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ISOLATION AND EVALUATION OF STARCHES AS EXCIPIENTS IN THE FORMULATION OF TABLETS

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ABSTRACT
The aim of this investigation was to find the alternatives to the presently used starches in Pharmaceutical Industry. The starches isolated from the different raw materials such as Bhagar, Sweet potato, Sago, Bajra, Banana were compared with the Corn starch (widely used in the Pharmaceutical and other industries) with respect to the cost, properties as a Pharmaceutical excipient and availability. Starches were isolated from five different sources. These sources were,1) Bhagar starch, obtained from the grains of Panicum Miliaceum, (Family: Graminae), 2), Sweet potato starch, obtained from the grains of Ipomoea batata, (Family: Convolvulaceae), 3) Sago starch, obtained from the pulp of the trunk of Metroxylon rumphii (Family: Palmae), 4) Bajra starch, obtained from the grains of Pennisetum typhoides (Family: Graminae), 5) Banana starch, obtained from the unripe pulp of fruit Musa paradisiaca (Family: Musaceae). These isolated starches were studied as an excipients in the formulation of tablets. Tablets of diclofenac sodium were prepared using these isolated starches as disintegrant in the concentration of fifteen and ten percent respectively. The physical properties of these tablets were studied to evaluate the diluents, binding and disintegrating properties of isolated starches. It was observed that Bajra starch has good white colour, lowest cost of raw material, lowest projected cost and better disintegration time. Therefore, it can be considered as best alternative for corn starch.

KEYWORDS: Bhagar starch, Sweet potato starch, sago starch, bajra starch, banana starch, diclofenac sodium.

INTRODUCTION
As there is a wide use of starches in the Pharmaceutical as well as other industries such as food, textile, etc., the Corn alone may not be sufficient to meet the requirement of the above industries. Therefore it is necessary to find some comparable alternative to the Corn starch. Attempts of all sorts were made to find the different alternatives to the Corn starch.

Corn starch[1] is used as one of the tablet excipient in the Pharmaceutical industry for the reason that it is low in cost, having good tablet disintegration capacity, good tablet binding capacity in the form of pastes and also a good tablet diluents. Therefore the other starches isolated from different source were also evaluated for the above properties especially in the tablet manufacturing.

In the country like India there is agricultural diversity. So, the crops produced in the different regions are based upon the local climatic conditions. Maize (Corn) is produced mainly in Punjab state. So, the Corn or its products are to be transported in the different state of India due to which the cost of the some will shoot up. But if the starch from the locally available source is used which may be comparatively cheaper and readily available.

MATERIALS
Isolated starches were compared with corn starch, which is supplied by Venus Chemicals, Nagpur. Diclofenac sodium drug is used for table formulation, which is supplied by Novartis India Limited, Mumbai. Solvents and all other reagents were of analytical grade and were procured locally.

METHODS
1) Isolation of Bhagar starch
Bhagar grains were cleaned and steeped in water for 24 hours. Then crushed in mixer. Impurities were removed by screening. Solution of hypochlorite was added for alkali treatment and the solution was kept for 6 hours. Then washing with fresh water were given upto neutralisation of the solution. Kept it for neutralisation. The settled starch were removed and dried at room temperature. The quantity of starch obtained from 300g of the grains of Bhagar was 150g.

2) Isolation of Sweet potato starch

Sweet potato were thoroughly washed and crushed in a mixer by adding calcium hydroxide. This mass was passed over a series of electrical shaker screen. The separated starchy solution was collected and the screened mesh was again re-ground, washed with calcium hydroxide solution and re-sieved. The starchy solution was kept for sedimentation for 2 hours. Then washings given upto neutralisation. Solution was treated with sodium hypochloride for 2 hours. Washings were given again for neutralisation. Settled starch particles were collected and dried at room temperature. The quantity of starch obtained from 1000 g of the Sweet potatoes was 200 g.

3) Isolation of Sago Starch

Sago flour was suspended in water. Suspension was treated with sodium hypochlorite solution and kept for 3 hours. Impurities were removed by screening and washed upto neutralisation. Settled starch particles were dewatered in a centrifuge and dried at room temperature. The quantity of starch obtained from 1000 g of Sago was 800 g.

4) Isolation of Bajra Starch

Bajra grains were dipped in water for 35 hours. Crushed in mixer and suspended in water and kept for sedimentation. Impurities were removed by screening. Solution was kept for sedimentation. Settled particles of starch were collected and dried at room temperature. The quantity of starch obtained from 1000 g Bajra grain was 300 g.

5) Isolation of Banana Starch

The unripe unpeeled bananas were cut into small pieces and minced in mixer using 0.05 N NaOH. The slurry was the filtered through muslin cloth. The filtrate was allowed to stand for 6 hours and sedimented starch were given washings to remove alkali completely. It was dried in air. The pulp remaining on cloth was again suspended in 0.05 N NaOH and filtered through muslin cloth till no milky filtrate was obtained. The quantity of starch obtained from 1000 g of the unripe Banana was 100 g.

Preparation of tablets

Tablets were formulated to contain 50 mg of diclofenac sodium using 15% and 10% disintegrant maize starch and other isolated starches. Table were formulated using wet granulation technique where teh binding agent used was the paste of respective disintegrant starch. Weight of each tablet was 200 mg.

RESULTS AND DISCUSSION

Properties – The following properties were studied for isolated and compared with commercially used Maize starch I.P.-

Microscopic character[4], acidity[7], gelatinization temperature[4], % solubility in water at room temperature[3,4], period of dextrin formation[4], ash value[7], loss on drying[6], bacterial count.[6] The results of these are given in table 1.

Viscisities of isolated starches and commercially used Maize starch in their paste for (2.5%) were studied using Brookefield Viscometer. Viscosities of Maize, Bhagar, Sweet Potaoes, Sago, Bajra and Banana Starches found to be 16.9, 13.93, 5.9, 29.0, 5,53, 6.08 centipoises respectively.

Rheology of starches

The properties like (1) angle of repose[5] and (2) % compressibility[2] were studied. The results of these are given in Table 2.

Disintegration test apparatus of I.P. specification was used for the determination of disintegration time of the tablets. The results of tablets are given in table 3.

Hardness and weight variations of prepared tablets are mentioned in table 4 and friability of tablets are given in table 5.

Cost of raw materials and cost of isolated starches are given in table 6.

TABLE – 1: Properties of Maize and Isolated Starches.

PROPERTIES	MAIZE	BHAGAR	SWEET POTATO	SAGO	BAJRA	BANANA
Starch grain size (µm)	25	48	35	45	28	50
Acidity (ml of 0.1M NaOH)	0.8	1.4	1.6	0.7	1.8	0.4
Gelatinization temperature ^{0}C	60 - 65	65 - 70	70 - 75	72 – 77	58 – 63	80 – 85
% Solubility	0.779	0.852	0.688	0.022	0.900	0.034
Period of dextrin formation (min)	38	30	42	125	35	110
Ash value (%)	0.170	0.35	0.43	0.20	0.07	0.27
% LOD	12	12.7	11	10.7	14	12.4
Bacterial count (no. of colonies)	120	170	190	185	130	200

TABLE – 2: Rheology of Maize and Isolated Starches.

PROPERTIES	MAIZE	BHAGAR	SWEET POTATO	SAGO	BAJRA	BANANA
Angle of Repose (^{0})	37.74	35.21	33.69	28.61	32.96	37.79
Compressibility (%)	18	3	11	7	10	9

TABLE – 3: Disintegration Time of the Tablets.

Tablets Containing	Disintegration Time of Tablets Containing	
	15 % Disintegrant	10 % Disintegrant
MAIZE STARCH	6.6 min	8.1 min
BHAGAR STARCH	7.7 min	9 min
SWEET POTATO STARCH	14.11 min	15.12 min
SAGO STARCH	15.4 min	16.2 min
BAJRA STARCH	8 min	9.1 min
BANANA STARCH	6.1 min	7.6 min

TABLE – 4: Hardness and Weight Variation of Tablets.

S. No.	Tablets	Hardness of Tablets (Kg/cm^2)		Average Weight of Tablets (g)	
		Mean	% Coefficient of Variation	Avg. Wt.	% Coefficient of Variation
(I) For Tablets of 15% Disintegrant					
1	MAIZE STARCH	4.24	2.109498	0.1923	2.581425644
2	BHAGAR STARCH	4.2	1.683588	0.1906	1.890919
3	SWEET POTATO STARCH	4.12	2.030728	0.1924	2.233304
4	SAGO STARCH	4.08	2.050637	0.1916	2.110902624
5	BAJRA STARCH	4.16	1.316641	0.1947	1.878646
6	BANANA STARCH	4.18	2.620682	0.1904	2.416656
(II) For Tablets of 10% Disintegrant					
1	MAIZE STARCH	4.26	1.285734	0.1886	2.095624
2	BHAGAR STARCH	4.18	3.19236	0.1879	1.302469
3	SWEET POTATO STARCH	4.10	1.724651	0.1897	2.000408
4	SAGO STARCH	4.08	2.050637	0.1907	2.075317
5	BAJRA STARCH	4.18	2.620682	0.1898	1.187377
6	BANANA STARCH	4.18	2.001579	0.1872	1.755521

TABLE – 5: Friability of Tablets.

Tablets	% Friability	
	15% Disintegrant	10% Disintegrant
MAIZE	0.50%	0.52%
BHAGAR	0.41%	0.44%
SWEET POTATO	0.20%	0.21%
SAGO	0.11%	0.12%
BAJRA	0.43%	0.46%
BANANA	0.60%	0.63%

TABLE – 6: Projected Cost of Isolated Starches.

S. No.	Raw Materials	Practical Yield (%)	Cost of Raw Materials (Rs. Per Kg)	Projected Cost of Starches (Rs. Per Kg)
1	MAIZE	70 %	20	45
2	BHAGAR	50 %	24	53
3	SWEET POTATO	20 %	8	45
4	SAGO	80 %	26	40
5	BAJRA	30 %	6	25
6	BANANA	10 %	6	65

According to results given in table 1, the particle size of Maize starch, Bhagar starch, Sweet potato starch, Sago starch, Bajra starch and Banana starch were found as 25 µm, 48 µm, 35 µm, 45 µm, 28 µm and 50 µm respectively. Out of these the size of Maize starch was small. Small particle is the need of pharmaceutical preparation.

Acidity test was passed by all starches because no any starch samples crossed the limit of 2 ml.

As evident from the table 1, it was found that gelatinization temperature of all starches in sequence were found as 60 - 65^{0}C, 65 - 70^{0}C, 70 - 75^{0}C, 72 - 77^{0}C, 58 - 63^{0}C, 80 - 85^{0}C respectively. Bajra starch required lowest temperature than the other starches. Gelatinization

temperature determines temperature at which paste formed. Hence Bajra starch is better for paste formation.

From table 1, it was found that Bajra starch having greater solubility in water at room temperature than other starches. Water solubility is important factor for any dosage form formulation.

According to table 1, period of dextrin formation of Bhagar starch was found as better than other starches. Period of dextrin formation is the time required for the syrup formation.

As evident from table 1, % ash values of all starches in sequence were found as 0.170%, 0.35%, 0.43%, 0.20%, 0.07%, 0.27% respectively. Bajra starch having lowest percent ash value than other starches.

Microbial limit test was performed by B.P. procedure. According to results in table 1, it was observed that all starches in sequence were formed the number of colonies as 120, 170, 190,185, 130, 200 respectively. Escherchia coli and Salmonella microorganisms were absent in all starch samples.

According to table 2, angle of repose of Maize starch, Bhagar starch, Sweet potato starch, Sago starch, Bajra starch and Banana starch were found as 37.74^0, 35.21^0, 33.69^0, 28.61^0, 32.96^0 and 37.79^0 respectively. It is considered that if angle of repose is lower than 30^0, it is a good flow promoter. Hence according to results, it was observed that Sago starch is a good flow promoter.

As evident from 2, it was observed that Maize starch having good compressibility. Hence compressibility determined the stronger hardness of tablets.

According to table 3, disintegration time of Maize starch tablets, Bhagar starch tablets, Sweet potato starch tablets, Sago starch tablets, Bajra starch tablets and Banana starch tablets for 15% and 10% disintegrant concentration were found to be 6.6 min, 7.7 min, 14.11 min, 15.4 min, 8 min, 6.1 min and 8.1 min, 9 min, 15.12 min, 16.2 min, 9.1 min and 7.6 min respectively. Banana starch tablet required short time for disintegration than the other starch tablets. Hence Banana starch is a better disintegrant.

As evident from table 4, it is observed that all starches pass weight variation test.

According to table 5, all tablets pass % friability test.

From table 6, it is observed that Bajra starch has good white colour, lowest cost of raw material and lowest projected cost and better disintegration time. Therefore it can be considered as best alternative for Maize starch.

CONCLUSION

From the results it was observed that Bajra starch has good white colour, lowest cost of raw material and lowest projected cost and better disintegration time than Sweet potato starch and Sago starch. As far as flow property and disintegration property is concerned, the Bajra starch is almost comparable to Maize starch. So, it can be a better substitute for Maize starch.

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