

		ACCELERATED STABILITY DATA		Page No: Page 1 of 2
Format No:F/QCGN/034/06				
PRODUCT NAME: Genset (Cetirizine hydrochloride Tablet BP 10 mg)				
B.No. : GF210101	Mfg. Date: JAN-2021		Batch Size: 30.0 L	
	Exp. Date: DEC-2023		Pack Size: Blister (3x10'S)	
	Label Claim: Each Film coated tablet contains: Cetirizine hydrochloride Tablet BP 10 mg			Reason for stability: Validation Batch study
				Period: 6 Month
				Date of Loading:11.01.2021

Tests	Limits	Initial 02.02.2021			3 rd Month 11.04.2021			6 th Month 11.07.2021		
		Results			Results			Results		
Description	White coloured, caplet shaped, film coated tablet with break line on one side and plain on other side	Complies			Complies			Complies		
Average Weight	120.00 mg ± 5.0 % (114.00 mg to 126.00 mg)	119.60 mg			119.26 mg			119.05 mg		
Disintegration Time	Not more than 30 minutes	04 Min 05 Sec			04 Min 27 Sec			04 Min 56 Sec		
Dissolution: Cetirizine Hydrochloride BP -10 mg	Not less than 85.0 % of labeled amount.	Min 93.82 %	Max 103.94 %	Avg. 98.79 %	Min 97.75 %	Max 103.03 %	Avg. 100.54 %	Min 93.12 %	Max 102.61 %	Avg. 98.73 %
Related substances: Impurity A Impurity B Impurity G Single maximum unknown impurity Total impurities	Not more than 0.3 % Not more than 0.3 % Not more than 0.3 % Not more than 0.2 % Not more than 1.0 %	Not Detected Not Detected Not Detected Not Detected Not Detected			Not Detected Not Detected Not Detected Not Detected Not Detected			Not Detected Not Detected Not Detected Not Detected Not Detected		
Assay: Each Film coated tablet contains: Cetirizine Hydrochloride BP -10 mg	Not less than 95.0 % and Not more than 105.0 %	100.89 %			100.79 %			100.41 %		

	ACCELERATED STABILITY DATA		Page No: Page 2 of 2
			Format No: F/QCGN/034/06
PRODUCT NAME: Genset (Cetirizine hydrochloride Tablet BP 10 mg)			Storage Condition: 40°C ± 2°C & 75% RH ± 5%
B.No. : GF210101	Mfg. Date: JAN-2021	Batch Size: 30.0 L	Reason for stability: Validation Batch study
	Exp. Date: DEC-2023	Pack Size: Blister (3x10'S)	Period: 6 Month
	Label Claim: Each Film coated tablet contains: Cetirizine hydrochloride Tablet BP 10 mg		Date of Loading: 11.01.2021

Microbiological limits:				
Total Aerobic Microbial count	NMT 1000 cfu/g	10 cfu/g		30 cfu/g
Total Yeasts and mould counts	NMT 100 cfu/g	<10 cfu/g		<10 cfu/g
E.Coli	Should be Absent	Absent	NA	Absent
Salmonella	Should be Absent	Absent		Absent
S.aureus	Should be Absent	Absent		Absent
P.aeruginosa	Should be Absent	Absent		Absent

Stability study:

Complete [☒]

Incomplete [☐]

Opinion: Based on the above stability studies, the product is ~~unstable~~ / stable for ⁰⁶ months.

Reference: ICH Guidelines

PREPARED BY: *D. J. S.*

DATE: 16/07/2021

CHECKED BY:

DATE:

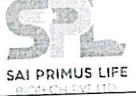
J. 16/07/2021

APPROVED BY: *Mr*

DATE:

16/07/2021

		LONG TERM STABILITY DATA				Page No: Page 1 of 2			
						Format No:F/QCGN/034/06			
PRODUCT NAME: GENSET (Cetirizine hydrochloride Tablet BP 10 mg)						Storage Condition:30°C ±2°C & 75% RH ± 5%			
B.No. : GF210101		Mfg. Date: JAN-2021		Batch Size: 30.0 L		Reason for stability: Validation Batch study			
		Exp. Date: DEC-2023		Pack Size: Blister (3x10'S)		Period: 36 Month			
		Label Claim: Each Film coated tablet contains: Cetirizine hydrochloride Tablet BP 10 mg				Date of Loading:11.01.2021			
Tests	Limits	Initial 02.02.2021	3 rd Month 11.04.2021	6 th Month 11.07.2021	9 th Month 11.10.2021	12 th Month 11.01.2022	18 th Month 11.07.2022	24 th Month 11.01.2023	36 th Month 11.01.2024
		Results	Results	Results	Results	Results	Results	Results	Results
Description	White coloured, caplet shaped, film coated tablet with break line on one side and plain on other side	Complies	Complies	Complies	Complies	Complies	Complies	Complies	Complies
Average Weight	120.00 mg ± 5.0 % (114.00 mg to 126.00 mg)	119.60 mg	120.11 mg	119.91 mg	120.32 mg	121.56 mg	121.96 mg	121.24 mg	123.14 mg
Disintegration Time	Not more than 30 minutes	04 Min 05 Ses	04 Min 21 Sec	04 Min 41 Sec	04 Min 25 Sec	05 Min 06 Sec	07 Min 11 Sec	07 Min 45 Sec	08 Min 20 Sec
Dissolution: Cetirizine Hydrochloride BP -10 mg	Not less than 85.0 % of labeled amount.	Min : 93.82% Max:103.94% Avg :98.79%	Min : 93.34% Max : 99.51% Avg :95.54 %	Min: 97.44 % Max:101.75% Avg: 99.88 %	Min: 95.36 % Max:102.59% Avg: 99.05 %	Min: 93.90 % Max:100.83% Avg: 98.52 %	Min: 91.23 % Max: 98.10 % Avg: 96.17 %	Min: 92.45 % Max: 97.27 % Avg: 95.47 %	Min: 88.17 % Max: 90.10 % Avg: 89.23 %
Related substances: Impurity A Impurity B Impurity G Single maximum unknown impurity Total impurities	Not more than 0.3 % Not more than 0.3 % Not more than 0.3 % Not more than 0.2 % Not more than 1.0 %	Not Detected Not Detected Not Detected Not Detected	Not Detected Not Detected Not Detected Not Detected	Not Detected Not Detected Not Detected Not Detected	Not Detected Not Detected Not Detected Not Detected	Not Detected Not Detected Not Detected Not Detected	Not Detected Not Detected Not Detected Not Detected	Not Detected Not Detected Not Detected Not Detected	Not Detected Not Detected Not Detected Not Detected
Assay: Each Film coated tablet contains: Cetirizine Hydrochloride BP -10 mg	Not less than 95.0 % and Not more than 105.0 %	100.89 %	100.55 %	99.99 %	100.02 %	99.36 %	98.12 %	98.48 %	97.18 %

	LONG TERM STABILITY DATA						Page No: Page 2 of 2	
							Format No: F/QCGN/034/06	
PRODUCT NAME: GENSET (Cetirizine hydrochloride Tablet BP 10 mg)								Storage Condition: 30°C ± 2°C & 75% RH ± 5%
B.No.: GF210101	Mfg. Date: JAN-2021			Batch Size: 30.0 L			Reason for stability: Validation Batch study	
	Exp. Date: DEC-2023			Pack Size: Blister (3x10'S)			Period: 36 Month	
	Label Claim: Each Film coated tablet contains: Cetirizine hydrochloride Tablet BP 10 mg						Date of Loading: 11.01.2021	
Microbiological limits:								
Total Aerobic Microbial count	NMT 1000 cfu/g	10 cfu/g						40 cfu/g
Total Yeasts and mould counts	NMT 100 cfu/g	<10 cfu/g	NA	NA	NA	NA	NA	<10 cfu/g
E.Coli	Should be Absent	Absent						Absent
Salmonella	Should be Absent	Absent						Absent
S.aureus	Should be Absent	Absent						Absent
P.aeruginosa	Should be Absent	Absent						Absent

Complete [✓]

Incomplete [✗]

Stability study:

Opinion: Based on the above stability studies, the product is ~~unstable~~ / stable for 36th months.

Reference: ICH Guidelines

PREPARED BY: 
DATE: 22/01/2024

CHECKED BY: 
DATE: 22/01/2024

APPROVED BY: 
DATE: 22/01/2024



ACCELERATED STABILITY DATA

Page No: Page 1 of 2

Format No:F/QCGN/034/06

PRODUCT NAME: Genset (Cetirizine hydrochloride Tablet BP 10 mg)

Storage Condition: 40°C ±2°C & 75% RH ± 5%

B.No. : GF210216

Mfg. Date: FEB-2021

Batch Size: 30.0 L

Reason for stability: Validation Batch study

Exp. Date: JAN-2024

Pack Size: Blister (3x10'S)

Period: 6 Month

Label Claim: Each Film coated tablet contains:
Cetirizine hydrochloride Tablet BP 10 mg

Date of Loading:01.03.2021

Tests	Limits	Initial 12.03.2021			3 rd Month 01.06.2021			6 th Month 01.09.2021		
		Results			Results			Results		
Description	White coloured, caplet shaped, film coated tablet with break line on one side and plain on other side	Complies			Complies			Complies		
Average Weight	120.00 mg ± 5.0 % (114.00 mg to 126.00 mg)	120.70 mg			125.30 mg			124.13 mg		
Disintegration Time	Not more than 30 minutes	05 Min 12 Ses			04 Min 51 Sec			05 Min 43 Sec		
Dissolution: Cetirizine Hydrochloride BP -10 mg	Not less than 85.0 % of labeled amount.	Min 95.56 %	Max 101.86 %	Avg. 98.88 %	Min 90.82 %	Max 98.72 %	Avg. 94.11 %	Min 94.01 %	Max 99.17 %	Avg. 96.97 %
Related substances: Impurity A Impurity B Impurity G Single maximum unknown impurity Total impurities	Not more than 0.3 % Not more than 0.3 % Not more than 0.3 % Not more than 0.2 % Not more than 1.0 %	Not Detected Not Detected Not Detected Not Detected Not Detected			Not Detected Not Detected Not Detected Not Detected Not Detected			Not Detected Not Detected Not Detected Not Detected Not Detected		
Assay: Each Film coated tablet contains: Cetirizine Hydrochloride BP -10 mg	Not less than 95.0 % and Not more than 105.0 %	101.03 %			99.09 %			98.88 %		

		ACCELERATED STABILITY DATA		Page No: Page 2 of 2
				Format No: F/QCGN/034/06
PRODUCT NAME: Genset (Cetirizine hydrochloride Tablet BP 10 mg)				Storage Condition: 40°C ± 2°C & 75% RH ± 5%
B.No. : GF210216	Mfg. Date: FEB-2021	Batch Size: 30.0 L	Reason for stability: Validation Batch study	
	Exp. Date: JAN-2024	Pack Size: Blister (3x10'S)	Period: 6 Month	
	Label Claim: Each Film coated tablet contains: Cetirizine hydrochloride Tablet BP 10 mg		Date of Loading: 01.03.2021	

Microbiological limits:				
Total Aerobic Microbial count	NMT 1000 cfu/g	10 cfu/g		30 cfu/g
Total Yeasts and mould counts	NMT 100 cfu/g	<10 cfu/g	NA	<10 cfu/g
E.Coli	Should be Absent	Absent	NA	Absent
Salmonella	Should be Absent	Absent		Absent
S.aureus	Should be Absent	Absent		Absent
P.aeruginosa	Should be Absent	Absent		Absent

Stability study:

Complete [✓]

Incomplete [✗]

Opinion: Based on the above stability studies, the product is ~~unstable~~ / stable for 6 months.

Reference: ICH Guidelines

PREPARED BY: DD
DATE: 06/09/2021

CHECKED BY: JT
DATE: 06/09/2021

APPROVED BY: AV
DATE: 06/09/2021

		LONG TERM STABILITY DATA					Page No: Page 1 of 2		
							Format No:F/QCGN/034/06		
PRODUCT NAME: GENSET (Cetirizine hydrochloride Tablet BP 10 mg)							Storage Condition:30°C ±2°C & 75% RH ± 5%		
B.No. : GF210216		Mfg. Date: FEB-2021		Batch Size: 30.0 L			Reason for stability: Validation Batch study		
		Exp. Date: JAN-2024		Pack Size: Blister (3x10'S)			Period: 36 Month		
		Label Claim: Each Film coated tablet contains: Cetirizine hydrochloride Tablet BP 10 mg					Date of Loading:01.03.2021		
Tests	Limits	Initial 12.03.2021	3 rd Month 01.06.2021	6 th Month 01.09.2021	9 th Month 01.12.2021	12 th Month 01.03.2022	18 th Month 01.09.2022	24 th Month 01.03.2023	36 th Month 01.03.2024
		Results	Results	Results	Results	Results	Results	Results	Results
Description	White coloured, caplet shaped, film coated tablet with break line on one side and plain on other side	Complies	Complies	Complies	Complies	Complies	Complies	Complies	Complies
Average Weight	120.00 mg ± 5.0 % (114.00 mg to 126.00 mg)	120.70 mg	125.60 mg	125.11 mg	125.23 mg	124.80 mg	125.20 mg	125.57 mg	125.48 mg
Disintegration Time	Not more than 30 minutes	05 Min 12 Sec	04 Min 37 Sec	04 Min 55 Sec	05 Min 22 Sec	05 Min 52 Sec	05 Min 43 Sec	06 Min 03 Sec	07 Min 35 Sec
Dissolution: Cetirizine Hydrochloride BP -10 mg	Not less than 85.0 % of labeled amount.	Min : 95.56 % Max:101.86% Avg : 98.88%	Min : 92.80 % Max:102.67% Avg : 97.08%	Min : 95.73 % Max:102.03% Avg : 99.36%	Min : 96.01 % Max:100.25% Avg : 98.59%	Min : 94.52 % Max : 99.02% Avg : 97.62%	Min : 93.60 % Max : 96.83% Avg : 95.32%	Min : 93.21 % Max : 95.36% Avg : 94.44%	Min : 87.15 % Max : 89.10% Avg : 88.47%
Related substances: Impurity A Impurity B Impurity G Single maximum unknown impurity Total impurities	Not more than 0.3 % Not more than 0.3 % Not more than 0.3 % Not more than 0.2 % Not more than 1.0 %	Not Detected Not Detected Not Detected Not Detected	Not Detected Not Detected Not Detected Not Detected	Not Detected Not Detected Not Detected Not Detected	Not Detected Not Detected Not Detected Not Detected	Not Detected Not Detected Not Detected Not Detected	Not Detected Not Detected Not Detected Not Detected	Not Detected Not Detected Not Detected Not Detected	Not Detected Not Detected Not Detected Not Detected
Assay: Each Film coated tablet contains: Cetirizine Hydrochloride BP -10 mg	Not less than 95.0 % and Not more than 105.0 %	101.03 %	99.96 %	99.84 %	98.16 %	98.02 %	97.71 %	97.26 %	96.04 %

		LONG TERM STABILITY DATA					Page No: Page 2 of 2 Format No:F/QCGN/034/06		
PRODUCT NAME: GENSET (Cetirizine hydrochloride Tablet BP 10 mg)							Storage Condition: 30°C ±2°C & 75% RH ± 5%		
B.No. : GF210216	Mfg. Date: FEB-2021		Batch Size: 30.0 L		Reason for stability: Validation Batch study				
	Exp. Date: JAN-2024		Pack Size: Blister (3x10'S)		Period: 36 Month				
	Label Claim: Each Film coated tablet contains: Cetirizine hydrochloride Tablet BP 10 mg					Date of Loading:01.03.2021			
Microbiological limits: Total Aerobic Microbial count Total Yeasts and mould counts E.Coli Salmonella S.aureus P.aeruginosa	NMT 1000 cfu/g NMT 100 cfu/g Should be Absent Should be Absent Should be Absent	10 cfu/g <10 cfu/g Absent Absent Absent Absent	NA	NA	NA	NA	NA	NA	30 cfu/g <10 cfu/g Absent Absent Absent Absent

Stability study:

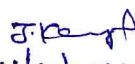
Complete [✓]

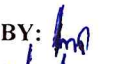
Incomplete [✗]

Opinion: Based on the above stability studies, the product is unstable / stable for months.

Reference: ICH Guidelines

PREPARED BY: 
 DATE: 11/03/2024

CHECKED BY: 
 DATE: 11/03/2024

APPROVED BY: 
 DATE: 11/03/2024



ACCELERATED STABILITY DATA

Page No: Page 1 of 2

Format No:F/QCGN/034/06

PRODUCT NAME: Genset (Cetirizine hydrochloride Tablet BP 10 mg)

Storage Condition: 40°C ± 2°C & 75% RH ± 5%

B.No. : GF210301

Mfg. Date: MAR-2021

Batch Size: 30.0 L

Reason for stability: Validation Batch study

Exp. Date: FEB-2024

Pack Size: Blister (3x10'S)

Period: 6 Month

Label Claim: Each Film coated tablet contains:
Cetirizine hydrochloride Tablet BP 10 mg

Date of Loading: 13.05.2021

Tests	Limits	Initial 05.06.2021			3 rd Month 13.08.2021			6 th Month 13.11.2021		
		Results			Results			Results		
Description	White coloured, caplet shaped, film coated tablet with break line on one side and plain on other side.	Complies			Complies			Complies		
Average Weight	120.00 mg ± 5.0 % (114.00 mg to 126.00 mg)	119.75 mg			119.85 mg			120.12 mg		
Disintegration Time	Not more than 30 minutes	05 Min 43 Ses			05 Min 58 Sec			06 Min 12 Sec		
Dissolution: Cetirizine Hydrochloride BP -10 mg	Not less than 85.0 % of labeled amount.	Min 98.19 %	Max 105.39 %	Avg. 102.01%	Min 97.37 %	Max 100.41 %	Avg. 98.28 %	Min 96.14 %	Max 98.23 %	Avg. 97.81 %
Related substances: Impurity A Impurity B Impurity G Single maximum unknown impurity Total impurities	Not more than 0.3 % Not more than 0.3 % Not more than 0.3 % Not more than 0.2 % Not more than 1.0 %	Not Detected Not Detected Not Detected Not Detected Not Detected			Not Detected Not Detected Not Detected Not Detected Not Detected			Not Detected Not Detected Not Detected Not Detected Not Detected		
Assay: Each Film coated tablet contains: Cetirizine Hydrochloride BP -10 mg	Not less than 95.0 % and Not more than 105.0 %	100.18 %			100.51 %			99.37 %		

		ACCELERATED STABILITY DATA		Page No: Page 2 of 2	
PRODUCT NAME: Genset (Cetirizine hydrochloride Tablet BP 10 mg)				Format No: F/QCGN/034/06	
B.No. : GF210301	Mfg. Date: MAR-2021		Batch Size: 30.0 L		Reason for stability: Validation Batch study
	Exp. Date: FEB-2024		Pack Size: Blister (3x10'S)		Period: 6 Month
	Label Claim: Each Film coated tablet contains: Cetirizine hydrochloride Tablet BP 10 mg				Date of Loading: 13.05.2021
Microbiological limits: Total Aerobic Microbial count Total Yeasts and mould counts E.Coli Salmonella S.aureus P.aeruginosa		NMT 1000 cfu/g NMT 100 cfu/g Should be Absent Should be Absent Should be Absent Should be Absent		10 cfu/g <10 cfu/g Absent Absent Absent Absent	
				NA	
				40 cfu/g <10 cfu/g Absent Absent Absent Absent	

Stability study:

Complete [☒]

Incomplete [☐]

Opinion: Based on the above stability studies, the product is ~~unstable~~ / stable for 06 months.

Reference: ICH Guidelines

PREPARED BY: D. D. D.
DATE: 18/11/2021

CHECKED BY: J. J. J.
DATE: 18/11/2021

APPROVED BY: M. M. M.
DATE: 18/11/2021



LONG TERM STABILITY DATA

Page No: Page 1 of 2

Format No:F/QCGN/034/06

PRODUCT NAME: Genset (Cetirizine hydrochloride Tablet BP 10 mg)

Storage Condition:30°C ±2°C & 75% RH ± 5%

B.No. : GF210301

Mfg. Date: MAR-2021

Batch Size: 30.0 L

Reason for stability: Validation Batch study

Exp. Date: FEB-2024

Pack Size: Blister (3x10'S)

Period: 36 Month

Label Claim: Each Film coated tablet contains:
Cetirizine hydrochloride Tablet BP 10 mg

Date of Loading:13.05.2021

Tests	Limits	Initial 05.06.2021 Results	3 rd Month 13.08.2021 Results	6 th Month 13.11.2021 Results	9 th Month 13.02.2022 Results	12 th Month 13.05.2022 Results	18 th Month 13.11.2022 Results	24 th Month 13.05.2023 Results	36 th Month 13.05.2024 Results
Description	White coloured, caplet shaped, film coated tablet with break line on one	Complies	Complies	Complies	Complies	Complies	Complies	Complies	Complies
Average Weight	120.00 mg ± 5.0 % (114.00 mg to 126.00 mg)	119.75 mg	120.31 mg	121.02 mg	121.26 mg	122.02 mg	122.45 mg	121.45 mg	123.70 mg
Disintegration Time	Not more than 30 minutes	05 Min 43 Sec	05 Min 50 Sec	05 Min 11 Sec	05 Min 43 Sec	06 Min 20 Sec	07 Min 32 Sec	07 Min 03 Sec	08 Min 15 Sec
Dissolution: Cetirizine Hydrochloride BP -10 mg	Not less than 85.0 % of labeled amount.	Min : 98.19 % Max : 105.39 % Avg.: 102.01	Min : 99.81 % Max : 102.85 % Avg.: 101.43%	Min : 99.01 % Max : 100.44 % Avg.: 100.02%	Min : 96.01 % Max :98.53 % Avg.: 97.02%	Min : 94.92 % Max :98.01 % Avg.: 96.45%	Min : 91.46 % Max :96.17 % Avg.: 94.12%	Min : 91.66 % Max :98.29 % Avg.: 95.16%	Min : 88.72 % Max :93.92 % Avg.: 90.89%
Related substances: Impurity A Impurity B Impurity G Single maximum unknown impurity Total impurities	Not more than 0.3 % Not more than 0.3 % Not more than 0.3 % Not more than 0.2 % Not more than 1.0 %	Not Detected Not Detected Not Detected Not Detected Not Detected	Not Detected Not Detected Not Detected Not Detected Not Detected	Not Detected Not Detected Not Detected Not Detected Not Detected	Not Detected Not Detected Not Detected Not Detected Not Detected	Not Detected Not Detected Not Detected Not Detected Not Detected	Not Detected Not Detected Not Detected Not Detected Not Detected	Not Detected Not Detected Not Detected Not Detected Not Detected	Not Detected Not Detected Not Detected Not Detected Not Detected
Assay: Each Film coated tablet contains: Cetirizine Hydrochloride BP -10 mg	Not less than 95.0 % and Not more than 105.0 %	100.18 %	99.96 %	98.52 %	98.37 %	97.95 %	97.10 %	98.15 %	97.43 %

		LONG TERM STABILITY DATA					Page No: Page 2 of 2 Format No:F/QCGN/034/06		
PRODUCT NAME: Genset (Cetirizine hydrochloride Tablet BP 10 mg)							Storage Condition: 30°C ± 2°C & 75% RH ± 5%		
B.No. : GF210301		Mfg. Date: MAR-2021		Batch Size: 30.0 L		Reason for stability: Validation Batch study			
		Exp. Date: FEB-2024		Pack Size: Blister (3x10'S)		Period: 36 Month			
		Label Claim: Each Film coated tablet contains: Cetirizine hydrochloride Tablet BP 10 mg					Date of Loading: 13.05.2021		
Microbiological limits: Total Aerobic Microbial count Total Yeasts and mould counts E.Coli Salmonella S.aureus P.aeruginosa	NMT 1000 cfu/g NMT 100 cfu/g Should be Absent Should be Absent Should be Absent Should be Absent	10 cfu/g <10 cfu/g Absent Absent Absent Absent	NA	NA	NA	NA	NA	NA	30 cfu/g <10 cfu/g Absent Absent Absent Absent

Stability study:

Complete [☒]

Incomplete [☐]

Opinion: Based on the above stability studies, the product is ~~unstable~~ / stable for 36th months.

Reference: ICH Guidelines

PREPARED BY: [Signature]
 DATE: 23/05/2024

CHECKED BY: [Signature]
 DATE: 23/05/2024

APPROVED BY: [Signature]
 DATE: 23/05/2024