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COMPARATIVE EVALUATION OF EXCIPIENTS FROM DIFFERENT VENDORS AND THEIR IMPACT ON IDENTIFIED FORMULATIONS

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ABSTRACT
The aim of present work is focused to develop an alternate vendor by comparative evaluation of excipients from different vendors and through their impact on identified formulations. Comparison of excipients from different vendors is based on a preliminary specification comparison, analytical results comparison and thorough evaluation of excipient based on its functional characteristics and later on a worst case formulation with respect to excipient tested is identified out of numerous formulations and the evaluated data is extrapolated for the rest of the formulations. Four excipients were identified based on their criticality and their functionality tests were developed based on their functional role in their respective formulations. From the observed results, it was concluded that the difference between the functional test results obtained from the existing and proposed source were less than 1 % for all the four excipients. From the results obtained it can be concluded that the proposed vendor materials for all the four excipients evaluated were equivalent with that of the existing vendor materials and therefore can be accepted as an alternate source.
Keywords: Alternate vendor, Excipients, Functionality, Formulation.

INTRODUCTION

Excipients are defined as any substances added in preparing an official preparation which shall be innocuous, shall have no adverse influence in the therapeutic efficacy of the active ingredients and shall not interfere with the tests of the pharmacopoeia[1,2]. Excipients are also defined as substances, other than he active drug substance of finished dosage form, which have been appropriately evaluated for safety and are included in a drug delivery system to either aid the processing of the drug delivery system during its manufacture, protect, support, enhance stability, bioavailability, or patient acceptability, assist in product identification; and enhance any other attribute of the overall safety and effectiveness of the drug product during its use[3]. An excipient is selected and used because it contributes one or more functional attributes[4] to the product characteristics. Because excipients can affect the safety and effectiveness of the dosage forms, manufacturers should understand the functional contributions of the excipients; that are their 'process ability'. Functionality is a desirable property of a material that aids manufacturing and improves the manufacture, quality or performance of the drug product. Functionality can only be properly tested by the manufacture and subsequent testing of a batch of product. Functionality testing is the direct testing of the concerned function of an excipient in a particular formulation and manufacturing process to verify that the excipient provides the intended functionality[5-7]. Alternate vendor development is one of the popular techniques of strategic sourcing, which improves the value we receive from suppliers[8]. Need for Alternate Vendor Development[9-11]; the intentions behind development of an alternate source for any excipients are:

- To find a vendor who can supply the material with superior quality through which the excipient does not directly effect the formulation.
- To break the monopoly of the existing approved vendor.
- To get the cost effective material.
- To ensure timely material availability with minimum lead times.

MATERIALS AND METHODS

Materials

A. Excipients (Maize starch, microcrystalline cellulose PH 112, Lactose monohydrate (Granulac 230), Lactose BP (450 mesh) and drugs.
B. Equipments.

Methods

Functionality evaluation of the excipients[12]

Maize starch

Maize starch is used as diluent, disintegrant, binder and thickening agent in most of the products[13,14].

Reason for Alternate vendor development

Maize starch, being as a widely used excipient, it was decided to have an alternate vendor and interchangeability option in order to avoid dependency on the existing vendor.

Specification comparison

GPC and Roquette vendor's claims as per USP-NF, hence vendor specifications compared with each other and USP-NF monograph.

Analytical results comparison of maize starch

Three batch samples of proposed vendors were tested as per existing vendor specification and test procedures. The results are being compared with each other.

Evaluation of Maize starch based on its functionality

Maize starches being widely used as tablet and capsule diluent, disintegrant and binder, the primary physical properties that can have direct effect are as follows:

Excipient Micromeritics study
The primary physical parameters which include particle size distribution, bulk density, moisture content, powder flow can have direct effect on formulation performance of tablets and capsules.

Compaction study to evaluate the diluent and dry binder properties
Under the similar experimental conditions maize starch from both the existing and proposed vendors was directly compressed using 8 mm round shaped punches.

Comparison of physical parameters
Physical parameters like tablet weight, thickness, diameter, hardness, disintegration time were compared with each other between the compressed materials of both the vendors.

Swelling study to evaluate the disintegration property
Slugs obtained from both the vendors were compared with each other by adding 1 drop (18 µl) of purified water to each of the compressed slug.

Bursting study to evaluate the disintegration property
This study was conducted to know the bursting time and bursting pattern by adding slug into 100 ml beaker containing purified water.

Open exposure study
Approximately 10 g of maize starch powder and slugs of both the vendors were kept in desiccators for exposure study at RT of 25 ± 2ºC and RH of 80 ± 10 % for the duration of 60 hours, to evaluate the effect of environmental condition on material physical attributes.

Viscosity study
Determination of viscosity of maize starch by using Brookfield viscometer (cap 2000+) 10 g of maize starch was taken and wetted with a little quantity of purified water, volume was made up to 100 ml with purified water and stirring was continued for 5 minutes to form slurry. The slurry was heated in a water bath up to 70ºC in order to maintain a temperature of 49 ºC during determination. Parameters were maintained constant during determination of both the vendor materials of maize starch.

Parameters maintained were as follows
RPM-50, Runtime-30 sec, Hold time-5 sec, Temperature-49ºC, Spindle- Cap spindle

Evaluation on Drug product
To evaluate the impact of proposed source of maize starch on product manufacturability and quality, trials were performed on drug product. Two separate trials were performed using each vendor's material. The raw materials, process parameters, equipment, manpower, environmental conditions and batch size were maintained constant keeping the source of maize starch as the only variable.

Manufacturing formula

Table 1: Manufacturing formula for Maize starch's drug product

S. No.	Ingredients	Quantity in kg for batch size of 5000 tablets
1.	Active Pharmaceutical Ingredient-1	2.00 Kg
2.	Maize starch	
3.	Purified water	
4.	Maize starch	
5.	Active Pharmaceutical ingredient-2	
6.	Pregelatinized maize starch	
7.	Colloidal silicon dioxide	
8.	Purified talc	
9.	Magnesium stearate	

Procedure of manufacturing
Sifting
Active Pharmaceutical ingredient was sifted through #40 and maize starch through #100

Binder solution preparation
Maize starch was added gradually with continuous stirring to purified water which is boiled to the temperature of 90-95 ºC to form slurry.

Dry mixing
Sifted material was transferred to rapid mixer granulator and dry mixed for 5 minutes.

Wet mixing
Binder solution was added into dry mixed material to distribute the binder solution uniformly till the granulation end point was reached.

Drying
Air drying: Wet material was air dried for 10 minutes. After air drying an inlet temperature 85-90 ºC was supplied till the moisture content of the material reaches 3.0 % w/w.

Sifting and milling
Dried materials were sifted through #24 and retentions were milled through 1.50 mm screen, milling and sifting were continued till all the material passes through #24.

Blending
Along with 24 mesh sifted granules, Active Pharmaceutical Ingredient-2, pregeltinized maize starch, colloidal silicon dioxide were sifted through 40 mesh, except the lubricants purified talc, magnesium stearate which were sifted through 80 mesh, were loaded in octagonal blender and mixed for 25 minutes, part quantity of the lubricated blend was taken and lubricants were mixed along with it and added back to the octagonal blender and lubricated for 5 minutes.

Compression
Compression of the blend was carried out using 9.5 mm circular FFBE punches and dies and tabletting attributes were evaluated.

Microcrystalline cellulose PH 112
Microcrystalline cellulose PH 112 is used as a diluent / filler in many drug products[13,15].

Reason for Alternate vendor Development
In order to avoid dependency on a single source

Specification comparison
Existing and proposed vendors, FMC and Mingtai respectively complies to USP-NF So both the vendor specifications are compared with each other and compared to USP-NF monograph

Analytical results comparison of 3 batches material from both the sources
Evaluation of Microcrystalline cellulose PH 112 based on its functionality
Excipient Micromeritics study

- Compaction study to evaluate the diluent and dry binder properties
- Comparison of tablet physical parameters
- Swelling study to evaluate the disintegration property
- Bursting study to evaluate the disintegration property
- Open exposure study (At 25 ± 2ºC and RH of 90 ± 10 %)

Evaluation on drug product
To evaluate the impact of proposed source of microcrystalline cellulose PH 112 on product manufacturability and quality trials were performed on drug product. Two separate trials were conducted using each vendor's material keeping all the experimental conditions constant keeping the source of MCC PH 112 as the only variable.

Manufacturing Formula

Table 2: Manufacturing formula for microcrystalline cellulose PH 112's drug product

S. No.	Ingredients	Quantity in Kg for tablets of batch size 12000
1.	Active Pharmaceutical Ingredient	0.840 Kg
2.	Lactose anhydrous (Supertab 21)	
3.	Microcrystalline cellulose PH 112	
4.	Starch Pregelatinized	
5.	Colloidal silicon dioxide	
6.	Stearic acid	

Manufacturing procedure
Sifting
Active Pharmaceutical Ingredient, lactose anhydrous (Supertab 21), microcrystalline cellulose PH 112, starch pregelatinized, colloidal silicon dioxide were sifted through 30 mesh. Stearic acid was sifted through 60 mesh.

Blending
Above sifted material except the lubricant were placed in octagonal blender and blended for 20 minutes at 7 RPM. Then the lubricant was mixed with part of blend ad transferred into the octagonal blender and blended further for 5 minutes.

Compression
Compression of the lubricated blend was done using 5.0 mm round concave punches.

Lactose monohydrate (Granulac 230)
Lactose monohydrate (Granulac 230) is widely used as diluent/filler[13].

Reason for Alternate Vendor Development
To avoid dependency only on existing vendor

Specification comparison
The proposed vendor's (DFE) specification was compared with the existing vendor (Meggle) specification and Ph.Eur. Monograph

Analytical results comparison for three batch samples from each vendor
Evaluation of Lactose monohydrate based on its functionality

- Excipient micromeritics study
- Comparison of physical parameters of slugs of lactose monohydrate (Granulac 230)
- Determination of disintegration pattern
- Exposure study (At 60ºC and 90 % RH for 48 hours)[16]

Evaluation on Drug product
Two separate trials were conducted using each vendor's Lactose monohydrate under the same experimental conditions keeping the source of the Lactose monohydrate (Granulac 230) as the only variable.

Manufacturing Formula

Table 3: Manufacturing formula for Lactose monohydrate (Granulac 230)'s drug product

S. No.	Ingredients	Quantity in Kg for the batch size of 5000 tablets
1.	Active Pharmaceutical Ingredient	1.394
2.	Maize starch	
3.	Colloidal Silicon dioxide	
4.	Lactose monohydrate(Granulac 230)	
5.	Hydroxy propyl cellulose	
6.	Purified water	
7.	Cross povidone	
8.	Calcium dihydrogen phosphate	
9.	Microcrystalline cellulose	
10.	Lactose monohydrate(Tablettose 70)	
11.	Colloidal silica	
12.	Magnesium stearate	

Procedure of manufacturing
Dispensing
The required quantity of materials were weighed and dispensed.

Pre-mixing
Active Pharmaceutical Ingredient and colloidal silicon dioxide were sifted through 40 mesh and the material was collected in a poly ethylene bag.

- Maize starch was sifted through 100 mesh and collected.
- Lactose monohydrate (Granulac 230) was sifted through 20 mesh.
- Cross povidone, microcrystalline cellulose, colloidal silicon dioxide and magnesium stearate were sifted through 40 mesh.

- Calcium dihydrogen phosphate was sifted through 30 mesh.
- lactose monohydrate (Tablettose 70) was sifted through 20 mesh and collected in a poly bag.
- The materials of steps 2.3, 2.4, 2.5 were collected in polybag and weight was recorded.
- The contents of steps 2, 2.1, 2.2 were blended for 10 minutes.

Preparation of binding agent
Hydroxy propyl cellulose (binder) was added by continuous stirring for 30 minutes until clear solution was formed.

Granulation process
Top spray granulation process parameters

Table 4: Top spray granulation parameters

S. No.	Parameters	Observations
1.	Number of spray guns	1
2.	Inlet temperature	60-70 ºC
3.	Product bed temperature	Not more than 40 ºC
4.	Exhaust temperature	30-45 ºC
5.	Atomization air	0.9 bar
6.	Blower drive speed	25 %
7.	Air flow	7 CFM
8.	Spray pump speed	12
9.	Spray rate	9 g/min

Top-spray granulation
The materials of step 2.7 were transferred into top spray bowl of Fluidized Bed Processor (FBP) setting all the parameters.

Pre warming
Pre warming was done until the product reached 40 ºC.

Spraying
The binder solution of step 3 was sprayed on the above prewarmed mixture.

Drying
After complete spraying the moisture content was checked at 50 ºC, it should not be more than 2.5 %w/w.

Sifting and milling
The above dried granules were sifted through 18 mesh and the retentions are milled through 1.0 mm screen and passed through 18 mesh, weight of the granules was recorded.

Blending
- The contents of step 2.6 were sifted through 18 mesh and weighed.
- The granules of step 6.1 and 7.1 were blended in double cone blender for 20 minutes.

Compression
Blend of both the batches were compressed[17] separately.

Lactose monohydrate BP (450 mesh)
Lactose BP 450 is being used as diluent, binder in most of the products[13,18].

Reason for Alternate Vendor Development
To avoid dependency only on the existing vendor

Specification comparison
The proposed vendor (Meggle) claims as per BP. The proposed vendor specification was compared with the existing vendor's (DFE) specification and also with BP monograph.

Analytical results comparison of three batch samples of existing vendor material with the proposed vendor lactose
Evaluation of lactose (450 mesh) based on its functionality
- Excipient Micromeritics study
- Comparison of physical parameters of slugs of lactose (450 mesh)
- Exposure study (At 90 % RH for 60 hours)

Evaluation on drug product
Two separate trials were carried out under the same experimental conditions keeping the source of lactose monohydrate (450 mesh) as the only variable.

Manufacturing Formula

Table 5: Manufacturing formula for Lactose monohydrate (450 mesh)'s drug product

S. No.	Ingredients	Quantity in Kg for the batch size of 5500 tablets
1.	Active Pharmaceutical Ingredient	1.018
2.	Lactose (450 mesh)	
3.	Maize starch	
4.	Povidone (PVP K-30)	
5.	Magnesium stearate	

Procedure of manufacturing
Sifting
Active pharmaceutical Ingredient and lactose were sifted through 40 mesh, maize starch was sifted through 100 mesh

Preparation of binder solution
The binder solution of povidone (PVP K-30) was prepared with purified water at 60-70ºC

Granulation
Materials of step 1 were dry mixed for 5 minutes followed by wet mixing by the addition of binder solution.

Drying
The above obtained granules were loaded in fluidized bed drier and dried at 90ºC and drying was continued till the moisture content of the granules reaches 2.0-3.0 % w/w.

Sifting and milling
Dried material was sifted through 24 mesh and the retentions were milled through 1.0 mm screen and sifted through 24 mesh.

Blending
The sifted granules were placed in octagonal blender and blended for 25 minutes, then magnesium stearate was added to small quantity of unlubricated blend and blended for further 5 minutes.

Compression
Compression was carried out by using 8.00 mm normal concave punches.

Evaluation of functional parameters of excipients

Excipient Micromeritics study

Table 6: Results for Excipient micromeritics study

S. No.	Parameters	Maize Starch		MCC PH 112		Lactose (Granulac 230)		Lactose (450 mesh)		Remarks
		E1	P1	E2	P2	E3	P3	E4	P4	
1.	Bulk density (g/ml)	0.47	0.43	0.36	0.36	0.46	0.43	0.43	0.36	Comparable
2.	Tapped density (g/ml)	0.72	0.66	0.48	0.53	0.83	0.79	0.81	0.62	Comparable
3.	Compressibility index	34.2	34.5	25	31	44	45	46.2	32.3	Comparable
4.	Hausner's Ratio	1.52	1.52	1.33	1.45	1.79	1.82	1.86	1.73	Comparable
5.	Flodex	29.4	29.4	83.3	83.3	29	29	29.4	29.4	Comparable
6.	Moisture content (in %w/w)	10.6	10.7	4.0	2.18	0.5	0.8	1.0	0.9	Comparable
7.	Particle Size Distribution									
	Mesh Size	%Weight Retained								Remark
	#20	0	0	0	0	0	0	0	0	Comparable
	#30	0	0	0	0	0	0	0	0	Comparable
	#40	0	0	0	0	0	0	0	0	Comparable
	#60	0	0	1	2	0	0	0	0	Comparable
	#80	0	0	10	11	0	0	0	0	Comparable
	#100	0	1	17	18	2	2	0	0	Comparable
	#200	0	4	44	36	6	4	2	80	Comparable
	In fines collector	94	92	28	33	94	96	96	12	Comparable

Compaction study to evaluate the Diluent and Dry binder properties

Table 7: Results for Compaction study

Parameters	Maize starch		MCC PH 112		Lactose (Granulac 230)		Lactose (450 mesh)		Remarks
	E1	P1	E2	P2	E3	P3	E4	P4	
Tablet weight (mg)	198-202	196-203	152-155	152-155	151-151	147-154	151-151	151-152	Comparable
Thickness (mm)	3.70-3.78	3.64-3.79	4.09-4.13	4.10-4.13	3.01-3.03	2.99-3.05	3.06-3.11	3.08-3.11	Comparable
Diameter (mm)	8.01-8.08	8.01-8.03	8.01-8.03	8.02-8.04	8.00-8.02	8.00-8.01	8.00-8.01	8.00-8.01	Comparable
Hardness (Kpa)	4.3-6.7	3.5-8.1	5.0-5.4	3.0-3.3	5.0-6.3	2.8-6.9	6.1-7.8	8.0-11.1	Comparable
Disintegration time (sec)	35	35	16	16	30	32	41	63	Comparable

Swelling study to evaluate the disintegration property

Table 8: Results for swelling study

S. No.	Excipient	Vendors	Observation	Remarks
1.	Maize starch	Roquette (Existing,E1)	The area at which the measured quantity of purified water (18 µl) was put that part was chipping out.	Both the vendors comply with each other.
		GPC (Proposed,P1)	The area at which the measured quantity of purified water (18µl) was placed that part was chipping out.	
2.	Microcrystalline cellulose PH 112	FMC (Existing,E2)	The area at which the measured quantity of purified water (18 µl) was put that part was swollen out.	Both the vendors comply with each other.
		Mingtai (Proposed,P2)	The area at which the measured quantity of purified water (18µl) was put that part was swollen out.	
3.	Lactose monohydrate (Granulac 230)	Meggle (Existing,E3)	The area at which the measured quantity of purified water (18µl) was put that part was chipping out.	Both the vendors comply with each other.
		DFE (Proposed,P3)	The area at which the measured quantity of purified water (18µl) was put that part was chipping out.	
4.	Lactose monohydrate (450 mesh)	DFE (Existing,E4)	The area at which the measured quantity of purified water (18µl) was put that part was swollen out.	Both the vendors comply with each other.
		Meggle (Proposed,P4)	The area at which the measured quantity of purified water was placed that part was swollen out.	

Bursting study to evaluate disintegration pattern

Table 9: Results for Bursting study

Excipients	Vendors	Bursting Time	Observation	Remarks
Maize starch	Roquette (Existing,E1)	5 seconds	The slug divided into parts and surface erosion took place.	Both the vendors complying with each other.
	GPC (Proposed,P1)	5 seconds	The slug divided into parts and surface erosion took place.	
MCC PH 112	FMC (Existing,E2)	5 seconds	Tablet was swollen and was broken into two halves horizontally.	Both the vendors complying with each other.
	Mingtai (Proposed,P2)	9 seconds	Tablet was swollen and was broken into two halves horizontally.	
Lactose monohydrate (Granulac 230)	Meggle (Existing,E3)	17 seconds	Slug was swollen and cracked from all the sides and formed a heap.	Both the vendors complying with each other.
	DFE (Proposed,P3)	18 seconds	Slug was swollen and cracked from all the sides and formed a heap.	
Lactose (450 mesh)	DFE (Existing,E4)	12 seconds	Slug was swollen and cracked from all the sides.	Both the vendors complying with each other.
	Meggle (Proposed,P4)	11 seconds	Slug was swollen and cracked from all the sides.	

Exposure study

Table 10: Results for Exposure study

Test	Maize starch		MCC PH 112		Lactose (Granulac 230)		Lactose (450 mesh)		Remarks
	At 80 ± 10 % RH for 60 hours		At 90 ± 10 % RH for 24 hours		At 90 % RH for 48 hours		At 90 % RH for 60 hours		
	E1	P1	E2	P2	E3	P3	E4	P4	
% Moisture content (% increase/decrease)	61.3	53.17	105	125	17	14.6	0.6	0.3	Comparable
Weight gain of powder (% increase/ decrease)	9.32	8.97	9.5	12.2	0.1	0.5	0	0.09	Comparable
Tablet weight (% increase/ decrease)	8.85	8.43	4.3	5.53	1.8	0.09	0.69	0.30	Comparable
Thickness (% increase/ decrease)	17.29	15.8	6.0	4.1	0.3	1.3	0.9	0.01	Comparable
Diameter (% increase/ decrease)	4.6	4.7	1.4	0.87	0.25	0.3	0.62	0.87	Comparable

Evaluation of excipients on drug product
Comparison of the micromeritics of the lubricated blend

Table 11: Results for micromeritics of the lubricated blend

SL No.	Parameters	Maize starch in drug product		MCC PH 112 in drug product		Lactose (Granulac 230 in drug product		Lactose (450 mesh)		Remarks
		E1	P1	E2	P2	E3	P3	E4	P4	
1.	Bulk density	0.46	0.49	0.62	0.64	0.33	0.36	0.58	0.57	Comparable
2.	Tapped density	0.67	0.67	0.81	0.81	0.45	0.42	0.81	0.74	Comparable
3.	Compressibility index	31.5	28.7	23	20.3	26.6	14	28	22	Comparable
4.	Hausner's ratio	1.46	1.4	1.3	1.25	1.36	1.19	1.39	1.29	Comparable
5.	Flodex	50	50	200	200	100	100	44.4	35.7	Comparable
6.	% Moisture content	4.91	5	2.4	1.7	1.6	2.1	1.5	1.6	Comparable
7.	Particle size distribution									
	Mesh size (#)	% weight retained								
	#20	0	0	0	0	0	0	0	0	Comparable
	#30	0	0	0	0	0	0	6	8	Comparable
	#40	2	2	1	1	2	4	10	12	Comparable
	#60	4	6	6	6	12	6	10	2	Comparable
	#80	14	12	6	8	53	52	4	6	Comparable
	#100	16	16	11	7	60	56	4	14	Comparable
	#200	50	40	15	15	81	86	10	12	Comparable
	In fines collector	94	92	10	12	19	14	58	50	Comparable

Comparative evaluation of compressed tablets

Table 12: Results for evaluation of compressed tablets

S. No.	Parameters	Maize starch in drug product			MCC PH 112 in drug product			Lactose (Granulac 230)			Lactose (450 mesh)		
		Standard	E1	P1	Standard	E2	P2	Standard	E3	P3	Standard	E4	P4
1	Weight of 20 tablets (g)	6.6g ± 2 %	6.6	6.6	1.4 g ± 3 %	1.4	1.4	1.25 ± 3 %	1.2	1.2	3.7 g ± 2 %	184	185
2	Individual tablet weight (mg)	330 mg ± 5 %	329	329	70 mg ± 10 %	70	71	125 mg ± 7.55 %	125	123	185 ± 4 %	171	181
3	Thickness (mm)	3.7 ± 0.2	3.73	3.72	3.1 ± 0.1	3.1	3.1	2.8 ± 0.1	2.9	3	3.4 ± 0.2	3.5	3.47
4	Hardness (Kpa)	Not Less Than 2	3.2	3	7-11	6	6	3-9	5	4	Not Less Than 3	5	4
5	Friability	Not More Than 1 %	0.4	0.1	NMT 1 %	0.3	0.3	NMT 1 %	0	0	NMT 1.0 %	0.03	0
6	Disintegration time	NMT 12 minutes	50 sec	61 sec	NMT 15 minutes	13 min	11 min	NMT 15 min	8	9.5	NMT 10 min	4.25	5.01

Where; E1-Existing vendor of maize starch (Roquette); P1-Proposed vendor of maize starch (GPC); E2-Existing source of microcrystalline cellulose PH 112 (FMC); P2-Proposed source of microcrystalline cellulose PH 112 (Mingtai); E3-Existing source of Lactose monohydrate Granulac 230 (Meggle); P3-Proposed source of Lactose monohydrate Granulac 230 (DFE); E4-Existing source of Lactose 450 mesh (DFE); P4-Proposed source of Lactose 450 mesh (Meggle)

RESULTS AND DISCUSSION

Four excipients were identified based on their criticality and their functionality tests were developed based on their functional role in their respective formulations. The selection of the drug product trial was based on biopharmaceutical classification, the formulation in which the particular excipient was being used in higher quantity. Functionality test design, drug product trials were done with respect to the excipients category and results were evaluated between different vendors. Maize starch is used as diluent, disintegrant, binder and thickening agent in most of the pharmaceutical products. As a part of the evaluation of maize starch based on its functional parameters, Excipient micromeritics study, compaction study to evaluate binder and diluent property, swelling and bursting study to evaluate the disintegration property and exposure study were performed. The results with the materials from the existing vendor (Roquette) and proposed vendor (GPC) were found to be comparable and the same were confirmed with the evaluation on drug product. The results are given in Tables 6-12. Microcrystalline cellulose PH 112 is used as diluent, to increase the dosage form volume or weight and occasionally referred as dry binder in most of the pharmaceutical formulations. As a part of the evaluation of Microcrystalline cellulose PH 112 based on its functional parameters, Excipient micromeritics study, Compaction study to evaluate binder and diluent property, Swelling and bursting study to evaluate the disintegration property and exposure study were performed. The results with the materials from the existing vendor (FMC International) and proposed vendor (Mingtai) were found to be comparable and the same were confirmed with the evaluation on drug product. The results are given in Tables 6-12. Lactose monohydrate (Granulac 230) is widely used as diluent, to increase the dosage form volume or weight and to more limited extent in lyophilized products and infant formulations. Various lactose grades are commercially available that have different physical properties. This permits the selection of the most suitable material for a particular application. As a part of the evaluation of Lactose monohydrate (Granulac 230) based on its functional parameters, Excipient micromeritics study, Compaction study to evaluate binder and diluent property, Swelling and bursting study to evaluate the disintegration property and exposure study were performed. The results with the materials from the existing vendor (Meggle) and proposed vendor (DFE) were found to be comparable and the same were confirmed with the evaluation on drug product. The results are given in Tables 6-12. Lactose monohydrate (450 mesh) is widely used as diluents in formulations. Various lactose grades are commercially available that have different physical properties. This permits the selection of the most suitable material for a particular application. As a part of the evaluation of Lactose monohydrate (450 mesh) based on its functional parameters, Excipient micromeritics study, Compaction study to evaluate binder and diluent property, Swelling and bursting study to evaluate the disintegration property and exposure study were performed. The results with the materials from the existing vendor (DFE) and proposed vendor (Meggle) were found to be comparable and the same were confirmed with the evaluation on drug product. The results are given in Tables 6-12.

Conflict of interest for this work

Excipients play a very important key role in the formulation. Same excipient can be obtained from many sources, so change in the source may have an effect in the evaluation parameters of the formulation; sometimes due to change in the source of excipient and vendor the whole commercial batch of the formulation can be rejected. So, in order to prevent this, each and every excipient should be evaluated thoroughly. This type of work prevents huge loses to the Pharmaceutical industry.

CONCLUSION

The Samples of Maize starch, Microcrystalline cellulose PH 112, Lactose monohydrate (Granulac 230), Lactose monohydrate (450 mesh) from existing vendor and proposed vendor were analyzed and the results were found to be comparable and therefore the materials from proposed vendors can be accepted as an alternate source for the existing vendors.

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