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Formulation, Evaluation & Comparative Study of Effects of Super Disintegrants in Herbal Fast Dissolving Tablet of Nyctanthes Arbor Tristis

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ABSTRACT

The purpose of this research work was to formulate & evaluate the herbal fast dissolving tablet of Nyctanthes Arbor Tristis. Taxonomically, the plant was authenticated by the Padmashri vikhe patil college of Arts, Science, & Commerce in pravaranagar. Ref.No./PVPC/Bot./2023-24/235. The aimed is to treat inflammation associated with Sciatica. A two independent variables of superdisintegrants are used such as crosspovidone & croscarmellose sodium. Using DOE software, 3^2 full factorial design was used to examine the combined impact of two formulation variables. TLC was performed to identify the beta sitosterol with RF value of 0.77. to determine the physicochemical interaction between the drug & the excipients, FTIR study was done. FTIR study revealed that there is no interaction of the drug and excipient. In this investigation, the tablets were formulated and assessed via direct compression. The powder mixture were compressed into tablet using single punch tablet machine. All the formulations were evaluated for their characteristic such as weight variation, hardness, thickness, friability, disintegration time(DT), and dissolution rate. It was determined from all evaluation parameter that the F9 batch was the optimized batch. It was found that an optimized batch (F9) has good cumulative drug release in 20 minutes (88.87%), DT of 56 seconds, and hardness of 2.923kg/cm^2. The comparative studies are done with the marketed formulation. With the commercial formulation, the optimized batchF9 satisfies all standard specification.

KEYWORDS: Superdisintegrants, Fast Dissolving Tablet, Factorial Design, Nyctanthes Arbor Tristis.

INTRODUCTION:

Fast dissolving tablets (FDTs) are defined as “a solid dosage form containing medicinal substance or active ingredients that , when placed upon the tongue, disintegrate rapidly, usually within matter of seconds.” Fast dissolving tablets, commonly referred to as mouth- dissolving tablets, dissolving into pieces within the mouth without the need of water[1]. Faster solubility, faster absorption, and faster onset of action have all been found. Fast- dissolving tablet disintegration is commonly occur in less than a minutes[2]. Therefore one way to improve the onset of action is to construct fast dissolving tablets. Fast or mouth dissolving tablet has been formulated for pediatric, geriatric patients[3]. A fast dissolving tablet can be developed via a wide range of techniques, include wet granulation, freezed drying, spray drying, and direct compression[4]. Herbal remedies work well for all kinds of diseases. In general herbal formulation can be

standardized graphically so that the medication is made with ingredients gather from various location[5]. The purpose of this research is to create a fast dissolving tablet that has enough mechanical integrity and dissolve more quickly in the oral cavity without a requirement of water. In order to increase the rate of dissolution and facilate faster disintegration, superdisintegrants such as crosspovidone & croscarmellose sodium are utilized in varying proportions[6].

Nyctanthes arbor tristis (NAT)linn, commonly referred to as harsinghar or parijata, is a significant traditional plant in india. The Oleaceae family includes a tradional medicinal herb nyctanthes arbor tristis. The current study focuses on arthritis, it has been demonstrated that the leaves of the nyctanthes arbor tristis plant can treat arthritis and provide relief from fever, pain and inflammation. The entire plant possesses several therapeutic property, include antifungal, antidiabetic, antioxidant properties[7]. These pharmacological effects are caused by flavonoids, tannins, saponins, glycosides, alkaloids, steroids, and phenolic chemicals, which are found in plants according to phytochemical study of botanical specimen. The chemical drugs that are used to treat a variety of illness are expensive and have range of undesirable effects. Herbal medication, which are less expensive and had no risk of adverse effect[8].

MATERIALS AND METHODS-

Materials- green fresh leaves of nyctanthes arbor tristis was collected during the winter season. The plant was authenticated taxonomically from Padmashri vikhe patil college of arts, commerce and science in pravaranagar. Ref.No./PVPC/Bot./2023-24/235. This leaf sample was washed thoroughly with tap water, some leaves were shade dried and grinded finely into the powder. Using different amounts of microcrystalline cellulose(MCC), crosspovidone, croscarmellose sodium,lactose, magnesium stearate and talc, herbal tablet of nyctanthes arbor tristis were prepared by the direct compression technique.

Methods-

FTIR- Due to their close proximity, the drug and excipient may interact, which could cause the incompatibility. FTIR spectroscopy was used to determine whether the drug and particular excipient were compatible. FTIR experiments were conducted on pure drug sample, excipients and drug-excipient in ratio 1:1[9].

TLC- stationay phase- silica gel G , Mobile phase- (ethyl acetate: glacial acetic acid: aceti nitrile), detecting agent- sulphuric acid. TLC particularly useful in determining the purity of chemical substances. Using a capillary tube two centimeters from the bottom of the tlc plate, a spot of each fraction was applied to activate tlc plates. The plates was then placed in a developing chamber with the proper solvent system for precisely the quantity of time required for the developing solvent to completely cover the three- fourth of the TLC plate. After being removed from the developing chamber, the plate was dried. Compound spots that are seen for the presence of specific compounds using sulphuric acid[10].The RF value of each spot was calculated by the formula:

Rf= distance travelled by the solute(cm)/ distance travelled by the solvent(cm).

PRE-COMPRESSION EVALUATION OF THE POWDER-

1. **Angle of repose**: The angle of repose is the maximum angle that forms between the surface of the powder pile and the horizontal surface. The angle of repose values for the majority of pharmaceutical powders fall between 25 to 45[11].

Table 1: Angle Of Repose And Flowability

Sr.No.	Angle of Repose	Flowability
1	25-30	Excellent
2	31-35	Good
3	36-45	Fair possible
4	46-55	Poor
5	56-65	Very poor
6	>66	Very, very poor

2. **Bulk density**- The volume of a known mass of powder that went through the screen is used for determining the bulk density[12].

   Bulk density= M/Vb

3. **Tapped density**- It is obtained by tapping the measuring cylinder containing known mass of powder and then measuring the volume of powder. It was performed using electro lab tapped density apparatus[13].
4. **Compressibility index**- Carrs compressibility index and hausner ratio gives the indication about the ease with which a powder material can flow using following equations[14], Carrs compressibility index (CI): CI= (tapped density- bulk density)/tapped density*100

   Hausners ratio (HR): HR= Tapped density/bulk density

Table 2: Scale Of Flowabilty For CI And HR

Sr. No.	Carr's Index	Hausner's Ratio	Flowability
1	5-15	1.05-1.18	Excellent
2	12-16	1.14-1.20	Good
3	18-21	1.20-1.26	Fair passable
4	23-35	1.30-1.54	Poor
5	33-38	1.50-1.61	Very poor
6	>40	>1.67	Very very poor

FORMULATION OF FAST DISSOLVING TABLETS-

Fast dissolving tablets of Nyctanthes Arbor Tristis were prepared by direct compression method. All ingredients were mixed step by step. Then pass through sieve and mixed with drug. Lubricants such as talc and magnesium stearate were added in these powder mix atlast and again mixed for 5 minutes. The active blend were compressed into tablets 300 mg using single punch tablet machine. On the basis of results of preliminary batches, final formulation batches were prepare by using 3^2 factorial design for nyctanthes arbor tristis. fast dissolving tablet formulation table was given below.

Table 3: Formula For Fast Dissolving Tablet.

Ingredients (mg)	Formulation Batches								
	F1	**F2**	**F3**	**F4**	**F5**	**F6**	**F7**	**F8**	**F9**
Crude Extract	100.00	100.00	100.00	100.00	100.00	100.00	100.00	100.00	100.00

Crosspovidone	12.50	12.50	8.75	8.75	5.00	5.00	5.00	12.50	8.75
Croscarmellose sodium	12.50	1.25	12.50	1.25	12.50	1.25	6.88	6.88	6.88
Methyl cellulose	4.00	4.00	4.00	4.00	4.00	4.00	4.00	4.00	4.00
Mannitol	98.97	110.22	102.72	113.97	106.47	117.72	112.09	104.59	108.34
Propylparaben	0.03	0.03	0.03	0.03	0.03	0.03	0.03	0.03	0.03
Magnesium stearate	8.00	8.00	8.00	8.00	8.00	8.00	8.00	8.00	8.00
Talc	14.00	14.00	14.00	14.00	14.00	14.00	14.00	14.00	14.00

POST COMPRESSION EVALUATION OF TABLETS-

1. **Tablet thickness**- We took measurements with a digital vernier caliper on 5 tablets that were chosen at random. Between ± 5% of the standard value should be adhered for both tablet thickness[15].
2. **Hardness**- Hardness is the measure of a tablets resistance to the mechanical shocks. Monsanto hardness tester is used to perform these test. The tablet is crack by rotating a threaded bolt, which force the upper plunger against the spring. The unit of measurement for facture force is kg/cm^2[16].
3. **Friability**- Sample of 10 entire tablets is taken if the average weight of the tablets is greater than 0.65 g, then precisely weigh the necessary quantity of tablets. After placing the tablets, rotate the drum 100 times (25 rpm for 4 min). take out the tablets, tidy them of any loose dust, and weigh them precisely[17]. Friability is calculated using following formula, F=(1-w/wo)100
4. **Weight variation test**- The USP weight variation test is carried out by weighing each of the twenty tablets separately, calculating out their average weights, and then comparing each tablets weight to the average. The weight variation test value is given as percentage[17]. Weight variation = (Iw - Aw)/ Aw*100.
5. **Disintegration test**- Disintegration test was carried out at 37^0c ±2^0c in 900 ml of distilled water. The disintegration test apparatus is used. The time in seconds is required for complete disintegration of tablets with no palpable mass remaining in the apparatus was measured[18].
6. **In- vitro dissolution study**- Using the USP dissolving tasting II (paddle type), the release rate nyctanthes arbor tristis from fast dissolving tablet is ascertained. The dissolution test was conclude at 37 ± 0.5^0c and 50 rpm with 900 ml of PH 6.8 buffer. Every hour for 20 minutes, a sample of solution 5 ml was taken out of the dissolving equipment and replaced with new dissolving medium. The absorbance of these solutions was measured at 273 nm after the solution has been suitably diluted[19].

RESULT AND DISCUSSION-

TLC- Stationary phase- silica gel G, Mobile phase- (ethyl acetate: glacial acetic acid: aceto nitrile)

Table 4: TLC Of Nyctanthes Arbor Tristis

sr.no	solvent system	detecting agent	Standard Rf value	Rf value
1.	ethyl acetate: glacial acetic acid: aceto nitrile	sulphuric acid	0.83- 0.86	0.77

FTIR- FTIR studies of the pure extract powder, super disintegrants and combination of drug and super disintegrants containing highest proportion were carried out to found any interaction between drug and excipients used in the formulation. FT-IR study was performed using IR spectroscopy (SHIMADZU).

Figure 1: FTIR Spectra Of Drug Sample.

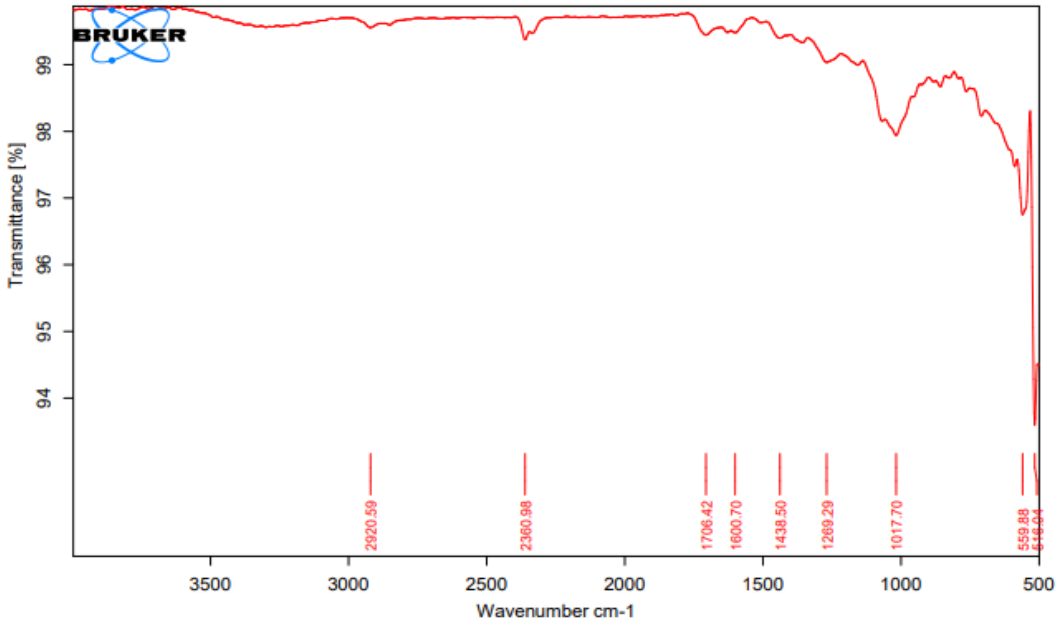


Figure 2: FTIR Spectra Of Excipient

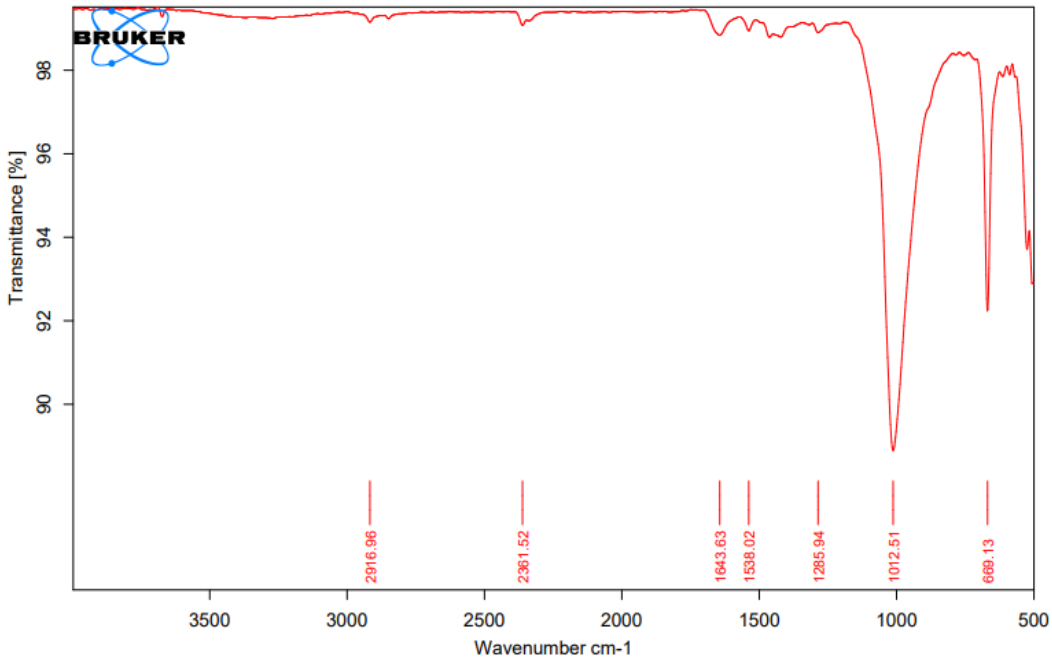
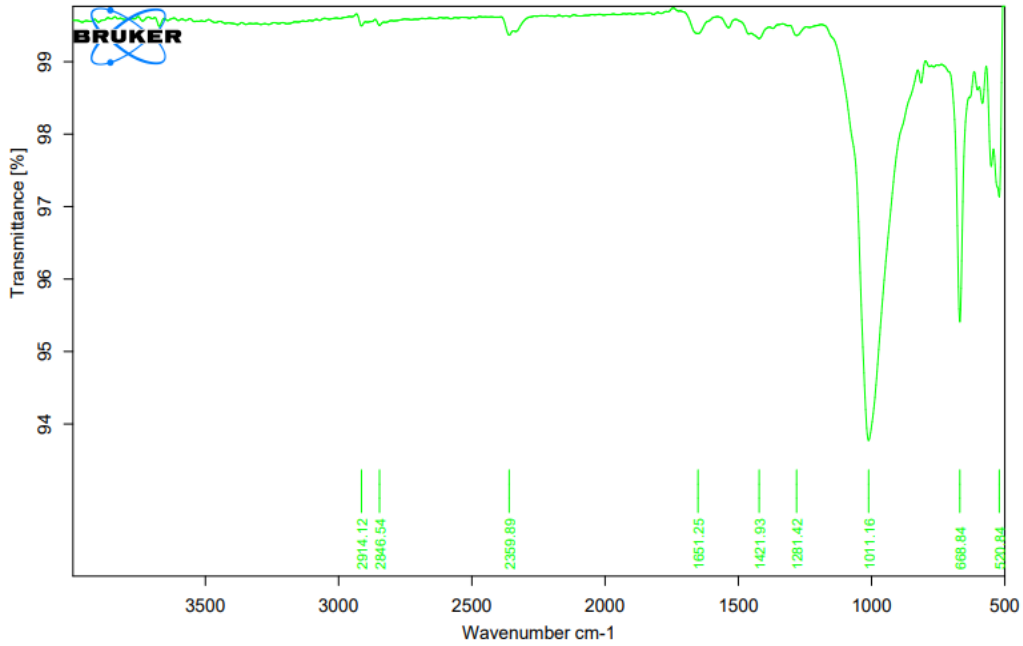


Figure 3: FTIR Spectra Of Drug + Excipient



Discussion- FTIR spectral studies indicated that drug is compatible with all the excipient. The FTIR spectrum of physical mixture shows the all characteristic peaks of drug sample, thus conforming that no interaction of drug occurred with the components of the formulation.

PREFORMULATION EVALUATION STUDY OF TABLET- These batches were evaluated for parameters like bulk density, tapped density, cars index, hausners ratio and angle of repose. The value for angle of repose in the range of 25 to 30 showing excellent flow property the value for cars index was in the range of 12 to 16 and for hausners ratio between 1.14 to 1.20. Each of the values are within the permissible range.

Table 5: Result Of Preformulation Study Of Powder Blends

Bulk Density (gm/ml)	Tapped Density (gm/ml)	Angle of repose	Carr's Index	Hausner's Ratio
0.5383	0.646	10.13	16.71	1.20

POSTCOMPRESSION EVALUATION OF TABLETS-

Evaluation for thickness, weight variation, hardness, friability & disintegration. All the formulation were evaluated & all the values were in acceptable limit as per the standards.

Table 6: Result For Thickness, Weight Variation, Hardness, Friability & Disintegration.

Batch	Thickness (mm)	Weight variation	Hardness (kg/cm^2)	Friability (%)	Disintegration (sec)
F1	3	Passes	2.62	0.68	52
F2	3	Passes	2.34	0.72	46
F3	3	Passes	2.67	0.80	44
F4	3	Passes	2.25	0.60	45
F5	3	Passes	2.42	0.79	42

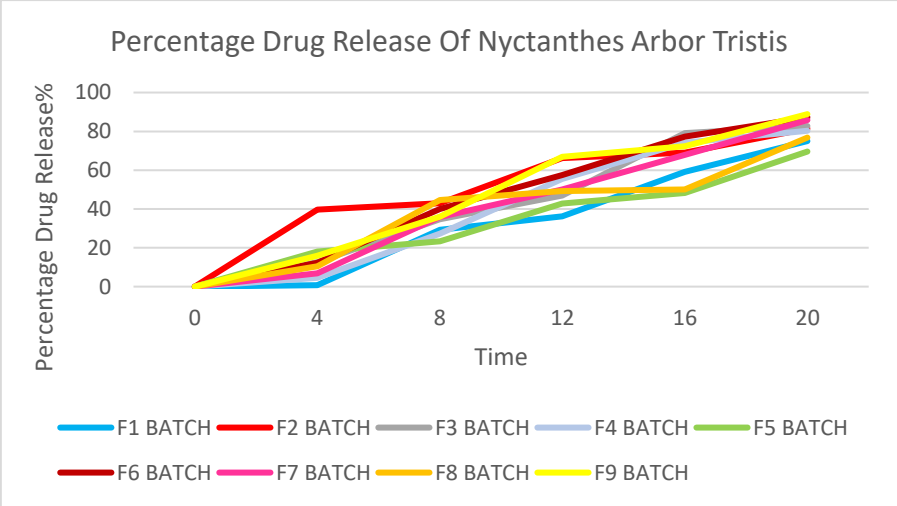
F6	3	Passes	2.32	0.92	47
F7	3	Passes	2.71	0.99	54
F8	3	Passes	2.65	0.84	53
F9	3	Passes	2.923	0.62	56

In vitro dissolution test-The tablet belonging to all 9 formulation (F1 to F9) were evaluated, all showed fast dissolving pattern for drug release as given in table 7. The formulation batch F9 showed the drug release about 88.87%. the batch F9 shows effective drug release.

Table 7. Results Of In- Vitro Dissolution

Time (hrs)	**Formulation Batch (% Drug Release)**								
	F1	**F2**	**F3**	**F4**	**F5**	**F6**	**F7**	**F8**	**F9**
0	0	0	0	0	0	0	0	0	0
4	0.8	39.6	12.6	4.5	18	12.3	6.9	10.5	15.9
8	29.31	42.9	34.8	27.3	23.4	40	35.8	44.6	36
12	36.2	66.3	47	55.5	42.8	57.43	50.03	49.2	66.9
16	59.12	69	79.1	74.2	48.2	77.3	67.93	50	72.4
20	75	81.42	82.71	80.3	69.6	87.2	85.8	76.8	88.87

Figure 4: Percentage Drug Release Of Nyctanthes Arbor Tristis



COMPARATIVE DISSOLUTION STUDY OF MARKETED FORMULATION & OPTIMIZED FORMULATION BATCH (F9)-

The dissolution profile of optimized formulation batch (F9) was compared with marketed mefenamic acid dispersible tablet.

Table 8. Comparative In Vitro Release Data Mefenamic Acid Dispersible Tablet And Optimized Formulation (F9) Batch.

TIME (min	**Percentage drug release (%)**	
	Formulation (f9) batch	**Marketed formulation**
0	0	0
4	15.9	7.29

8	36	56
12	66.9	63.4
16	72.4	88.6
20	88.87	97.3

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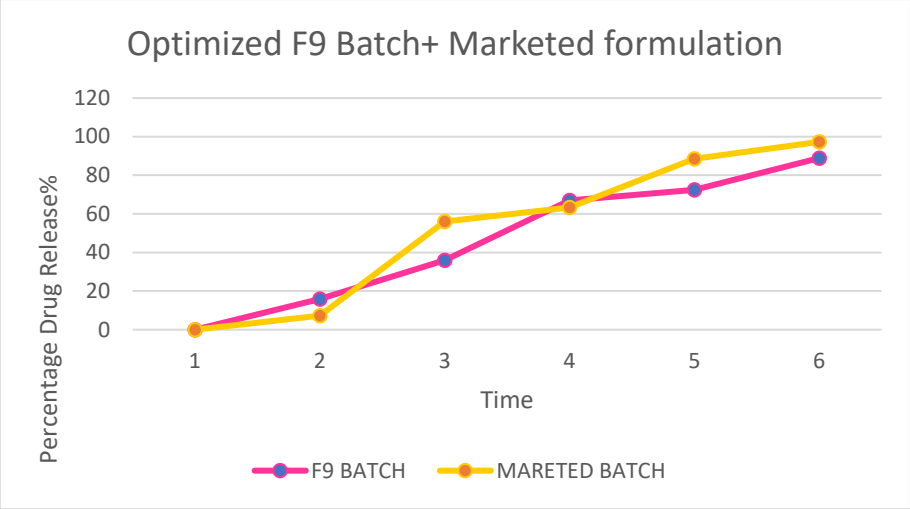
Figure 5: Comparative In Vitro Release Data Mefenamic Acid Dispersible Tablet And Optimized Formulation (F9) Batch



Discussion- the percentage drug release of marketed sample and optimized formulation (F9) batch was found to be 97.3% and 88.87% at 20 minutes. The drug release of optimized formulation of nyctanthes arbor tristis orally disintegrating tablets was found to be similar to marketed product. The optimize batch F9 meet all the standard specification with the marketed formulation.

CONCLUSION

The goal of this investigation has been achieved by preparing herbal fast dissolving tablet with the aid of super disintegrating agent. The results of a 3^2 full factorial design revealed that the super disintegrants significantly affect the dependent variables, disintegration time, friability & percentage drug release. From above all different evaluation parameter it was concluded that F9 batch was the optimized batch. The comparative evaluation studies proves that F9 batch which have satisfy all the criteria and official limits with the marketed formulation.

Future aspects-The results further suggest in vivo experimentation of the tablets for further exploration.

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