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Review Article

Process Validation of Remogliflozin Etabonate Sustained Release Formulation

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ABSTRACT

Failure in developing an effective process for the manufacturing of drug products may lead to severe consequences like product recalls and plant closure. As a result, process validation has gained a prime focus as an essential product development activity. In the limelight of this notion, the research goal of current work was to carry out prospective process validation for the manufacture of Remogliflozin Etabonate sustained release tablets along with a tablet containing them. Remogliflozin Etabonate mini tablets production was trialed and tested for results. The Formulation that gave promising results was considered and concluded for process validation. Protocol and batch manufacturing record (BMR) were prepared for three consecutive batches of the same size, method, equipment, and validation criteria. The critical process parameters were identified; mini-tablets were compressed by using the direct compression method and evaluated. The results of three consecutive batches were compiled with specifications. It indicated that the process employed here offers a high degree of assurance to produce quality products meeting pre-determined specification limits and quality attributes. Three process validation batches of same size, manufacturing process, equipment & validation criteria was taken. The critical parameter involved in sifting, dry mixing, preparation of granulating agent, wet mixing, wet milling, drying, sizing, lubrication and compression stages were identified and evaluated. The outcome indicated that this process validation data provides high degree of assurance that manufacturing process produces product meeting its predetermined specifications and quality attributes.

INTRODUCTION

OBJECTIVE: The Validation protocol for Remogliflozin Etabonate Tablets has been prepared for the following purpose.

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- To validate the manufacturing process as described in the master formula record.
- To provide a means to demonstrate that the product can be consistently and reproducibly manufactured and the product meets the specification.

PRE- VALIDATION REQUIREMENT:

- Ensure that all raw materials are analyzed as per specification and released.
- Ensure that all equipments are calibrated.
- Ensure that all manufacturing equipments are cleaned as per their respective standard, cleaning procedures and line clearance obtained
- Ensure that all environmental conditions in the manufacturing area are as per the Manufacturing instructions,
- Ensure that the test procedures, references / working standards and Reagents are available.
- Ensure that trained personnel are available for all operations.
- Ensure that all safety wear is available at the work places.

MANUFACTURING FORMULA FOR GRANULATION

Sr. No	Ingredient	Spec.	% of overages	Qt/ Tab (Mg)	STD. Qt (Kg)
1	Remogliflozin Etabonate	IP	---	100	--
2	PVP-K30	IP	---	8	--
3	Microcrystalline Cellulose	IP	---	21.4	--
4	Magnesium Stearate	IP	---	3.6	--
5	HPMC-K100lv+Eudragit L-100	IP	---	100+10	--
6	Talc	IP	---	5	--
7	Titanium Dioxide	IP	---	qs	--
250 mg					--

MANUFACTURING FORMULA FOR COATING

Sr. No	Ingredient	Spec.	Qt/ Tab (Mg)	STD. Qt (Kg)
1.	PVP-K30	IP	8	--
2.	Microcrystalline Cellulose	IP	21.4	--
3.	Magnesium Stearate	IP	3.6	--
4.	HPMC-K100lv+Eudragit L-100	IP	100+10	--
5.	Talc	IP	5	--
6.	Titanium Dioxide	IP	qs	--

MANUFACTURING PROCESS:

A] Granulation Process: Get the line clearance for granulation process: Before commencing the actual compounding of the batch ensure the complete cleaning of all Equipment's and the area as per the standard operating procedure. Pass Remogliflozin Etabonate & Magnesium Stearate IP through 30 # sieve by using sifter.

1. Mix Remogliflozin Etabonate for 5 minutes in R.M.G with fast speed & Chopper off.
2. **Preparation of Binding solution:**

Add H.P.M.C -K100lv and Eudragit L-100 slowly in 22.0 Lt purified water with continuous stirring for complete dispersion of H.P.M.C in water.

3. Add step 3 to step 2 with constant stirring at high speed for 5 minutes in R.M.G

4. Pass the wet mass through 6 mm sieve of Multimill & collect in bowls.

5. Dry the sieved granules in fluid bed dryer for 60 minutes at 60°C.

6. Pass dried granules through 20 # sieve of sifter. Those granules have not pass through 20 # sieve, then pass through1.5 mm sieve of Multimill & then repass through 20 # sieve by using sifter.

7. Give the sample to determine moisture content in I.R moisture balance at 105°C for 10 minutes. (Limit NMT 2% at 105°C for 15 minutes.)

8. Sift PVP-K30, Microcrystalline Cellulose, Talc & Titanium Dioxide through 40 # sieve by using sifter.

9. Mix with step 7 in a contra blender for 30 minutes.

10. Mix Cross with step 10 in a contra blender for 10 minutes.

11. Pass Magnesium stearate IP THROUGH 60 # sieve & mix with step 11 for 5 minutes in a contra blender.

12. Transfer the lubricated blended granules in a suitable Container. (Permissible limit: 99.00 % to 100 %)

13. After completion of the batch affix proper **"AWAITING FOR RELEASE"** labels on the Container, ensure that the area and the equipment's are cleaned as per SOP.

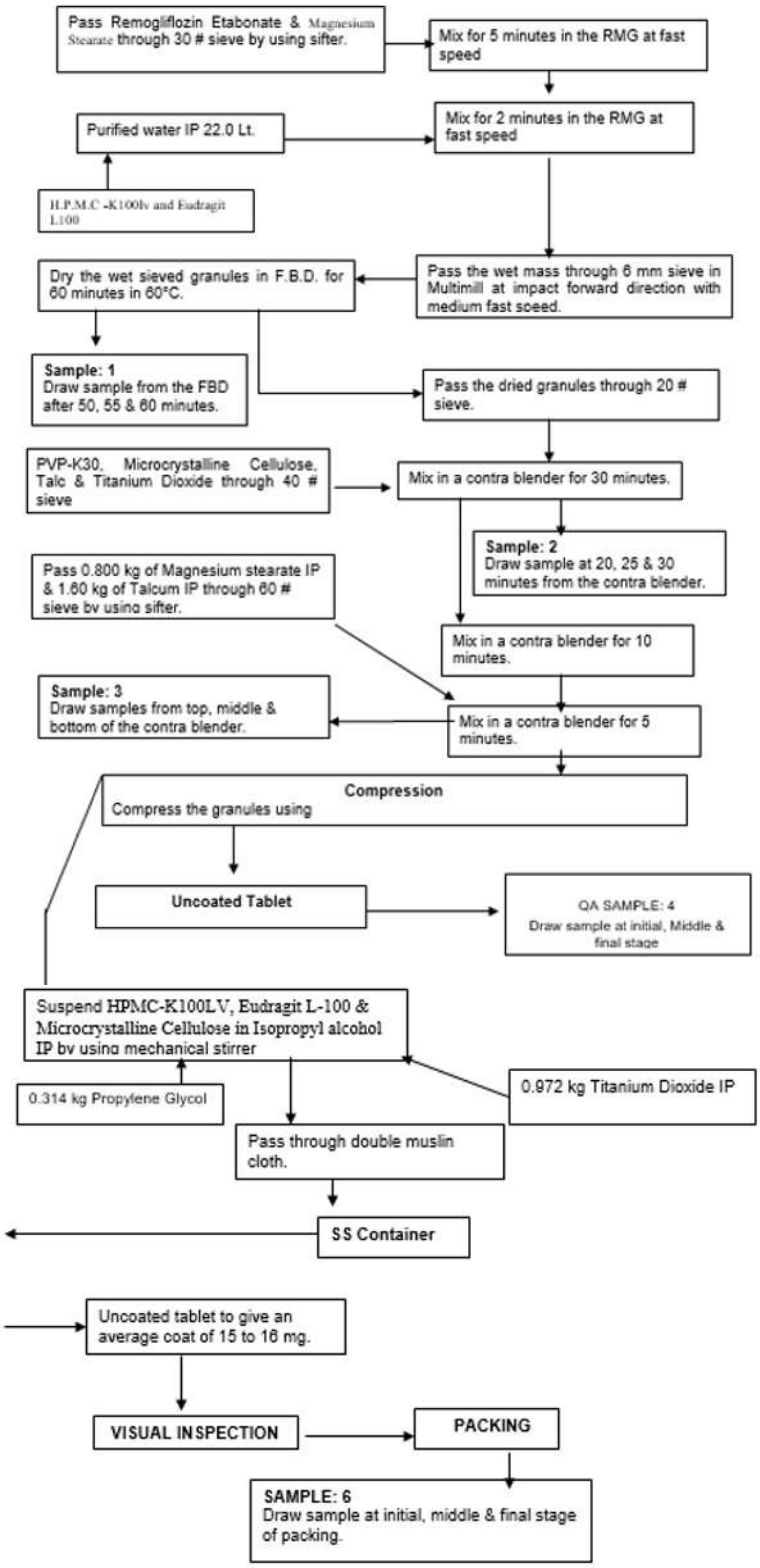
B] COMPRESSION

Compress the lubricated granules only after Reauthorization, if there is undue time lag between lubrication and further processing.

C] COATING:

<table>
<tr><th>Sr. No.</th><th>OPERATION</th></tr>
<tr><td>A</td><td>PREPARATION OF COATING SOLUTION:</td></tr>
<tr><td>1.</td><td>Suspend HPMC-K100LV, Eudragit L-100 & Microcrystalline Cellulose in Isopropyl alcohol IP by using mechanical stirrer</td></tr>
<tr><td>2.</td><td>Pass Titanium Dioxide IP through the 100 # sieve of mechanical shifter.
Add Titanium dioxide IP in Isopropyl alcohol IP with continuous stirring till dispersed uniformity. Then the mixture passes through double muslin clothes & collects in clean Dry S.S container.</td></tr>
<tr><td>3.</td><td>Add step 3 to step 2 with constant stirring for complete distribution.</td></tr>
<tr><td>4.</td><td>Add PVP K-30 and Talc in step 5 with continuous stirring.</td></tr>
<tr><td>5.</td><td>Pass the final solution through colloid mill & keep in well closed container.</td></tr>
<tr><td>6.</td><td>Place uncoated dedusted tablets in a clean, dry coating pan (36"). Heat the tablets by inching the coating pan.</td></tr>
<tr><td>B</td><td>COATING PROCESS</td></tr>
<tr><td>7.</td><td>Place uncoated tablets in a clean, dry Neocota.</td></tr>
<tr><td>8.</td><td>Before start up coating the using following setting
<table>
<tr><th>Parameter</th><th>Observed Value</th><th>Limits</th></tr>
<tr><td>Pan Speed</td><td></td><td>3-6 RPM</td></tr>
<tr><td>Inlet Temp.</td><td></td><td>60°C-65°C</td></tr>
<tr><td>Tablet Bed Temp.</td><td></td><td>45°C-55°C</td></tr>
<tr><td>Spray Rate</td><td></td><td>200-300 ml/min.</td></tr>
<tr><td>Atomization Air pressure</td><td></td><td>2.0 - 3.5 Kg/cm^2</td></tr>
<tr><td>Peristaltic Pump RPM</td><td></td><td>75 – 125 R.P.M.</td></tr>
</table></td></tr>
<tr><td>9.</td><td>Tablets are coated to give in average coat of 8 to 10 mg & dry the film coated tablets in the pan with inlet temperature 40 to 50°C for 5 to 10 minutes to remove all the trace of solvents.</td></tr>
</table>

Flow Chart



UNIFORMITY OF DRYING: Granulation (Stage 1)

1. Prepare stage 1 as per process flow diagram. Collect the samples from top, Middle &

bottom of the Fluid bed dryer after 50, 55 & 60 minutes and analyse the samples as per the following Acceptance criteria.

2. Determine the results of the batches and record in the following tables.

Acceptance Criteria for Granulation of Stage 1

TEST	ACCEPTANCE
Description	A White colored granular powder
Moisture content	NMT 2 %

Tests	Batch No:F4								
	After 50 minutes			After 55 minutes			After 60 minutes		
	Top	Middle	Bottom	Top	Middle	Bottom	Top	Middle	Bottom
Description	A White colored powder	A White colored powder	A White colored powder	A White colored powder	A White colored powder	A White colored powder	A White colored powder	A White colored powder	A White colored powder
Moisture content	4.3%	4.3%	4.1%	3.7%	3.6%	3.9%	2%	2.9%	2.0%
Mean	4.23 %			3.73%			2.3%		

UNIFORMITY OF DRYING: Granulation (Stage 1)

Tests	Batch No:F5								
	After 50 minutes			After 55 minutes			After 60 minutes		
	Top	Middle	Bottom	Top	Middle	Bottom	Top	Middle	Bottom
Description	A White colored powder	A White colored powder	A White colored powder	A White colored powder	A White colored powder	A White colored powder	A White colored powder	A White colored powder	A White colored powder
Moisture content	4.2%	4.1%	4.2%	3.6%	3.7%	3.9%	1.9%	2.0%	2.1%
Mean	4.17%			3.73%			2.0%		

UNIFORMITY OF DRYING: Granulation (Stage 1)

Tests	Batch No:F6								
	After 50 minutes			After 55 minutes			After 60 minutes		
	Top	Middle	Bottom	Top	Middle	Bottom	Top	Middle	Bottom
Description	A White colored powder	A White colored powder	A White colored powder	A White colored powder	A White colored powder	A White colored powder	A White colored powder	A White colored powder	A White colored powder
Moisture content	4.2%	4.2%	4.3%	3.8%	3.7%	3.9%	2%	2.9%	2.9%
Mean	4.23			3.8			2.93		

UNIFORMITY OF MIXING: (Stage 2)

1. Prapare stage 2 as per process flow diagram. Collect the sample from top, Middle & bottom of the Contra-bleeder after 20, 25 & 30

Minutes and analysis the sampes as per the following Acceptance criteria.

2. Determine the results of three batches and record in the following tables.

Acceptance Criteria for Granulation of stage 2

TEST	ACCEPTANCE
Description	A White crystalline granular powder
Remogliflozin Etabonate	68.68 % (w/w) (65.25 % w/w to 75.55 % w/w)

The uniformity of mixing the limit of % Relative Standard deviation NMT 2.0 %

Tests	Batch Number: F4								
	After 20 Minutes.			After 25 Minutes.			After 30 Minutes.		
	Top	Middle	bottom	Top	Middle	bottom	Top	Middle	bottom
Description	White crystal - line granules	White crystal - line granules	White crystal - line granules	White crystal - line granules	White crystal - line granules	White crystal - line granules	White crystal - line granules	White crystal - line granules	White crystal - line granules
Remogliflozin Etabonate	68.83% w/w	68.79% w/w	67.76% w/w	67.61% w/w	68.61% w/w	68.64% w/w	68.55% w/w	68.25% w/w	68.69% w/w
Mean	68.36% w/w			68.29% w/w			68.50% w/w		
Standard Deviation	0.5374			0.5879			0.2257		
% Relative Standard Deviation	0.79			0.86			0.33		

UNIFORMITY OF MIXING: Granulation (Stage 2)

Tests	Batch Number: F5								
	After 20 Minutes.			After 25 Minutes.			After 30 Minutes.		
	Top	Middle	bottom	Top	Middle	bottom	Top	Middle	bottom
Description	White crystal - line granules	White crystal - line granules	White crystal - line granules	White crystal - line granules	White crystal - line granules	White crystal - line granules	White crystal - line granules	White crystal - line granules	White crystal - line granules
Remogliflozin Etabonate	68.78% w/w	67.42% w/w	69.33% w/w	68.97% w/w	68.29% w/w	67.36% w/w	68.45% w/w	68.11% w/w	68.81% w/w
Mean	68.51% w/w			68.21% w/w			68.46% w/w		
Standard Deviation	0.9807			0.8054			0.3488		
% Relative Standard Deviation	1.43			1.18			0.51		

UNIFORMITY OF MIXING: Granulation (Stage 2)

Tests	Batch Number: F6								
	After 20 Minutes.			After 25 Minutes.			After 30 Minutes.		
	Top	Middle	bottom	Top	Middle	bottom	Top	Middle	bottom
Description	White crystal - line granules	White crystal - line granules	White crystal - line granules	White crystal - line granules	White crystal - line granules	White crystal - line granules	White crystal - line granules	White crystal - line granules	White crystal - line granules
Remogliflozin Etabonate	68.8% w/w	68.40% w/w	67.20% w/w	68.70% w/w	68.40% w/w	69.40% w/w	68.50% w/w	68.10% w/w	68.70% w/w
Mean	68.13% w/w			68.83% w/w			68.43% w/w		
Standard Deviation	0.83266			0.51316			0.305505		
% Relative Standard Deviation	1.22%			0.75%			0.45%		

UNIFORMITY OF MIXING: Granulation (Stage 3)

1. Prepare stage 3 as per process flow diagram. To collect the samples from top, middle & bottom of the contra blender after 5 minutes and analysis the samples as per the following acceptances criteria.

2. Determine the results of three batches and record in the following tables.

The uniformity of mixing the limit of % of Relative standard deviation NMT 2.0 %

Acceptance Criteria for granulation of stage 3

Test	Acceptance
Description	A White crystalline granular powder
Remogliflozin Etabonate	66.67 % (w/w) (63.33 to 73.33% w/w)

Tests	Batch No. F4			Batch No. F5			Batch No. F6		
	Top	Middle	Bottom	Top	Middle	Bottom	Top	Middle	Bottom
Description	White crystal - line granules	White crystal - line granules	White crystal - line granules	White crystal - line granules	White crystal - line granules	White crystal - line granules	White crystal - line granules	White crystal - line granules	White crystal - line granules
Remogliflozin Etabonate	66.86 % w/w	67.11% w/w	66.54% w/w	66.34% w/w	66.03% w/w	66.70% w/w	66.6 % w/w	66.5% w/w	66.8 % w/w
Mean	66.84% w/w			66.35% w/w			66.63% w/w		
Standard Deviation	0.2863			0.3370			0.152753		
% Relative Standard Deviation	0.43%			0.51%			0.23%		

UNIFORMITY OF COMPRESSION:

Determine the results of three batches and record following tables.

Acceptance Criteria for Compressed Tablet

Test	Acceptance
Description.	Whitish in colour solid roundish unit dosage form
Individual Tablet Wt.	250 mg ± 5 % (237.5 mg to 262.5 mg.)
Wt of 20 Tablets	12.5 g ± 5 % (12.44 to 12.57 gm)
Thickness	3.0 mm ± 0.2 mm (2.8 to 3.2 mm)
Disintegration Time	---
Friability	NMT 1.0 %
Hardness	NLT 4.0 kg / cm^2
Dissolution Test	NLT 80 % in 24hrs
Assay of Remogliflozin Etabonate	Between 95.0 to 110.0 % on label claim 250 mg.

Uniformity for compressed tablets:-

Tests	Batch Numbers								
	F4			F5			F6		
	Initial	Middle	End	Initial	Middle	End	Initial	Middle	End
Description	Whitish in colour solid roundish unit dosage form	Whitish in colour solid roundish unit dosage form	Whitish in colour solid roundish unit dosage form	Whitish in colour solid roundish unit dosage form	Whitish in colour solid roundish unit dosage form	Whitish in colour solid roundish unit dosage form	Whitish in colour solid roundish unit dosage form	Whitish in colour solid roundish unit dosage form	Whitish in colour solid roundish unit dosage form
Individual Tablet wt.	242.9 to 258.4 mg	235.8 to 258.9 mg	239 to 259.2 mg	243.8 to 258.2 mg	243.8 to 258.2 mg	243.8 to 255.3 mg	242.9 to 258.4 mg	242.0 to 258.0 mg	243.9 to 259.4 mg
Wt of 20 Tablets.	5.013 gm	4.992 gm	5.004 gm	5.027 gm	5.047 gm	5.044 gm	5.016 gm	4.988 gm	5.008 gm
Thickness	3.23 to 3.40 mm	3.23 to 3.40 mm	3.23 to 3.40 mm	3.23 to 3.40 mm	3.26 to 3.37 mm	3.24 to 3.37 mm	3.23 to 3.39 mm	3.24 to 3.38 mm	3.23 to 3.36 mm
Disintegration time	---	---	---	---	---	---	---	---	---
Hardness	4 to 4.5 kg / cm^2	3 to 4.0 kg / cm^2	3 to 4.5 kg / cm^2	3 to 4.5 kg / cm^2	4 to 4.5 kg / cm^2	4 to 4.5 kg / cm^2	4 to 5.0 kg / cm^2	4 to 5.5 kg / cm^2	4 to 5.5 kg / cm^2
Friability	0.08%	0.12%	0.08%	0.06%	0.08%	0.06%	0.02%	0.02%	0.00%
Dissolution Test	93.03%	94.52%	93.54%	92.245 %	91.88%	92.48%	92.08%	91.40%	91.55%
Assay	100.58 %	100.70 %	100.14 %	100.07 %	100.98 %	100.03 %	100.84 %	100.67 %	100.27 %

UNIFORMITY OF FILM-COATED TABLETS

After compressed the Tablets, Coat the tablet as per Flow Chart. To collect the coated tablet at bottom, Middle & top of the coating pan.

Determine the results of three batches and record in the following tablets.

Acceptance Criteria for Film Coated Tablet

Test	Acceptance
Description.	Whitish in colour solid roundish unit dosage form
Identification Test of Remogliflozin Etabonate	Should be positive.
Uniformity of weight in mg. (Wt of 20 Tablets)	250 mg ± 5 % (237.5 mg to 262.5 mg.)
Average Weight	12.5 g ± 5 % (12.44 to 12.57 gm)
Disintegration Time	---
Thickness	3.0 mm ± 0.2 mm (2.8 to 3.2 mm)
Hardness	NLT 4.0 kg / cm^2
Dissolution Test	NLT 80 % in 30 Min.
Assay of Remogliflozin Etabonate	Between 95.0 to 110.0 % on label claim 250 mg.

Uniformity of Film coated Tablets.

Tests	Batch Numbers								
	F4			F5			F6		
	Initial	Middle	End	Initial	Middle	End	Initial	Middle	End
Description	Whitish in colour solid roundish unit dosage form	Whitish in colour solid roundish unit dosage form	Whitish in colour solid roundish unit dosage form	Whitish in colour solid roundish unit dosage form	Whitish in colour solid roundish unit dosage form	Whitish in colour solid roundish unit dosage form	Whitish in colour solid roundish unit dosage form	Whitish in colour solid roundish unit dosage form	Whitish in colour solid roundish unit dosage form
Identification Test	Complies	Complies	Complies	Complies	Complies	Complies	Complies	Complies	Complies
Uniformity of weight in mg. (wt. of 20 tabs)	242.9 to 258.4 mg	235.8 to 258.9 mg	239 to 259.2 mg	243.8 to 258.2 mg	243.8 to 258.2 mg	243.8 to 255.3 mg	242.9 to 258.4 mg	242.0 to 258.0 mg	243.9 to 259.4 mg
Average Weight.	5.013 gm	4.992 gm	5.004 gm	5.027 gm	5.047 gm	5.044 gm	5.016 gm	4.988 gm	5.008 gm
Disintegration time	----	----	----	----	----	----	----	----	----
Dissolution Test	93.25%	93.15%	92.82%	97.28%	96.20%	96.38%	95.47%	95.59%	95.41%
Hardness	4 to 4.5 kg / cm^2	3 to 4.0 kg / cm^2	3 to 4.5 kg / cm^2	3 to 4.5 kg / cm^2	4 to 4.5 kg / cm^2	4 to 4.5 kg / cm^2	4 to 5.0 kg / cm^2	4 to 5.5 kg / cm^2	4 to 5.5 kg / cm^2
Thickness	3.23 to 3.40 mm	3.23 to 3.40 mm	3.23 to 3.40 mm	3.23 to 3.40 mm	3.26 to 3.37 mm	3.24 to 3.37 mm	3.23 to 3.39 mm	3.24 to 3.38 mm	3.23 to 3.36 mm
Assay of Remogliflozin Etabonate	100.58 %	100.70 %	100.14 %	100.07 %	100.98 %	100.03 %	100.84 %	100.67 %	100.27 %

UNIFORMITY OF PACKING (FINISHED PRODUCT):

1. To collect the finished product at initial, middle & End of the packing.
2. Determine the results of three batches and record the following tables.

Acceptance Criteria for Finished Product:

Test	Acceptance
Description.	Whitish in colour solid roundish unit dosage form
Identification Test of Remogliflozin Etabonate	Should be positive.
Uniformity of weight in mg. (Wt of 20 Tablets)	250 mg ± 5 % (237.5 mg to 262.5 mg.)
Average Weight	250 mg ± 5 % (237.5 mg to 262.5 mg.)
Disintegration Time	---
Thickness	3.0 mm ± 0.2 mm (2.8 to 3.2 mm)
Hardness	4.0 kg / cm^2
Dissolution Test	NLT 80 % in 30 Min.
Assay of Remogliflozin Etabonate	Between 95.0 to 110.0 % on label claim 250 mg.

Uniformity of Finished product:

Tests	Batch Numbers								
	2015			2025			2035		
	Initial	Middle	End	Initial	Middle	End	Initial	Middle	End
Description	Whitish in colour solid roundish unit dosage form	Whitish in colour solid roundish unit dosage form	Whitish in colour solid roundish unit dosage form	Whitish in colour solid roundish unit dosage form	Whitish in colour solid roundish unit dosage form	Whitish in colour solid roundish unit dosage form	Whitish in colour solid roundish unit dosage form	Whitish in colour solid roundish unit dosage form	Whitish in colour solid roundish unit dosage form
Identification Test	Complies	Complies	Complies	Complies	Complies	Complies	Complies	Complies	Complies
Uniformity of weight in mg. (wt. of 20 tabs)	242.9 to 258.4 mg	235.8 to 258.9 mg	239 to 259.2 mg	243.8 to 258.2 mg	243.8 to 258.2 mg	243.8 to 255.3 mg	242.9 to 258.4 mg	242.0 to 258.0 mg	243.9 to 259.4 mg
Average Weight.	5.013 gm	4.992 gm	5.004 gm	5.027 gm	5.047 gm	5.044 gm	5.016 gm	4.988 gm	5.008 gm
Disintegration time	----	----	----	----	----	----	----	----	----
Dissolution Test	93.25%	93.15%	92.82%	97.28%	96.20%	96.38%	95.47%	95.59%	95.41%
Hardness	4 to 4.5 kg / cm^2	3 to 4.0 kg / cm^2	3 to 4.5 kg / cm^2	3 to 4.5 kg / cm^2	4 to 4.5 kg / cm^2	4 to 4.5 kg / cm^2	4 to 5.0 kg / cm^2	4 to 5.5 kg / cm^2	4 to 5.5 kg / cm^2
Thickness	3.23 to 3.40 mm	3.23 to 3.40 mm	3.23 to 3.40 mm	3.23 to 3.40 mm	3.26 to 3.37 mm	3.24 to 3.37 mm	3.23 to 3.39 mm	3.24 to 3.38 mm	3.23 to 3.36 mm
Assay	100.58%	100.70%	100.14%	100.07%	100.98%	100.03%	100.84%	100.67%	100.27%

VALIDATION SUMMARY

ACCEPTANCE CRITERIA:

A minimum of three consecutive production Batches will monitored for concurrent process Validation. Final validation report summarizes the results of the validation study as per the protocol, which includes review of results for meeting specific consistently. From the above three consecutive batches data we can conclude that the results are meet with as per specification & also review the data at the granulation stage-1. So we can conclude that 60 minutes time's is sufficient time for drying & batches having uniformity of drying at granulation stage -1. From the above three consecutive batches data we can conclude that the results are meet with as per specification & also review the data at the granulation stage-2, in 30 minutes mixing time having low RSD value. So we can conclude that 30 minutes time's is sufficient time for mixing & batches having uniformity of mixing at granulation stage -2. From the above three consecutive batches data we can conclude that the results are meet with as per specification & also review the data at the granulation stage-3, all three batches having low RSD value. So, we can conclude that all three batches having uniformity of mixing at granulation stage -3.

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