SAI PRIMUS LIFE BIOTECH PVT LTD	ACCELERATED STABILITY DATA		Page No: Page 1 of 3
PRODUCT NAME: AMLOPERIN 5MG/5MG			Foramt No:F/QCGN/034/06
B.No. : GF200405	Mfg. Date: APR-2020	Batch Size: 6.0 L	Storage Condition:40°C ±2°C & 75% RH ± 5%
	Exp. Date: MAR-2023	Pack Size: Alu Alu (3x10'S)	Reason for stability: Validataion Batch study
	Label Claim: Each uncoated tablet contains: Amlodipine Besylate BP equivalent to Amlodipine 5 mg Perindopril Erbumine BP 5 mg		Period: 6 Month Date of Loading:29.04.2020

Tests	Limits	Initial 29.04.2020	3rd Month 29.07.2020	6th Month 29.10.2020
		Results	Results	Results
Description	Off white, round, biconvex, uncoated tablet with breakline on one side and plain on other side.	Complies	Complies	Complies
Average Weight	140.0 mg ± 5.0 % (Between 133.0 mg to 147.0 mg)	141.65 mg	141.60 mg	140.40 mg
Disintegration Time	Not more than 15 minutes	02 min 12 sec	02 min 43 sec	01 min 02 sec
Dissolution Amlodipine Besylate BP eq. to Amlodipine 5 mg	Not less than 80.0 % of labeled amount.	Min: 92.92 % to Max: 101.47 % Avg: 95.12 %	Min: 92.85 % to Max: 102.34 % Avg: 99.79 %	Min: 93.04 % to Max: 101.23 % Avg: 97.57 %
Perindopril Erbumine BP 5 mg	Not less than 80.0 % of labeled amount.	Min: 97.46 % to Max: 102.12 % Avg: 98.49 %	Min: 100.53 % to Max: 102.65 % Avg: 101.48 %	Min:94.84 % to Max:99.88 % Avg: 97.29 %

SAI PRIMUS LIFE BIOTECH PVT LTD	ACCELERATED STABILITY DATA		Page No: Page 2 of 3
PRODUCT NAME: AMLOPERIN 5MG/5MG			Foramt No:F/QCGN/034/06
	Mfg. Date: APR-2020	Batch Size: 6.0 L	Storage Condition:40°C ±2°C & 75% RH ± 5%
B.No. : GF200405	Exp. Date: MAR-2023	Pack Size: Alu Alu (3x10'S)	Reason for stability: Validataion Batch study
	Label Claim: Each uncoated tablet contains: Amlodipine Besylate BP equivalent to Amlodipine 5 mg Perindopril Erbumine BP 5 mg		Period: 6 Month Date of Loading:29.04.2020

Related substances				
Amlodipine impurity A	NMT 1.0%	ND	ND	ND
Perindopril Impurity B	NMT 1.5%	ND	ND	ND
Perindopril Impurity C	NMT 0.6%	ND	ND	ND
Perindopril Impurity E	NMT 0.4%	ND	ND	ND
Perindopril Impurity F	NMT 1.5%	ND	ND	ND
Single maximum unknown impurity	NMT 0.5%	BDL	BDL	BDL
Total unknown impurity	NMT 1.0%	BDL	BDL	BDL
Total unknown impurity	NMT 5.0%	BDL	BDL	BDL
Assay:				
Each uncoated tablets Contains:				
Amlodipine Besylate BP eq. to Amlodipine 5 mg	Not less than 90.0 % and Not more than 110.0 %	100.29 %	102.74 %	99.53 %
Perindopril Erbumine BP 5 mg	Not less than 90.0 % and Not more than 110.0 %	101.03 %	99.26 %	98.83 %
Microbiological limits:				
Total Aerobic Microbial count	NMT 1000 cfu/g	10 cfu /g	NA	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	NA	Absent
S.aureus	Should be Absent	Absent	NA	Absent
P.aeruginosa	Should be Absent	Absent	NA	Absent

SAI PRIMUS LIFE BIOTECH PVT LTD	ACCELERATED STABILITY DATA		Page No: Page 3 of 3
PRODUCT NAME: AMLOPERIN 5MG/5MG			Foramt No:F/QCGN/034/06
B.No. : GF200405	Mfg. Date: APR-2020	Batch Size: 6.0 L	Storage Condition:40°C ±2°C & 75% RH ± 5%
	Exp. Date: MAR-2023	Pack Size: Alu Alu (3x10'S)	Reason for stability: Validataion Batch study
	Label Claim: Each uncoated tablet contains: Amlodipine Besylate BP equivalent to Amlodipine 5 mg Perindopril Erbumine BP 5 mg		Period: 6 Month
			Date of Loading:29.04.2020

Stability study: Complete [✓] Incomplete [✗]

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

Reference: ICH Guidelines

PREPARED BY: J. Kayal
DATE: 05/11/2020

CHECKED BY:
DATE: 05/11/2020

APPROVED BY:
DATE: 05/11/2020

SAI PRIMUS LIFE BIOTECH PVT LTD	LONG TERM STABILITY DATA		Page No: Page 1 of 3
			Foramt No:F/QCGN/034/06
PRODUCT NAME: AMLOPERIN 5MG/5MG			Storage Condition:30°C ±2°C & 75% RH ± 5%
B.No. : GF200405	Mfg. Date: APR-2020	Batch Size: 6.0 L	Reason for stability: Validataion Batch study
	Exp. Date: MAR-2023	Pack Size: Alu Alu (3x10'S)	Period: 36 Month
	Label Claim: Each uncoated tablet contains: Amlodipine Besylate BP equivalent to Amlodipine 5 mg Perindopril Erbumine BP 5 mg		Date of Loading:29.04.2020

Tests	Limits	Initial 29.04.2020	3rd Month 29.07.2020	6th Month 29.10.2020	9th Month 29.01.2021	12th Month 29.04.2021	18th Month 29.10.2021	24th Month 29.04.2022	36th Month 29.04.2023
		Results	Results	Results	Results	Results	Results	Results	Results
Description	Off white, round, biconvex, uncoated tablet with breakline on one side and plain on other side.	Complies	Complies	Complies	Complies	Complies	Complies	Complies	Complies
Average Weight	140.0 mg±5.0 % (Between 133.0 mgto147.0mg)	141.65 mg	141.61 mg	140.35 mg	140.28 mg	140.70 mg	136.70 mg	138.12 mg	137.20 mg
Disintegration Time	Not more than 15 minutes	02 min 12 sec	02 min 20 sec	01 min 08 sec	01 min 22 sec	01 min 36 sec	02 min 20 sec	03 min 15 sec	04 min 05 sec
Dissolution Amlodipine Besylate BP eq. to Amlodipine 5 mg	Not less than 80.0 % of labeled amount.	Min: 92.92 % to Max: 101.47 % Avg: 95.12 %	Min: 93.69 % to Max: 102.57 % Avg: 99.61 %	Min: 96.10 % to Max: 100.91 % Avg: 99.01 %	Min: 94.42 % to Max: 100.12 % Avg: 97.94%	Min: 93.72 % to Max: 100.19 % Avg: 97.78 %	Min: 99.68 % to Max: 106.30 % Avg: 103..47 %	Min: 95.19 % to Max: 99.49 % Avg: 97.57 %	Min: 92.42 % to Max: 96.10 % Avg: 94.35 %
Perindopril Erbumine BP 5 mg	Not less than 80.0 % of labeled amount.	Min: 97.46 % to Max: 102.12 % Avg: 98.49 %	Min: 100.59 % to Max: 101.65 % Avg: 101.17 %	Min: 97.89 % to Max:99.95 % Avg: 98.47 %	Min:94.88 % to Max:99.75 % Avg: 97.61%	Min: 92.30 % to Max:99.53 % Avg: 94.55 %	Min: 96.55 % to Max:104.32 % Avg: 99.79 %	Min: 94.76 % to Max:101.52 % Avg: 98.16 %	Min: 94.86 % to Max:100.71 % Avg: 97.37 %

SAI PRIMUS
LIFE BIOTECH PVT LTD

LONG TERM STABILITY DATA

Foramt No:F/QCGN/034/06

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

PRODUCT NAME: AMLOPERIN 5MG/5MG

Reason for stability: Validataion Batch study

	Mfg. Date: APR-2020	Batch Size: 6.0 L
	Exp. Date: MAR-2023	Pack Size: Alu Alu (3x10'S)
B.No. : GF200405	Label Claim: Each uncoated tablet contains: Amlodipine Besylate BP equivalent to Amlodipine 5 mg Perindopril Erbumine BP 5 mg	

Period: 36 Month

Date of Loading:29.04.2020

Related substances									
Amlodipine impurity A	NMT 1.0%	ND	ND	ND	ND	ND	ND	ND	ND
Perindopril Impurity B	NMT 1.5%	ND	ND	ND	ND	ND	ND	ND	ND
Perindopril Impurity C	NMT 0.6%	ND	ND	ND	ND	ND	ND	ND	ND
Perindopril Impurity E	NMT 0.4%	ND	ND	ND	ND	ND	ND	ND	ND
Perindopril Impurity F	NMT 1.5%	ND	ND	ND	ND	ND	ND	ND	ND
Single maximum unknown impurity	NMT 0.5%	BDL	BDL	BDL	BDL	BDL	BDL	BDL	0.36%
Total unknown impurity	NMT 1.0%	BDL	BDL	BDL	BDL	BDL	BDL	BDL	0.36%
Total unknown impurity	NMT 5.0%	BDL	BDL	BDL	BDL	BDL	BDL	BDL	0.36%
Assay:									
Each uncoated tablets Contains:									
Amlodipine Besylate BP eq. to Amlodipine 5 mg	Not less than 90.0 % and Not more than 110.0 %	100.29 %	102.05 %	101.18 %	100.49 %	100.39 %	99.76 %	97.29 %	97.29 %
Perindopril Erbumine BP 5 mg	Not less than 90.0 % and Not more than 110.0 %	101.03 %	99.58 %	99.22 %	99.16 %	99.18 %	97.36 %	96.16 %	96.16 %

SAI PRIMUS
LIFE BIOTECH PVT LTD

LONG TERM STABILITY DATA

Page No: Page 3 of 3
Foramt No:F/QCGN/034/06
Storage Condition:30°C ±2°C & 75% RH ± 5%
Reason for stability: Validataion Batch study
Period: 36 Month
Date of Loading:29.04.2020

PRODUCT NAME: AMLOPERIN 5MG/5MG

B.No. : GF200405

Mfg. Date: APR-2020 | **Batch Size: 6.0 L**

Exp. Date: MAR-2023 | **Pack Size: Alu Alu (3x10'S)**

Label Claim: Each uncoated tablet contains:
Amlodipine Besylate BP equivalent to Amlodipine 5 mg
Perindopril Erbumine BP 5 mg

Microbiological limits:									
Total Aerobic Microbial count	NMT 1000 cfu/g	10 cfu /g	NA	NA	NA	NA	NA	NA	40 cfu /g
Total Yeasts and mould counts	NMT 100 cfu/g	<10 cfu/g	NA	NA	NA	NA	NA	NA	<10 cfu/g
E.Coli	Should be Absent	Absent	NA	NA	NA	NA	NA	NA	Absent
Salmonella	Should be Absent	Absent	NA	NA	NA	NA	NA	NA	Absent
S.aureus	Should be Absent	Absent	NA	NA	NA	NA	NA	NA	Absent
P.aeruginosa	Should be Absent	Absent	NA	NA	NA	NA	NA	NA	Absent

Stability study: Complete [✓] Incomplete [✗]

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

Reference: ICH Guidelines

PREPARED BY: J. Kayal.
DATE: 11/05/2023.

CHECKED BY:
DATE: 11/05/2023

APPROVED BY:
DATE: 11/05/2023

SAI PRIMUS LIFE BIOTECH PVT LTD	ACCELERATED STABILITY DATA		Page No: Page 1 of 2
			Foramt No:F/QCGN/034/06
PRODUCT NAME: AMLOPERIN 5MG/5MG			Storage Condition:40°C ±2°C & 75% RH ± 5%
B.No. : GF200501	Mfg. Date: MAY-2020	Batch Size: 6.0 L	Reason for stability: Validataion Batch study
	Exp. Date: APR-2023	Pack Size: Alu Alu (3x10'S)	Period: 6 Month
	Label Claim: Each uncoated tablet contains: Amlodipine Besylate BP equivalent to Amlodipine 5 mg Perindopril Erbumine BP 5 mg		Date of Loading:27.05.2020

Tests	Limits	Initial 27.05.2020	3rd Month 03.09.2020	6th Month 27.11.2020
		Results	Results	Results
Description	Off white, round, biconvex, uncoated tablet with breakline on one side and plain on other side.	Complies	Complies	Complies
Average Weight	140.0 mg ± 5.0 % (Between 133.0 mg to 147.0 mg)	143.80 mg	141.12 mg	140.70 mg
Disintegration Time	Not more than 15 minutes	01 min 02 sec	01 min 21 sec	02 min 31 sec
Dissolution Amlodipine Besylate BP eq. to Amlodipine 5 mg	Not less than 80.0 % of labeled amount.	Min: 101.54 % to Max: 104.66 % Avg: 102.85 %	Min: 87.13 % to Max: 101.79 % Avg: 96.30 %	Min: 98.18 % to Max: 100.82 % Avg: 99.67 %
Perindopril Erbumine BP 5 mg	Not less than 80.0 % of labeled amount.	Min: 96.67 % to Max: 99.52 % Avg: 98.13 %	Min: 98.88 % to Max: 101.63 % Avg: 100.03 %	Min: 85.97 % to Max: 96.40 % Avg: 90.66 %
Related substances Amlodipine impurity A	NMT 1.0%	ND	ND	ND
Perindopril Impurity B	NMT 1.5%	ND	ND	ND
Perindopril Impurity C	NMT 0.6%	ND	ND	ND
Perindopril Impurity E	NMT 0.4%	ND	ND	ND
Perindopril Impurity F	NMT 1.5%	ND	ND	ND
Single maximum unknown impurity	NMT 0.5%	BDL	BDL	BDL
Total unknown impurity	NMT 1.0%	BDL	BDL	BDL
Total unknown impurity	NMT 5.0%	BDL	BDL	BDL

SAI PRIMUS LIFE BIOTECH PVT LTD	ACCELERATED STABILITY DATA		Page No: Page 2 of 2
			Foramt No:F/QCGN/034/06
PRODUCT NAME: AMLOPERIN 5MG/5MG			**Storage Condition:40°C ±2°C & 75% RH ± 5%**
B.No. : GF200501	**Mfg. Date: MAY-2020**	**Batch Size: 6.0 L**	**Reason for stability: Validataion Batch study**
	Exp. Date: APR-2023	**Pack Size: Alu Alu (3x10'S)**	**Period: 6 Month**
	Label Claim: Each uncoated tablet contains: Amlodipine Besylate BP equivalent to Amlodipine 5 mg Perindopril Erbumine BP 5 mg		**Date of Loading:27.05.2020**

Assay: **Each uncoated tablets Contains:**				
Amlodipine Besylate BP eq. to Amlodipine 5 mg	Not less than 90.0 % and Not more than 110.0 %	100.83 %	101.98 %	99.06 %
Perindopril Erbumine BP 5 mg	Not less than 90.0 % and Not more than 110.0 %	98.61 %	99.11 %	98.18 %
Microbiological limits:				
Total Aerobic Microbial count	NMT 1000 cfu/g	20 cfu /g	NA	20 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	NA	Absent
S.aureus	Should be Absent	Absent	NA	Absent
P.aeruginosa	Should be Absent	Absent	NA	Absent

Stability study: Complete [✓] Incomplete [^]

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

Reference: ICH Guidelines

PREPARED BY: J.Kayal **DATE:** 04/12/2020

CHECKED BY: **DATE:** 04/12/2020

APPROVED BY: **DATE:** 04/12/2020

SAI PRIMUS
LIFE BIOTECH PVT LTD

LONG TERM STABILITY DATA

Foramt No:F/QCGN/034/06

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

PRODUCT NAME: AMLOPERIN 5MG/5MG

Reason for stability: Validation Batch study

B.No. : GF200501	**Mfg. Date: MAY-2020**	**Batch Size: 6.0 L**	**Period: 36 Month**
	Exp. Date: APR-2023	**Pack Size: Alu Alu (3x10'S)**	**Date of Loading:27.05.2020**
	Label Claim: Each uncoated tablet contains: Amlodipine Besylate BP equivalent to Amlodipine 5 mg Perindopril Erbumine BP 5 mg		

Tests	Limits	Initial 27.05.2020	3rd Month 03.09.2020	6th Month 27.11.2020	9th Month 27.02.2021	12th Month 27.05.2021	18th Month 27.11.2021	24th Month 27.05.2022	36th Month 27.05.2023
		Results	Results	Results	Results	Results	Results	Results	Results
Description	Off white, round, biconvex, uncoated tablet with breakline on one side and plain on other side.	Complies	Complies	Complies	Complies	Complies	Complies	Complies	Complies
Average Weight	140.0 mg ± 5.0 % (Between 133.0 mg to 147.0 mg	143.80 mg	141.22 mg	140.10 mg	140.08 mg	140.01 mg	139.95 mg	140.85 mg	139.20 mg
Disintegration Time	Not more than 15 minutes	01 min 02 sec	01 min 25 sec	02 min 21 sec	02 min 43 sec	02 min 52 sec	02 min 58 sec	03 min 15 sec	02 min 39 sec
Dissolution									
Amlodipine Besylate BP eq. to Amlodipine 5 mg	Not less than 80.0 % of labeled amount.	Min: 101.54 % to Max: 104.66 % Avg: 102.85 %	Min: 88.27 % to Max: 101.50 % Avg: 96.41 %	Min: 96.80 % to Max: 101.06 % Avg: 98.30 %	Min: 95.51 % to Max: 100.59 % Avg: 98.31 %	Min: 95.50 % to Max: 99.15 % Avg: 97.47 %	Min: 94.24 % to Max: 98.26 % Avg: 96.36 %	Min: 91.19 % to Max: 97.56 % Avg: 95.16 %	Min: 96.27 % to Max: 100.43 % Avg: 97.44 %
Perindopril Erbumine BP 5 mg	Not less than 80.0 % of labeled amount.	Min: 96.67 % to Max: 99.52 % Avg: 98.13 %	Min: 93.34 % to Max: 101.87 % Avg: 98.95 %	Min: 91.24 % to Max: 98.39 % Avg: 94.22 %	Min: 90.03 % to Max: 99.70 % Avg: 96.19 %	Min: 90.69 % to Max: 99.12 % Avg: 95.45 %	Min: 91.54 % to Max: 98.98 % Avg: 96.25 %	Min: 89.57 % to Max: 96.90 % Avg: 94.15 %	Min: 94.65 % to Max: 99.18 % Avg: 96.72 %
Related substances									
Amlodipine impurity A		ND	ND	ND	ND	ND	ND	ND	ND
Perindopril Impurity B	NMT 1.0%	ND	ND	ND	ND	ND	ND	ND	ND
Perindopril Impurity C	NMT 1.5%	ND	ND	ND	ND	ND	ND	ND	ND
Perindopril Impurity E	NMT 0.6%	ND	ND	ND	ND	ND	ND	ND	ND
Perindopril Impurity F	NMT 0.4%	ND	ND	ND	ND	ND	ND	ND	ND
Single maximum unknown impurity	NMT 1.5%	BDL	BDL	BDL	BDL	BDL	BDL	BDL	BDL
Total unknown impurity	NMT 0.5%	BDL	BDL	BDL	BDL	BDL	BDL	BDL	BDL
Total unknown impurity	NMT 5.0%	BDL	BDL	BDL	BDL	BDL	BDL	BDL	BDL

SAI PRIMUS
LIFE BIOTECH PVT LTD

LONG TERM STABILITY DATA

Foramt No:F/QCGN/034/06

PRODUCT NAME: AMLOPERIN 5MG/5MG

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

B.No. : GF200501	**Mfg. Date: MAY-2020**	**Batch Size: 6.0 L**	**Reason for stability: Validation Batch study**
	Exp. Date: APR-2023	**Pack Size: Alu Alu (3x10'S)**	**Period: 36 Month**
	Label Claim: Each uncoated tablet contains: Amlodipine Besylate BP equivalent to Amlodipine 5 mg Perindopril Erbumine BP 5 mg		**Date of Loading:27.05.2020**

Assay: **Each uncoated tablets Contains:** Amlodipine Besylate BP eq. to Amlodipine 5 mg	Not less than 90.0 % and Not more than 110.0 %	100.83 %	102.15 %	99.94 %	99.37 %	99.12 %	98.98 %	97.01 %	98.80 %
Perindopril Erbumine BP 5 mg	Not less than 90.0 % and Not more than 110.0 %	98.61 %	99.30 %	97.58 %	97.55 %	97.48 %	97.02 %	95.86 %	97.70 %
Microbiological limits:									
Total Aerobic Microbial count	NMT 1000 cfu/g	20 cfu /g	NA	NA	NA	NA	NA	NA	NA
Total Yeasts and mould counts	NMT 100 cfu/g	<10 cfu/g	NA	NA	NA	NA	NA	NA	NA
E.Coli	Should be Absent	Absent	NA	NA	NA	NA	NA	NA	NA
Salmonella	Should be Absent	Absent	NA	NA	NA	NA	NA	NA	NA
S.aureus	Should be Absent	Absent	NA	NA	NA	NA	NA	NA	NA
P.aeruginosa	Should be Absent	Absent	NA	NA	NA	NA	NA	NA	NA

Stability study: Complete [✓] Incomplete [✗]

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

Reference: ICH Guidelines

PREPARED BY: J. kanyal
DATE: 05/06/2023

CHECKED BY:
DATE: 05/06/2023

APPROVED BY:
DATE: 05/06/2023

SAI PRIMUS LIFE BIOTECH PVT LTD	ACCELERATED STABILITY DATA		Page No: Page 1 of 2
			Foramt No:F/QCGN/034/06
PRODUCT NAME: AMLOPERIN 5MG/5MG			**Storage Condition:40°C ±2°C & 75% RH ± 5%**
B.No. : GF200502	**Mfg. Date: MAY-2020**	**Batch Size: 6.0 L**	**Reason for stability: Validataion Batch study**
	Exp. Date: APR-2023	**Pack Size: Alu Alu (3x10'S)**	**Period: 6 Month**
	Label Claim: Each uncoated tablet contains: Amlodipine Besylate BP equivalent to Amlodipine 5 mg Perindopril Erbumine BP 5 mg		**Date of Loading:28.05.2020**

Tests	Limits	Initial 28.05.2020 Results	3rd Month 03.09.2020 Results	6th Month 28.11.2020 Results
Description	Off white, round, biconvex, uncoated tablet with breakline on one side and plain on other side.	Complies	Complies	Complies
Average Weight	140.0 mg ± 5.0 % (Between 133.0 mg to 147.0 mg	142.59 mg	140.25 mg	139.70 mg
Disintegration Time	Not more than 15 minutes	02 min 04 sec	01 min 05 sec	02 min 15 sec
Dissolution Amlodipine Besylate BP eq. to Amlodipine 5 mg Perindopril Erbumine BP 5 mg	Not less than 80.0 % of labeled amount. Not less than 80.0 % of labeled amount.	Min: 96.99 % to Max: 104.18 % Avg: 101.47 % Min: 95.28 % to Max: 97.71 % Avg: 96.46 %	Min: 95.94 % to Max: 102.22 % Avg: 99.21 % Min: 98.23 % to Max: 103.93 % Avg: 101.12 %	Min: 95.35 % to Max:101.02 % Avg: 98.00 % Min: 86.95 % to Max:96.75% Avg: 90.49 %
Related substances Amlodipine impurity A Perindopril Impurity B Perindopril Impurity C Perindopril Impurity E Perindopril Impurity F Single maximum unknown impurity Total unknown impurity Total unknown impurity	 NMT 1.0% NMT 1.5% NMT 0.6% NMT 0.4% NMT 1.5% NMT 0.5% NMT 1.0% NMT 5.0%	 ND ND ND ND ND BDL BDL BDL	 ND ND ND ND ND BDL BDL BDL	 ND ND ND ND ND BDL BDL BDL

SAI PRIMUS LIFE BIOTECH PVT LTD	ACCELERATED STABILITY DATA		Page No: Page 2 of 2
			Foramt No:F/QCGN/034/06
PRODUCT NAME: AMLOPERIN 5MG/5MG			Storage Condition:40°C ±2°C & 75% RH ± 5%
B.No. : GF200502	Mfg. Date: MAY-2020	Batch Size: 6.0 L	Reason for stability: Validataion Batch study
	Exp. Date: APR-2023	Pack Size: Alu Alu (3x10'S)	Period: 6 Month
	Label Claim: Each uncoated tablet contains: Amlodipine Besylate BP equivalent to Amlodipine 5 mg Perindopril Erbumine BP 5 mg		Date of Loading:28.05.2020

Assay: **Each uncoated tablets Contains:** Amlodipine Besylate BP eq. to Amlodipine 5 mg	Not less than 90.0 % and Not more than 110.0 %	101.61 %	102.29 %	99.85 %
Perindopril Erbumine BP 5 mg	Not less than 90.0 % and Not more than 110.0 %	99.36 %	101.64 %	97.92 %
Microbiological limits:				
Total Aerobic Microbial count	NMT 1000 cfu/g	20 cfu /g	NA	40 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	NA	Absent
S.aureus	Should be Absent	Absent	NA	Absent
P.aeruginosa	Should be Absent	Absent	NA	Absent

Stability study: Complete [✓] Incomplete [✗]

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

Reference: ICH Guidelines

PREPARED BY: J.Kayal **DATE:** 05/12/2020

CHECKED BY: **DATE:** 05/12/2020

APPROVED BY: **DATE:** 05/12/20

SAI PRIMUS LIFE BIOTECH PVT LTD	LONG TERM STABILITY DATA		Page No: Page 1 of 2
			Foramt No:F/QCGN/034/06
PRODUCT NAME: AMLOPERIN 5MG/5MG			Storage Condition:30°C ±2°C & 75% RH ± 5%
B.No. : GF200502	Mfg. Date: MAY-2020	Batch Size: 6.0 L	Reason for stability: Validation Batch study
	Exp. Date: APR-2023	Pack Size: Alu Alu (3x10'S)	Period: 36 Month
	Label Claim: Each uncoated tablet contains: Amlodipine Besylate BP equivalent to Amlodipine 5 mg Perindopril Erbumine BP 5 mg		Date of Loading:28.05.2020

Tests	Limits	Initial 28.05.2020	3rd Month 03.09.2020	6th Month 28.11.2020	9th Month 28.02.2021	12th Month 28.05.2021	18th Month 28.11.2021	24th Month 28.05.2022	36th Month 28.05.2023
		Results	Results	Results	Results	Results	Results	Results	Results
Description	Off white, round, biconvex, uncoated tablet with breakline on one side and plain on other side.	Complies	Complies	Complies	Complies	Complies	Complies	Complies	Complies
Average Weight	140.0 mg ± 5.0 % (Between 133.0 mg to 147.0 mg	142.59 mg	141.25 mg	140.50 mg	140.31 mg	140.29 mg	140.25 mg	141.53 mg	141.25 mg
Disintegration Time	Not more than 15 min	02 min 04 sec	01 min 39 sec	03 min 27 sec	03 min 39 sec	03 min 50 sec	03 min 58 sec	04 min 22 sec	04 min 09 sec
Dissolution									
Amlodipine Besylate BP eq. to Amlodipine 5 mg	Not less than 80.0 % of labeled amount.	Min: 96.99 % to Max: 104.18 % Avg: 101.47 %	Min: 96.88 % to Max: 102.54 % Avg: 99.71 %	Min: 99.14 % to Max: 101.93 % Avg: 99.94 %	Min: 96.67 % to Max: 100.29 % Avg: 98.69 %	Min: 95.14 % to Max: 99.58 % Avg: 97.28 %	Min: 96.54 % to Max: 99.23 % Avg: 97.26 %	Min: 94.27 % to Max: 97.40 % Avg: 96.11 %	Min: 93.11 % to Max: 99.78 % Avg: 96.22 %
Perindopril Erbumine BP 5 mg	Not less than 80.0 % of labeled amount.	Min: 95.28 % to Max: 97.71 % Avg: 96.46 %	Min: 100.44 % to Max: 101.33 % Avg: 100.90 %	Min: 92.56 % to Max: 100.64 % Avg: 95.49 %	Min: 91.38 % to Max: 100.11 % Avg: 96.47 %	Min: 91.20 % to Max: 99.88 % Avg: 96.12 %	Min: 91.48 % to Max: 98.65 % Avg: 97.29 %	Min: 90.16 % to Max: 98.11 % Avg: 96.17 %	Min: 95.08 % to Max: 98.92 % Avg: 97.58 %
Related substances									
Amlodipine impurity A		ND	ND	ND	ND	ND	ND	ND	ND
Perindopril Impurity B	NMT 1.0%	ND	ND	ND	ND	ND	ND	ND	ND
Perindopril Impurity C	NMT 1.5%	ND	ND	ND	ND	ND	ND	ND	ND
Perindopril Impurity E	NMT 0.6%	ND	ND	ND	ND	ND	ND	ND	ND
Perindopril Impurity F	NMT 0.4%	ND	ND	ND	ND	ND	ND	ND	ND
Single maximum unknown impurity	NMT 1.5%	BDL	BDL	BDL	BDL	BDL	BDL	BDL	BDL
Total unknown impurity	NMT 0.5%	BDL	BDL	BDL	BDL	BDL	BDL	BDL	BDL
Total unknown impurity	NMT 1.0% NMT 5.0%	BDL	BDL	BDL	BDL	BDL	BDL	BDL	BDL

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LONG TERM STABILITY DATA

Page No: Page 2 of 2
Foramt No:F/QCGN/034/06
Storage Condition:30°C ±2°C & 75% RH ± 5%
Reason for stability: Validation Batch study
Period: 36 Month
Date of Loading:28.05.2020

PRODUCT NAME: AMLOPERIN 5MG/5MG

B.No. : GF200502

Mfg. Date: MAY-2020
Exp. Date: APR-2023
Batch Size: 6.0 L
Pack Size: Alu Alu (3x10'S)

Label Claim: Each uncoated tablet contains:
Amlodipine Besylate BP equivalent to Amlodipine 5 mg
Perindopril Erbumine BP 5 mg

Assay: **Each uncoated tablets Contains:** Amlodipine Besylate BP eq. to Amlodipine 5 mg Perindopril Erbumine BP 5 mg	Not less than 90.0 % and Not more than 110.0 % Not less than 90.0 % and Not more than 110.0 %	101.61 % 99.36 %	102.48 % 101.94 %	97.45 % 98.93 %	98.14 % 98.91 %	97.95 % 98.87 %	97.55 % 98.24 %	97.02 % 97.19 %	98.60 % 97.40 %
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	20 cfu /g <10 cfu/g Absent Absent Absent Absent	NA NA NA NA NA NA	NA NA NA NA NA NA	NA NA NA NA NA NA	NA NA NA NA NA NA	NA NA NA NA NA NA	NA NA NA NA NA NA	30 cfu /g <10 cfu/g Absent Absent Absent Absent

Stability study: Complete [✓] Incomplete [X]

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

Reference: ICH Guidelines

PREPARED BY: M.M
DATE: 03/06/23

CHECKED BY: PS
DATE: 03/06/2023

APPROVED BY:
DATE: 03/06/2023