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Research Article

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Process Validation of Bempedoic Acid Film-Coated Tablets

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Abstract Process validation is establishing documented evidence which provides a high degree of assurance that a specified process will consistently produce a product meeting its predetermined specifications and quality characteristics. Bempedoic acid is used as an active pharmaceutical ingredient. Other raw materials used are: Microcrystalline cellulose, Lactose monohydrate, Sodium starch glycolate, Hydroxypropyl cellulose, Colloidal silicon dioxide and purified water. Process validation was done to reduce variation between various batches, to decrease the risk of defect costs and also to ensure that quality is built into the process at every step and not just tested at the end. Process validation was selected for that 3 consecutive batches were selected because if desired quality is found in first batch, it is accidental, second batch quality is regulated and quality in the third batch is Validation. Manufacturing of validation batches were performed as per instructions mentioned in Master Manufacturing Docket, all samples were withdrawn during manufacturing as per approved protocol and samples were analyzed for various tests like hardness, thickness, friability, uniformity of weight, uniformity of blend, average weight of 20 tablets, uniformity of dosage units and dissolution etc.

Keywords Pharmaceutical process validation, validation protocol, manufacturing steps, bempedoic acid, evaluation, tablets

Introduction

Definitions of Process Validation

According to European commission, "Validation is described as documented evidence that the process, operated within established parameters, can execute effectively and reproducibly to produce a medicinal product meeting its predetermined specifications and quality attributes."

According to USFDA, "Process validation is establishing documented evidence which provides a high degree of assurance that a specified process will consistently produce a product meeting its predetermined specifications and quality characteristics."

According to ICH, "Process validation is the means of ensuring and providing documentary evidence that processes within their specified design parameters are capable of repeatedly and reliably producing a finished product of the required quality."

According to WHO, "Validation is the documented act of proving that any procedure, process, equipment, material, activity or system actually leads to expected result" [1-2].

Benefits of Validation

- Assurance of quality
- Reduction of quality costs

- Process optimization
- Safety
- Better customer quality [3, 4]

Need of Process Validation

- Introduction of totally new product.
- Installation of new equipment.
- Alteration of process and equipment.
- Where process results cannot be fully verified during routine production by inspection and test, the process must be validated according to procedures.
- Routine end-product tests have insufficient sensitivity to verify the desired safety and efficacy of the finished devices; Clinical or destructive testing would be required.
- Routine end-product tests do not reveal all variations in safety and efficacy that may occur in the finished devices. It is suspected that the process is barely capable of meeting the device specifications [5].

Types of Process Validation

1). Prospective validation

This validation is usually carried out prior to distribution either of a new product or a product made under a revised manufacturing process. It is performed on at least three consecutive batches.

2). Concurrent Validation

This validation involves in-process monitoring of critical processing steps and product testing. This helps to generate documented evidence to exhibit that the production process is in a state of control.

3). Retrospective Validation

This validation is achieved by the review of the historical manufacturing testing data to prove that the process has always remained in control. This type of validation of a process for a product is already in distribution.

4). Revalidation

Re-validation provides the evidence that changes in a process and/or the process environment that are introduced do not adversely affect process characteristics and product quality [6-8].

Advantages of Process Validation:

- Expanded real time monitoring and adjustment of process.
- Enhanced ability to statistically evaluate process performance and product variables. eg: Individuals, mean, range, control limits.
- Enhanced data and evaluation capabilities and increased confidence about process reproducibility and product quality.
- Improved ability to set target parameters and control limits for routine production, correlating with validation results.
- Enhanced reporting capability [9].

Materials and Methods

Materials

Bempedoic acid is used as an active pharmaceutical ingredient. Other raw materials used are: Microcrystalline cellulose, Lactose monohydrate, Sodium starch glycolate, Hydroxypropyl cellulose, Colloidal silicon dioxide and purified water.

Equipments/Instruments

Table 1: Equipments/Instruments Used During In-Process Testing of Validation Batch

S. No.	Test	Processing Instruments
1.	Weight verification	Weighing balance / Smart test 50
2.	Thickness verification	Vernier caliper / Smart test 50
3.	Hardness testing	Hardness tester / Smart test 50
4.	Friability testing	Friability tester
5.	Dissolution time	Dissolution test apparatus
6.	Loss on drying	Halogen moisture balance

Method

Manufacturing steps

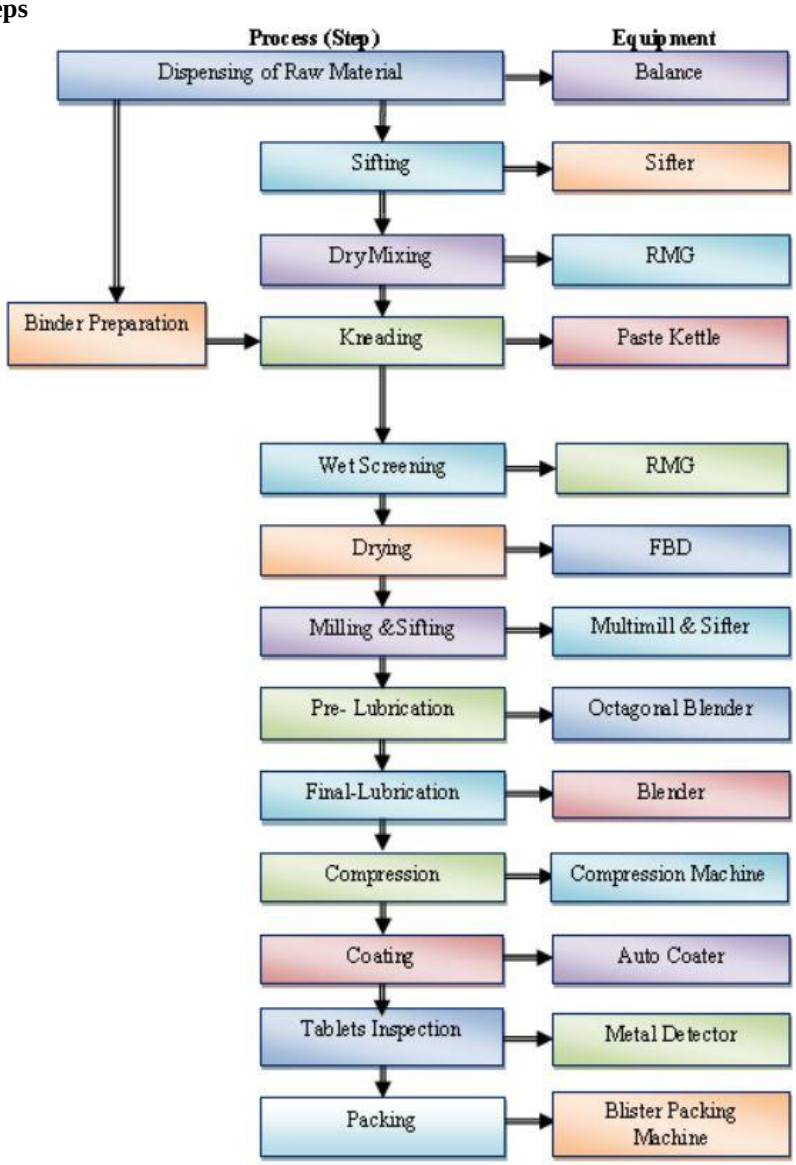

Figure 1: Manufacturing Process Flow Chart

Sampling for Process Validation

Table 2: Sampling Testing Plan

Compression Stage			
Different speed at optimum hardness	• Slow speed 01 sample • Optimum speed 01 sample • High speed 01 sample (01 x 03 = 03 samples from LHS and RHS)	20 tablets	Appearance, average weight of 20 tablets and uniformity of weight
		10 tablets	Thickness, Hardness
		Take tablets equivalent to 6.5 gm.	Friability test
		$03^{\#}$ x 10 = 30 tablets	Uniformity of dosage units (By content uniformity)
Different hardness at optimum speed	• Low hardness 01 sample • Optimum hardness 01 sample • High hardness 01 sample (01 x 03 = 03 samples from LHS and RHS)	20 tablets	Appearance, average weight of 20 tablets and uniformity of weight
		10 tablets	Thickness, Hardness
		Take tablets equivalent to 6.5 gm.	Friability test
		$03^{\#\#}$ x 06 = 18 tablets	Dissolution (To be performed on first batch only) (At low hardness, optimum hardness and high hardness) (For information only)
Hopper challenge study	• Full hopper nple • Half hopper nple • Quarter hopper 01 sample (01 x 03 = 03 samples from LHS and RHS	20 tablets	Appearance, average weight of 20 tablets and uniformity of weight
		10 tablets	Thickness, Hardness
		Take tablets equivalent to 6.5 gm.	Friability test
		$03^{\#}$ x 10 = 30 tablets	Uniformity of dosage units (By content uniformity)
Coating Stage			
Completion of coating of each lot	01 sample	Composite 50 tablets from front, rear, left, right and center of pan	Description, average weight

Standard Test Procedures for Process Validation

1). Description

20 tablets are taken at random and description was observed visually.

2). Average Weight

Twenty tablets were randomly selected from each batch and individually weighed. The average weight of 20 tablets was calculated.

3). Thickness

Twenty tablets were randomly selected from each batch and thickness was measured by using Digital Vernier Caliper.

4). Hardness

The crushing strength (Newton) of prepared tablets was determined for 10 tablets of each batch by using Monsanto tablet hardness tester.

5). Friability

Twenty tablets were weighed and placed in the Roche friability testing apparatus and apparatus was rotated at 100 rpm. After revolutions the tablets were deducted and weighed again. The percentage friability was measured using the formula:

$$\% F = \frac{W - Wt}{W} x\ 100$$

Where,

% F = Friability in percentage; W = Initial weight of tablet; Wt = Weight of tablets after revolution

6). Dissolution

Inject single injection of blank solution, 5 replicate injection of standard preparation and each sample preparation of single into the chromatographic system. Recorded the chromatograms and measured the principle peak responses.

7). Assay

Inject single injection of blank (diluent), 5 replicate injection of standard preparation and duplicate injections of sample preparation into liquid chromatographic system. Finally, record the chromatograms and measure the principle peak response.

8). Uniformity of Dosage unit by Content Uniformity

Inject single injection of blank (diluent), 5 replicate injection of standard preparation and single injection of sample preparation into the liquid chromatographic system. At last, the chromatograms were recorded and the principle peak response was measured.

Table 3: In-Process Specifications (Core Tablets)

S. No.	Test	Specifications
1.	Appearance	White to off-white, oval shaped uncoated tablets
2.	Targeted weight	300 mg
3.	Average weight of 20 tablets	300 mg ± 5 % (285 mg - 315 mg)
4.	Uniformity of weight	300 mg ± 7.5 % (277.5 mg – 322.5 mg)
5.	Thickness	4.80 ± 0.30 mm (4.50 mm – 5.1 mm)
6.	Hardness	35 N to 95 N
7.	Friability	NMT 1.0 % w/w
8.	Dissolution (By HPLC)	Time (Hrs) 2 4 6 8 10 12 14 16 20
9.	Assay (By HPLC)	NLT 90.0 % and NMT 110.0 % of labeled amount.
10.	Uniformity of Dosage units (By content uniformity) (By HPLC)	Readily pass criteria- RSD of all individual ≤ 4 %. Each location mean shall be within 90 % to 110 % of labeled amount and all individuals shall be within 75 % and 125 % of the labeled amount. Marginally pass criteria- RSD of all individual should be ≤ 6 %. Each location mean

	shall be within 90 % to 110 % of labeled amount and all individuals shall be within 75 % and 125 % of the labeled amount.

Table 4: In-Process Specifications (Coated Tablets)

S. No.	Test	Specifications
1.	Description	White to off-white, oval shaped coated tablets.
2.	Average weight	309.6 mg ± 5 % (294.12 mg to 325.08 mg)

In-Process Results of Different Speed (Slow Speed, Optimum Speed and High Speed) at Optimum Hardness:

Table 3: In-Process Results at Compression Stage for Speed Challenge of Batch No. 1, 2 & 3

S. No.	Test		Batch No. 1			Batch No. 2			Batch No. 3		
			Slow Speed (10 RPM)	**Optimum Speed (20 RPM)**	**High Speed (25 RPM)**	**Slow Speed (10 RPM)**	**Optimum Speed (20 RPM)**	**High Speed (25 RPM)**	**Slow Speed (10 RPM)**	**Optimum Speed (20 RPM)**	**High Speed (25 RPM)**
1.	**Appearance**	**LHS**	Complies	Complies	Complies	Complies	Complies	Complies	Complies	Complies	Complies
		RHS	Complies	Complies	Complies	Complies	Complies	Complies	Complies	Complies	Complies
2.	**Average weight of 20 tablets**	**LHS**	299.79 mg	300.09 mg	300.08 mg	297.62 mg	299.63 mg	301.17 mg	301.03 mg	300.14 mg	301.89 mg
		RHS	299.79 mg	299.9 mg	299.93 mg	298.39 mg	298.93 mg	299.97 mg	301.42 mg	301.52 mg	300.88 mg
3.	**Uniformity of weight**	**LHS**	Min: 297.1 mg Max: 302.2 mg	Min: 298.5 mg Max: 302.5 mg	Min: 297.2 mg Max: 302.5 mg	Min: 296.0 mg Max: 300.2 mg	Min: 295.9 mg Max: 302.8 mg	Min: 299.2 mg Max: 303.0 mg	Min: 298.2 mg Max: 303.8 mg	Min: 297.3 mg Max: 302.3 mg	Min: 299.1 mg Max: 303.8 mg
		RHS	Min: 297.2 mg Max: 301.7 mg	Min: 297.1 mg Max: 301.4 mg	Min: 297.2 mg Max: 303.3 mg	Min: 296.0 mg Max: 300.5 mg	Min: 296.8 mg Max: 301.1 mg	Min: 297.1 mg Max: 302.9 mg	Min: 299.3 mg Max: 304.1 mg	Min: 298.9 mg Max: 303.4 mg	Min: 298.7 mg Max: 303.7 mg
4.	**Thickness**	**LHS**	4.77 mm to 4.82 mm	4.66 mm to 4.73 mm	4.73 mm to 4.77 mm	4.66 mm to 4.70 mm	4.69 mm to 4.73 mm	4.68 mm to 4.71 mm	4.67 mm to 4.73 mm	4.66 mm to 4.73 mm	4.66 mm to 4.80 mm
		RHS	4.66 mm to 4.73 mm	4.64 mm to 4.72 mm	4.72 mm to 4.81 mm	4.65 mm to 4.72 mm	4.67 mm to 4.72 mm	4.69 mm to 4.73 mm	4.66 mm to 4.73 mm	4.66 mm to 4.72 mm	4.64 mm to 4.80 mm
5.	**Hardness**	**LHS**	41 N to 56 N	49 N to 63 N	49 N to 64 N	49 N to 68 N	54 N to 70 N	49 N to 68 N	62 N to 71 N	61 N to 72 N	67 N to 74 N
		RHS	53 N to 68 N	39 N to 66 N	49 N to 69 N	48 N to 69 N	42 N to 63 N	45 N to 69 N	59 N to 72 N	61 N to 75 N	58 N to 73 N
6.	**Friability**	**LHS**	0.08 %	0.09 %	0.08 %	0.04 %	0.04 %	0.05 %	0.04 %	0.02 %	0.03 %
		RHS	0.07 %	0.06 %	0.07 %	0.03 %	0.04 %	0.05 %	0.03 %	0.02 %	0.05 %

Uniformity of Dosage Units (By content Uniformity) (By HPLC) at Compression Stage for Different Speed at Optimum Hardness:

Table 4: Uniformity of Dosage Units at Slow Speed of 3 Batches

S. No.			Batch No. 1	Batch No. 2	Batch No. 3
Slow Speed	LHS	Min	97.70%	90.40%	98.20%
		Max	102.30%	105.50%	102.60%
		Avg.	99.88%	97.73%	99.89%
	RHS	Min	96.50%	97.40%	98.70%
		Max	103.40%	107.10%	102.60%
		Avg.	98.67%	101.27%	100.64%
Optimum Speed	LHS	Min	98.20%	97.40%	98.30%
		Max	102.40%	104.30%	103.20%
		Avg.	99.40%	100.92%	100.95%
	RHS	Min	98.40%	96.30%	94.90%
		Max	101.80%	103.40%	106.90%
		Avg.	100.35%	98.62%	100.68%
High Speed	LHS	Min	99.00%	95.00%	98.90%
		Max	102.40%	103.50%	102.60%
		Avg.	100.43%	99.27%	100.16%
	RHS	Min	98.60%	98.90%	98.30%
		Max	100.90%	102.30%	101.40%
		Avg.	99.47%	99.94%	100.58%

In-Process Results of Different Hardness (Low Hardness, Optimum Hardness and High Hardness) at Optimum Speed:

Table 5: In-process Results at Compression Stage for Hardness Challenge of Batch No. 1, 2 and 3

S. No.	Test		Batch No. 1			Batch No. 2			Batch No. 3		
			Low Hardness (31 N to 50 N)	Optimum Hardness (46 N to 66 N)	High Hardness (79 N to 99 N)	Low Hardness (32 N to 47 N)	Optimum Hardness (45 N to 68 N)	High Hardness (77 N to 97 N)	Low Hardness (37 N to 42 N)	Optimum Hardness (67 N to 77 N)	High Hardness (79 N to 95 N)
1.	Appearance	LHS	Complies	Complies	Complies	Complies	Complies	Complies	Complies	Complies	Complies
		RHS	Complies	Complies	Complies	Complies	Complies	Complies	Complies	Complies	Complies
2.	Average weight of 20 tablets	LHS	297.45 mg	299.21 mg	301.21 mg	300.4 mg	301.94 mg	300.98 mg	300.17 mg	299.56 mg	300.20 mg
		RHS	298.56 mg	300.22 mg	301.53 mg	301.28 mg	301.23 mg	301.35 mg	299.41 mg	299.96 mg	299.85 mg
3.	Uniformity of weight	LHS	Min: 294.2 mg Max: 300.2 mg	Min: 296.4 mg Max: 301.6 mg	Min: 297.6 mg Max: 303.6 mg	Min: 298.7 mg Max: 301.6 mg	Min: 299.9 mg Max: 303.9 mg	Min: 297.9 mg Max: 302.5 mg	Min: 297.2 mg Max: 304.2 mg	Min: 297.4 mg Max: 302.5 mg	Min: 297.4 mg Max: 303.1 mg
		RHS	Min: 294.1 mg Max:	Min: 297.2 mg Max:	Min: 298.8 mg Max:	Min: 299.3 mg Max:	Min: 298.7 mg Max:	Min: 299.0 mg Max:	Min: 294.2 mg Max:	Min: 297.1 mg Max:	Min: 297.1 mg Max:

4.	**Thickness**	**LHS**	301.9 mg 4.87 mm to 4.94 mm	302.5 mg 4.67 mm to 4.76 mm	303.7 mg 4.62 mm to 4.66 mm	302.9 mg 4.84 mm to 4.94 mm	302.9 mg 4.67 mm to 4.73 mm	303.1 mg 4.58 mm to 4.66 mm	303.4 mg 4.82 mm to 4.91 mm	303.2 mg 4.70 mm to 4.80 mm	303.5 mg 4.53 mm to 4.61 mm
		RHS	4.82 mm to 4.87 mm	4.67 mm to 4.75 mm	4.60 mm to 4.66 mm	4.82 mm to 4.91 mm	4.69 mm to 4.73 mm	4.59 mm to 4.63 mm	4.84 mm to 4.92 mm	4.70 mm to 4.81 mm	4.53 mm to 4.60 mm
5.	**Hardness**	**LHS**	36 N to 43 N	47 N to 58 N	81 N to 99 N	35 N to 47 N	49 N to 66 N	83 N to 97 N	37 N to 42 N	67 N to 74 N	79 N to 93 N
		RHS	36 N to 48 N	56 N to 66 N	82 N to 95 N	35 N to 45 N	45 N to 68 N	77 N to 96 N	36 N to 42 N	69 N to 77 N	87 N to 95 N
6.	**Friability**	**LHS**	0.04 %	0.06 %	0.06 %	0.06 %	0.05 %	0.06 %	0.04 %	0.04 %	0.02 %
		RHS	0.06 %	0.07 %	0.05 %	0.08 %	0.04 %	0.04 %	0.03 %	0.03 %	0.02 %

Table 6: Dissolution at Low Hardness, Optimum Hardness and High Hardness

Time Point	**Mean of % drug release of 6 Units**					
	Low Hardness		**Optimum Hardness**		**High Hardness**	
	LHS (31 to 43 N)	**RHS (35 to 50 N)**	**LHS (46 to 58 N)**	**RHS (56 to 66 N)**	**LHS (81 to 99 N)**	**RHS (79 to 95 N)**
2 hrs	49.68	49.58	50.18	48.98	48.78	48.98
4 hrs	69.38	69.78	72.08	71.18	70.68	71.18
6 hrs	80.68	82.28	85.68	84.68	83.48	84.68
8 hrs	85.78	88.88	93.58	92.48	90.58	92.48
10 hrs	88.28	91.68	97.58	96.88	94.78	96.88
12 hrs	89.28	93.78	99.48	98.68	96.28	98.68
14 hrs	88.58	94.98	100.48	99.88	96.68	99.88
16 hrs	88.18	93.88	100.48	100.68	97.58	100.68
20 hrs	88.18	94.88	101.38	100.88	97.78	100.88

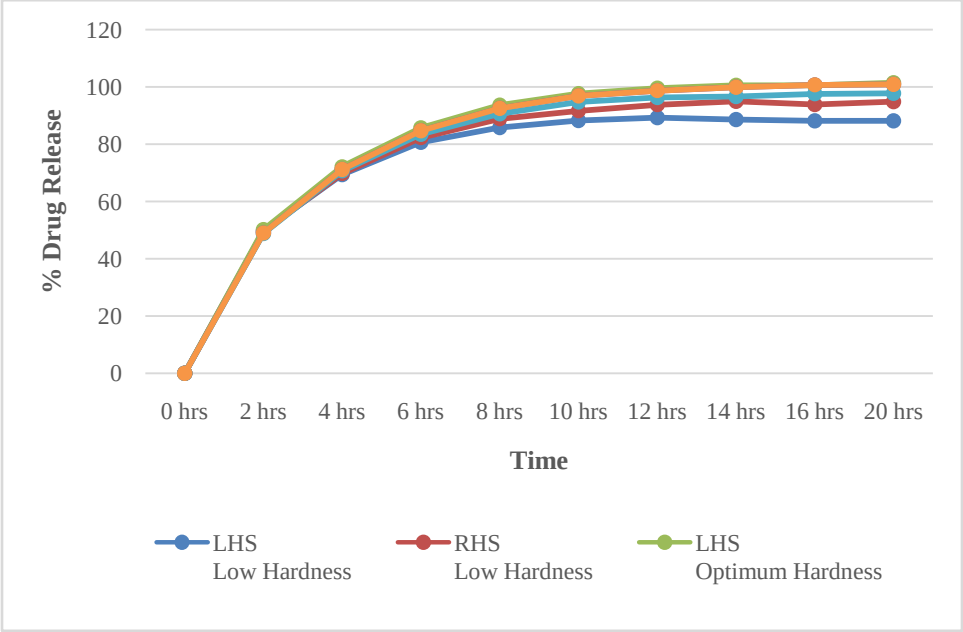

Figure 2: Comparison of Dissolution for Different Hardness (Low Hardness, Optimum Hardness and High Hardness) at Optimum Speed

In-process Results for Compression Process: Hopper Challenge study (Full Hopper, Half Hopper and Quarter Hopper) at Optimum Speed:

Table 7: In-process Results at Compression Stage for Hopper Challenge of Batch No.1, 2 and 3

S. No.	Test		Batch No. 1			Batch No. 2			Batch No. 3		
			Full Hopper	Half Hopper	Quarter Hopper	Full Hopper	Half Hopper	Quarter Hopper	Full Hopper	Half Hopper	Quarter Hopper
1.	Appearance	LHS	Complies	Complies	Complies	Complies	Complies	Complies	Complies	Complies	Complies
		RHS	Complies	Complies	Complies	Complies	Complies	Complies	Complies	Complies	Complies
2.	Average weight of 20 tablets	LHS	299.31 mg	300.29 mg	299.10 mg	300.36 mg	301.34 mg	301.50 mg	300.27 mg	299.78 mg	299.84 mg
		RHS	299.05 mg	299.98 mg	300.18 mg	301.99 mg	302.17 mg	301.24 mg	299.78 mg	298.91 mg	300.06 mg
3.	Uniformity of weight	LHS	Min: 295.4 mg Max: 301.5mg	Min: 295.9 mg Max: 303.4 mg	Min: 296.4 mg Max: 302.5 mg	Min: 297.1 mg Max: 302.9 mg	Min: 299.4 mg Max: 302.8 mg	Min: 298.4 mg Max: 303.2 mg	Min: 297.3 mg Max: 304.2 mg	Min: 297.1 mg Max: 302.7 mg	Min: 297.2 mg Max: 301.5 mg
		RHS	Min: 296.6 mg Max: 301.1 mg	Min: 295.8 mg Max: 303.6 mg	Min: 295.8 mg Max: 303.0 mg	Min: 300.3 mg Max: 303.8 mg	Min: 300.3 mg Max: 303.9 mg	Min: 299.9 mg Max: 302.8 mg	Min: 297.1 mg Max: 302.1 mg	Min: 297.1 mg Max: 300.4 mg	Min: 297.2 mg Max: 302.3 mg
4.	Thickness	LHS	4.77 mm to 4.94 mm	4.67 mm to 4.72 mm	4.60 mm to 4.76 mm	4.67 mm to 4.73 mm	4.68 mm to 4.71 mm	4.67 mm to 4.73 mm	4.67 mm to 4.73 mm	4.68 mm to 4.71 mm	4.67 mm to 4.73 mm
		RHS	4.69 mm to 4.87 mm	4.66 mm to 4.74 mm	4.60 mm to 4.79 mm	4.65 mm to 4.71 mm	4.66 mm to 4.72 mm	4.68 mm to 4.74 mm	4.65 mm to 4.71 mm	4.66 mm to 4.72 mm	4.68 mm to 4.74 mm
5.	Hardness	LHS	58 N to 73 N	60 N to 70 N	63 N to 73 N	62 N to 73 N	61 N to 74 N	63 N to 77 N	62 N to 73 N	61 N to 74 N	63 N to 77 N
		RHS	59 N to 72 N	61 N to 71 N	61 N to 72 N	59 N to 71 N	62 N to 80 N	63 N to 76 N	59 N to 71 N	62 N to 80 N	60 N to 76 N
6.	Friability	LHS	0.05 %	0.08 %	0.06 %	0.05 %	0.03 %	0.04 %	0.05 %	0.03 %	0.04 %
		RHS	0.07 %	0.09 %	0.07 %	0.04 %	0.04 %	0.03 %	0.03 %	0.04 %	0.05 %

Uniformity Dosage Units (By content Uniformity) (By HPLC) for Hopper Challenge Study (Full Hopper, Half Hopper and Quarter Hopper):

Table 8: Uniformity of Dosage Units at Full, Half and Quarter Hopper of 3 Batches

S. No.			Batch No. 1	Batch No. 2	Batch No. 3
Slow Speed	LHS	Min	97.50%	95.40%	93.70%
		Max	111.80%	99.10%	104.90%
		Avg.	101.97%	96.59%	97.44%
	RHS	Min	96.90%	93.80%	94.00%
		Max	106.40%	98.70%	99.50%
		Avg.	101.22%	96.32%	96.03%
Optimum	LHS	Min	95.80%	96.40%	97.70%

Speed		**Max**	102.90%	102.80%	104.50%
		Avg.	98.10%	97.98%	100.10%
	RHS	**Min**	96.20%	95.80%	95.60%
		Max	102.90%	106.80%	102.90%
		Avg.	98.05%	99.19%	97.82%
High Speed	**LHS**	**Min**	98.00%	97.20%	97.30%
		Max	102.40%	103.00%	106.60%
		Avg.	100.10%	100.29%	100.80%
	RHS	**Min**	98.10%	97.00%	97.00%
		Max	103.60%	103.30%	104.40%
		Avg.	100.47%	99.82%	101.06%

Table 9: Results of Yield and Assay after Compression

S. No	Parameters	Batch No. 1	Batch No. 2	Batch No. 3
1	Assay	(98.4 %)	(98.9 %)	(99.1 %)
2	Yield of compression	92.30 %	97.42 %	98.12 %
3	Batch Yield	94.21 %	94.83 %	95.01 %
4	% Reconciliation of Compression	99.51 %	99.08 %	99.83 %

Table 10: Results of Yield after Film Coating

S. No	Parameters	Batch No. 1	Batch No. 2	Batch No. 3
1	Yield of Coating	99.78%	99.36%	99.72%
2	Batch Yield	93.90%	95.33%	91.93%
3	% Reconciliation of Coating	99.78%	99.36%	99.72%

Conclusion

In this research work first of all the formulation and manufacturing process of the bempedoic acid tablet were evaluated as per the validation protocol. Process validation was done to reduce variation between various batches, to decrease the risk of defect costs and also to ensure that quality is built into the process at every step and not just tested at the end. Process validation was selected for that 3 consecutive batches were selected because if desired quality is found in first batch, it is accidental, second batch quality is regulated and quality in the third batch is Validation. Manufacturing of validation batches were performed as per instructions mentioned in Master Manufacturing Docket, all samples were withdrawn during manufacturing as per approved protocol and samples were analyzed for various tests like hardness, thickness, friability, uniformity of weight, uniformity of blend, average weight of 20 tablets, uniformity of dosage units and dissolution etc. The formulated tablets of all batches passed the acceptance criteria of evaluation parameters.

Hence, from the process validation study, it can be concluded that manufacturing process used for manufacturing of bempedoic acid180 mg tablets stands validated and no significant difference was found between the three batches.

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