

		ACCELERATED STABILITY DATA				Page No: Page 1 of 2						
						Format No: F/QCGN/034/06						
PRODUCT NAME: BONCIPRO-500 TABLETS(Ciprofloxacin Hydrochloride tablets BP 500 mg)						Storage Condition:40°C ±2°C & 75% RH ± 5%						
B.No. : G1822068		Mfg. Date: APR-2022		Batch Size: 3.0 L		Reason for stability: Validation Batch study						
		Exp. Date: Mar-2025		Pack Size: Blister (2x10'S)		Period: 6 Month						
		Label Claim: Each Film coated tablet contains: Ciprofloxacin hydrochloride BP equivalent to Ciprofloxacin-500 mg				Date of Loading:12.04.2022						
Tests		Limits		Initial 12.04.2022		3 rd Month 12.07.2022		6 th Month 12.10.2022				
				Results		Results		Results				
Description		Reddish pink coloured, oblong, biconvex film coated tablet with breakline on one side and plain on other sides.		Complies		Complies		Complies				
Average Weight		736.0 mg ± 5.0% (Limit:699.20 mg to 772.80 mg)		731.60mg		731.57 mg		730.89 mg				
Disintegration Time		Not more than 30 minutes		02 minutes 48 seconds		02 minutes 43 seconds		03 minutes 04 seconds				
Dissolution: Ciprofloxacin hydrochloride BP equivalent to Ciprofloxacin-500 mg		Not less than 85.0 % of labeled amount.		Min 93.75 %	Max 99.49 %	Avg. 96.89%	Min 89.81 %	Max 97.53 %	Avg. 95.07%	Min 91.02 %	Max 98.35 %	Avg. 94.28%
Related substances: Ciprofloxacin impurity C Ciprofloxacin impurity E Any individual impurity Total impurities		Not more than 0.5 % 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				
Assay: Each Film coated tablet contains: Ciprofloxacin hydrochloride BP equivalent to Ciprofloxacin-500 mg		Not less than 95.0 % and Not more than 105.0 %		103.56 %		100.38 %		100.50 %				
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/gss <10 cfu/g Absent Absent Absent Absent		NA		20 cfu/g <10 cfu/g Absent Absent Absent Absent				

	ACCELERATED STABILITY DATA		Page No: Page 2 of 2
			Format No: F/QCGN/034/06
PRODUCT NAME: BONCIPRO-500 TABLETS (Ciprofloxacin Hydrochloride tablets BP 500 mg)			Storage Condition: 40°C ± 2°C & 75% RH ± 5%
B.No. : G1822068	Mfg. Date: APR-2022	Batch Size: 3.0 L	Reason for stability: Validation Batch study
	Exp. Date: Mar-2025	Pack Size: Blister (2x10'S)	Period: 6 Month
	Label Claim: Each Film coated tablet contains: Ciprofloxacin hydrochloride BP equivalent to Ciprofloxacin-500 mg		Date of Loading: 12.04.2022

Stability study: Complete [☒] Incomplete [☒]

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

Reference: ICH Guidelines

PREPARED BY: *P.M.*
DATE: *17/10/2022*

CHECKED BY: *P*
DATE: *17/10/2022*

APPROVED BY: *h*
DATE: *17/10/2022*

	LONG TERM STABILITY DATA						Page No: Page 2 of 2		
							Format No:F/QCGN/034/06		
PRODUCT NAME: BONCIPRO-500 TABLETS(Ciprofloxacin Hydrochloride tablets BP 500 mg)							Storage Condition:30°C ±2°C & 75% RH ± 5%		
B.No. : G1822068	Mfg. Date: APR-2022			Batch Size: 3.0 L			Reason for stability: Validation Batch study		
	Exp. Date: Mar-2025			Pack Size: Blister (2x10'S)			Period: 36 Month		
	Label Claim: Each Film coated tablet contains: Ciprofloxacin hydrochloride BP equivalent to Ciprofloxacin-500 mg						Date of Loading:12.04.2022		
Assay: Each Film coated tablet contains: Ciprofloxacin hydrochloride BP equivalent to Ciprofloxacin-500 mg	Not less than 95.0 % and Not more than 105.0 %	103.56 %	99.64 %	100.02 %	100.46 %	101.11 %	100.33 %	99.90 %	97.58 %
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	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 36 months.

Reference: ICH Guidelines

PREPARED BY: *[Signature]*
DATE: 25/04/2025

CHECKED BY: *[Signature]*
DATE: 25/04/2025

APPROVED BY: *[Signature]*
DATE: 25/04/2025

	ACCELERATED STABILITY DATA					Page No: Page 1 of 2								
						Format No:F/QCGN/034/06								
PRODUCT NAME: BONCIPRO-500 TABLETS(Ciprofloxacin Hydrochloride tablets BP 500 mg)										Storage Condition:40°C ±2°C & 75% RH ± 5%				
B.No. : G1822116		Mfg. Date: SEP-2022			Batch Size: 3.0 L			Reason for stability: Validation Batch study						
		Exp. Date: AUG-2025			Pack Size: Blister (2x10'S)			Period: 6 Month						
		Label Claim: Each Film coated tablet contains: Ciprofloxacin hydrochloride BP equivalent to Ciprofloxacin-500 mg						Date of Loading:21.09.2022						
Tests		Limits		Initial 21.09.2022			3 rd Month 21.12.2022			6 th Month 21.03.2023				
				Results			Results			Results				
Description		Reddish pink coloured, oblong, biconvex film coated tablet with breakline on one side and plain on both sides.		Complies			Complies			Complies				
Average Weight		736.0 mg ± 5.0% (Limit:699.20 mg to 772.80 mg)		740.00mg			741.74 mg			740.53 mg				
Disintegration Time		Not more than 30 minutes		02 minutes 26 seconds			02 minutes 34 seconds			03 minutes 01 seconds				
Dissolution: Ciprofloxacin hydrochloride BP equivalent to Ciprofloxacin-500 mg		Not less than 85.0 % of labeled amount.		Min 92.42 %	Max 99.64 %	Avg. 95.81%	Min 90.19 %	Max 98.36 %	Avg. 94.28%	Min 91.79 %	Max 97.11 %	Avg. 94.45%		
Related substances: Ciprofloxacin impurity C Ciprofloxacin impurity E Any individual impurity Total impurities		Not more than 0.5 % 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				
Assay: Each Film coated tablet contains: Ciprofloxacin hydrochloride BP equivalent to Ciprofloxacin-500 mg		Not less than 95.0 % and Not more than 105.0 %		104.77 %			103.74 %			102.11 %				
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/gss <10 cfu/g Absent Absent Absent Absent			NA			20 cfu/g <10 cfu/g Absent Absent Absent Absent				

	ACCELERATED STABILITY DATA		Page No: Page 2 of 2
			Format No:F/QCGN/034/06
PRODUCT NAME: BONCIPRO-500 TABLETS(Ciprofloxacin Hydrochloride tablets BP 500 mg)			Storage Condition:40°C ±2°C & 75% RH ± 5%
B.No. : G1822116	Mfg. Date: SEP-2022	Batch Size: 3.0 L	Reason for stability: Validation Batch study
	Exp. Date: AUG-2025	Pack Size: Blister (2x10'S)	Period: 6 Month
	Label Claim: Each Film coated tablet contains: Ciprofloxacin hydrochloride BP equivalent to Ciprofloxacin-500 mg		Date of Loading:21.09.2022

Stability study:

Complete [✓]

Incomplete [✕]

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

Reference: ICH Guidelines

PREPARED BY: *M. H. J.*
DATE: *27/03/2023*

CHECKED BY: 
DATE: 24/03/2023

APPROVED BY: 
DATE: 27/03/2023

		LONG TERM STABILITY DATA					Page No: Page 1 of 2	
							Format No:F/QCGN/034/06	
PRODUCT NAME: BONCIPRO-500 TABLETS(Ciprofloxacin Hydrochloride tablets BP 500 mg)							Storage Condition:30°C ±2°C & 75% RH ± 5%	
B.No. : G1822116		Mfg. Date: SEP-2022			Batch Size: 3.0 L		Reason for stability: Validation Batch study	
		Exp. Date: AUG-2025			Pack Size: Blister (2x10'S)		Period: 36 Month	
		Label Claim: Each Film coated tablet contains: Ciprofloxacin hydrochloride BP equivalent to Ciprofloxacin-500 mg					Date of Loading:21.09.2022	
Tests	Limits	Initial 21.09.2022	3 rd Month 21.12.2022	6 th Month 21.03.2023	9 th Month 21.06.2023	12 th Month 21.09.2023	18 th Month 21.03.2024	24 th Month 21.09.2024
		Results	Results	Results	Results	Results	Results	Results
Description	Reddish pink coloured, oblong, biconvex film coated tablet with breakline on one side and plain on both sides.	Complies	Complies	Complies	Complies	Complies	Complies	Complies
Average Weight	736.0 mg ± 5.0% (Limit:699.20 mg to 772.80 mg)	740.00mg	741.52 mg	741.78 mg	732.85 mg	731.43 mg	731.13 mg	740.65 mg
Disintegration Time	Not more than 30 minutes	02 minutes 26 seconds	02 minutes 30 seconds	03 minutes 41 seconds	03 minutes 52 seconds	03 minutes 56 seconds	04 minutes 02 seconds	05 minutes 25 seconds
Dissolution: Ciprofloxacin hydrochloride BP equivalent to Ciprofloxacin-500 mg	Not less than 85.0 % of labeled amount.	Min 92.42 % Max 99.64 % Avg.95.81%	Min 91.35 % Max 99.71 % Avg.95.53%	Min 93.41 % Max 98.33 % Avg.95.87%	Min 95.45 % Max 99.74 % Avg.98.26%	Min 96.27 % Max 99.31 % Avg.98.52%	Min 95.09 % Max 98.72 % Avg.97.48%	Min 94.63 % Max 96.49 % Avg.95.53%
Related substances: Ciprofloxacin impurity C Ciprofloxacin impurity E Any individual impurity Total impurities	Not more than 0.5 %	Not Detected	Not Detected	Not Detected	Not Detected	Not Detected	Not Detected	Not Detected
	Not more than 0.3 %	Not Detected	Not Detected	Not Detected	Not Detected	Not Detected	Not Detected	Not Detected
	Not more than 0.2 %	Not Detected	Not Detected	Not Detected	Not Detected	Not Detected	Not Detected	BDL
	Not more than 1.0 %	Not Detected	Not Detected	Not Detected	Not Detected	Not Detected	Not Detected	BDL
Assay: Each Film coated tablet contains: Ciprofloxacin	Not less than 95.0 % and	104.77 %	103.04 %	102.74 %	103.04 %	102.79 %	101.63 %	99.97 %

		LONG TERM STABILITY DATA				Page No: Page 2 of 2		
						Format No: F/QCGN/034/06		
PRODUCT NAME: BONCIPRO-500 TABLETS (Ciprofloxacin Hydrochloride tablets BP 500 mg)						Storage Condition: 30°C ± 2°C & 75% RH ± 5%		
B.No. : G1822116		Mfg. Date: SEP-2022		Batch Size: 3.0 L		Reason for stability: Validation Batch study		
		Exp. Date: AUG-2025		Pack Size: Blister (2x10'S)		Period: 36 Month		
		Label Claim: Each Film coated tablet contains: Ciprofloxacin hydrochloride BP equivalent to Ciprofloxacin-500 mg				Date of Loading: 21.09.2022		
Microbiological limits:								
Total Aerobic Microbial count	NMT 1000 cfu/g	<10 cfu/gss	NA	NA	NA	NA	NA	NA
Total Yeasts and mould counts	NMT 100 cfu/g	<10 cfu/g						
E.Coli	Should be Absent	Absent						
Salmonella	Should be Absent	Absent						
S.aureus	Should be Absent	Absent						
P.aeruginosa	Should be Absent	Absent						

Stability study:

Complete [✓]

Incomplete [✗]

Opinion: Based on the above stability studies, the product is ~~unstable~~ / stable for 24th months.

Reference: ICH Guidelines

PREPARED BY:
DATE:

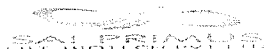
H.K. [Signature]
05/10/2024

CHECKED BY:
DATE:

J. [Signature]
05/10/2024

APPROVED BY:
DATE:

[Signature]
05/10/2024

	ACCELERATED STABILITY DATA					Page No: Page 1 of 2					
						Format No: F/QCGN/034/06					
PRODUCT NAME: BONCIPRO-500 TABLETS(Ciprofloxacin Hydrochloride tablets BP 500 mg)						Storage Condition: 40°C ±2°C & 75% RH ± 5%					
B.No. : G1822117	Mfg. Date: SEP-2022			Batch Size: 3.0 L			Reason for stability: Validation Batch study				
	Exp. Date: AUG-2025			Pack Size: Blister (2x10'S)			Period: 6 Month				
	Label Claim: Each Film coated tablet contains: Ciprofloxacin hydrochloride BP equivalent to Ciprofloxacin-500 mg					Date of Loading: 21.09.2022					
Tests	Limits	Initial 21.09.2022			3 rd Month 21.12.2022			6 th Month 21.03.2023			
		Results			Results			Results			
Description	Reddish pink coloured, oblong, biconvex film coated tablet with breakline on one side and plain on both sides.	Complies			Complies			Complies			
Average Weight	736.0 mg ± 5.0% (Limit: 699.20 mg to 772.80 mg)	730.15 mg			732.47 mg			731.19 mg			
Disintegration Time	Not more than 30 minutes	02 minutes 42 seconds			02 minutes 12 seconds			02 minutes 58 seconds			
Dissolution: Ciprofloxacin hydrochloride BP equivalent to Ciprofloxacin-500 mg	Not less than 85.0 % of labeled amount.	Min 90.17 %	Max 100.41 %	Avg. 94.08%	Min 91.36 %	Max 99.49 %	Avg. 95.43%	Min 92.41 %	Max 98.66 %	Avg. 95.54%	
Related substances: Ciprofloxacin impurity C Ciprofloxacin impurity E Any individual impurity Total impurities	Not more than 0.5 % 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			
Assay: Each Film coated tablet contains: Ciprofloxacin hydrochloride BP equivalent to Ciprofloxacin-500 mg	Not less than 95.0 % and Not more than 105.0 %	104.29 %			103.91 %			102.73 %			
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/gss <10 cfu/g Absent Absent Absent Absent			NA			20 cfu/g <10 cfu/g Absent Absent Absent Absent			

	ACCELERATED STABILITY DATA		Page No: Page 2 of 2
			Format No: F/QCGN/034/06
PRODUCT NAME: BONCIPRO-500 TABLETS (Ciprofloxacin Hydrochloride tablets BP 500 mg)			Storage Condition: 40°C ± 2°C & 75% RH ± 5%
B.No. : G1822117	Mfg. Date: SEP-2022	Batch Size: 3.0 L	Reason for stability: Validation Batch study
	Exp. Date: AUG-2025	Pack Size: Blister (2x10'S)	Period: 6 Month
	Label Claim: Each Film coated tablet contains: Ciprofloxacin hydrochloride BP equivalent to Ciprofloxacin-500 mg		Date of Loading: 21.09.2022

Stability study:

Complete [✓]

Incomplete [✗]

Opinion: Based on the above stability studies, the product is stable / stable for ^{6th} months.

Reference: ICH Guidelines

PREPARED BY: *P.M.*
DATE: *27/03/2023*

CHECKED BY: *[Signature]*
DATE: *27/03/2023*

APPROVED BY: *[Signature]*
DATE: *27/03/2023*

		LONG TERM STABILITY DATA					Page No: Page 1 of 2	
							Format No:F/QCGN/034/06	
PRODUCT NAME: BONCIPRO-500 TABLETS(Ciprofloxacin Hydrochloride tablets BP 500 mg)							Storage Condition:30°C ±2°C & 75% RH ± 5%	
B.No. : G1822117		Mfg. Date: SEP-2022		Batch Size: 3.0 L		Reason for stability: Validation Batch study		
		Exp. Date: AUG-2025		Pack Size: Blister (2x10'S)		Period: 36 Month		
		Label Claim: Each Film coated tablet contains: Ciprofloxacin hydrochloride BP equivalent to Ciprofloxacin-500 mg				Date of Loading:21.09.2022		
Tests	Limits	Initial 21.09.2022	3 rd Month 21.12.2022	6 th Month 21.03.2023	9 th Month 21.06.2023	12 th Month 21.09.2023	18 th Month 21.03.2024	24 th Month 21.09.2024
		Results	Results	Results	Results	Results	Results	Results
Description	Reddish pink coloured, oblong, biconvex film coated tablet with breakline on one side and plain on both sides.	Complies	Complies	Complies	Complies	Complies	Complies	Complies
Average Weight	736.0 mg ± 5.0% (Limit:699.20 mg to 772.80 mg)	730.15 mg	731.78 mg	731.89 mg	729.47 mg	728.13 mg	728.59 mg	737.25 mg
Disintegration Time	Not more than 30 minutes	02 minutes 42 seconds	02 minutes 56 seconds	03 minutes 02 seconds	03 minutes 13 seconds	03 minutes 20 seconds	03 minutes 40 seconds	04 minutes 28 seconds
Dissolution: Ciprofloxacin hydrochloride BP equivalent to Ciprofloxacin-500 mg	Not less than 85.0 % of labeled amount.	Min 90.17 % Max 100.41 % Avg.94.08%	Min 90.11 % Max 98.16 % Avg.94.14%	Min 93.49 % Max 99.71 % Avg. 96.60%	Min 94.69 % Max 99.59 % Avg. 97.22%	Min 93.17 % Max 98.43 % Avg. 96.94%	Min 92.87 % Max 97.93 % Avg. 96.01%	Min 94.17 % Max 98.80 % Avg. 96.44%
Related substances: Ciprofloxacin impurity C Ciprofloxacin impurity E Any individual impurity Total impurities	Not more than 0.5 % 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 BDL BDL
Assay: Each Film coated tablet contains: Ciprofloxacin	Not less than 95.0 % and	104.29 %	103.06 %	102.65 %	102.66 %	102.42 %	101.66 %	100.20 %

		LONG TERM STABILITY DATA				Page No: Page 2 of 2		
						Format No: F/QCGN/034/06		
PRODUCT NAME: BONCIPRO-500 TABLETS (Ciprofloxacin Hydrochloride tablets BP 500 mg)						Storage Condition: 30°C ± 2°C & 75% RH ± 5%		
B.No.: G1822117		Mfg. Date: SEP-2022		Batch Size: 3.0 L		Reason for stability: Validation Batch study		
		Exp. Date: AUG-2025		Pack Size: Blister (2x10'S)		Period: 36 Month		
		Label Claim: Each Film coated tablet contains: Ciprofloxacin hydrochloride BP equivalent to Ciprofloxacin-500 mg				Date of Loading: 21.09.2022		
Microbiological limits:								
Total Aerobic Microbial count	NMT 1000 cfu/g	<10 cfu/gss						
Total Yeasts and mould counts	NMT 100 cfu/g	<10 cfu/g	NA	NA	NA	NA	NA	NA
E.Coli	Should be Absent	Absent						
Salmonella	Should be Absent	Absent						
S.aureus	Should be Absent	Absent						

Stability study:

Complete [✓]

Incomplete [X]

Opinion: Based on the above stability studies, the product is ~~unstable~~ / stable for 24M months.

Reference: ICH Guidelines

PREPARED BY:
DATE:

H. K. J.
01/10/2024

CHECKED BY:
DATE:

J. K. J.
01/10/2024

APPROVED BY:
DATE:

H.
01/10/2024