**Initial**	**15 days**
Colour	white	white
Odour	Herbal characteristic	Herbal characteristic
Sedimentation	5.4	5.3
Redispersibility	8	11
Drug content	90%	92%
% Drug release	81.00	82.02
pH	6.1	6.3

Table no. 10:- Stability analysis of formulation F5 with evaluation parameters.

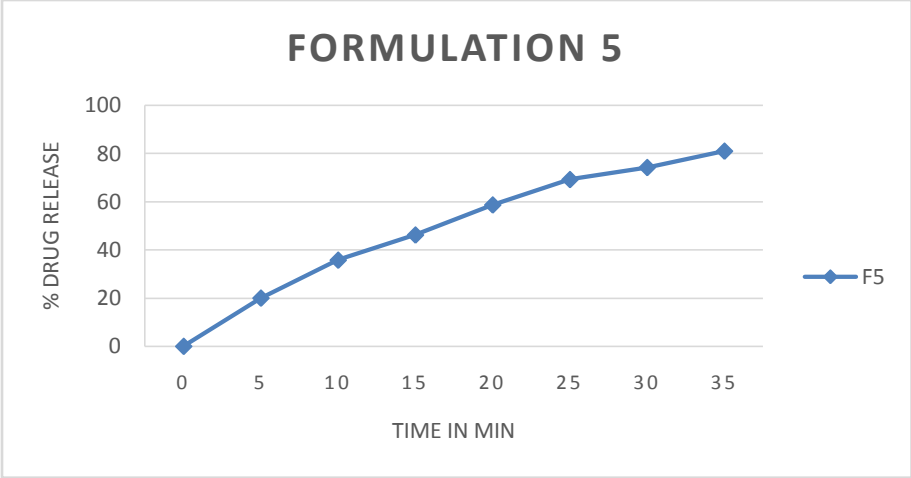

Fig. no. 5:- % drug release after stability study formulation F5.

Formulation antibacterial sensitivity test

Formulation	**Mycobacterium Tuberculosis (ZOI) 10^{-6}**
F1	38.30mm
F2	40.19mm
F3	42.70mm
F4	56.30mm
F5	93.88mm
F6	85.72mm

Table no. 11:- AST of formulation F1-F6.

The improved formulation (F5) was tested for antimicrobial sensitivity. The outcome is depicted in the image.

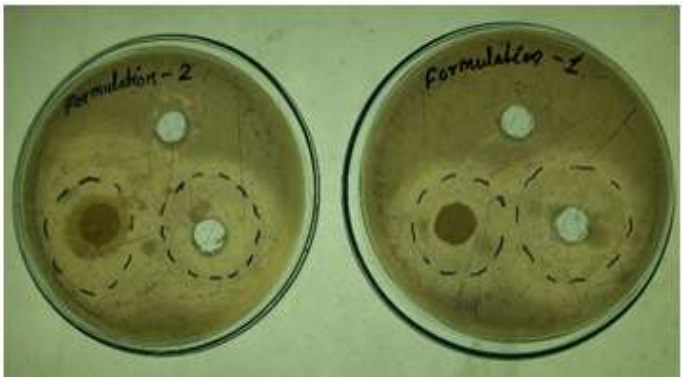

Fig no. 6:- AST of Formulation F1-F6.

Conclusion:-

We can infer from the study that the goal of work, created herbal dry syrup composition with synthesized medicine (Levofloxacin), has tremendous potential against pathogenic germs, i.e., Mycobacterium Tuberculosis, and may be utilised for treatment of TB and other disorders such as urinary tract infection, throat, and sinusitis infection. For most paediatric patients, the harsh taste of medications can be mitigated by herbal qualities, increasing patient compliance. The oral Reconstitutable suspension was tested for stability in a scaled-up amount. The in vitro research of the dry syrup formulation (F5) can be concluded here.

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Conflicts Of Interest:

Nil.

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