AMV-HPLC-001

ANALYTICAL METHOD VALIDATION PROTOCOL

HPLC Method for Assay and Impurities

Version: 1.0
Date: 04. Dezember 2025
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HPLC Method for Assay and Impurities

Fampridin (4-Aminopyridine)

Protocol Status: Draft for Approval

CAS Number: 504-24-5

Method: HPLC (High-Performance Liquid Chromatography)

Purpose: Assay (Purity) and Related Substances (Impurities)

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1. OBJECTIVE

The objective of this Analytical Method Validation Protocol is to demonstrate that the **HPLC method for determination of Assay (purity) and Related Substances (impurities)** in Fampridin API is **suitable for its intended purpose** and provides reliable, accurate, and reproducible results.

Regulatory Basis:

- ICH Q2(R1): Validation of Analytical Procedures: Text and Methodology

- ICH Q7: Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients

- EU GMP Annex 15: Qualification and Validation

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2. SCOPE

2.1 INCLUDED IN SCOPE

This protocol covers validation of the HPLC method for:

1. **Assay (Content):** Quantitative determination of Fampridin content (%)

2. **Related Substances (Impurities):** Identification and quantification of impurities (%)

Validation Parameters (per ICH Q2(R1)):

- Specificity

- Linearity

- Accuracy

- Precision (Repeatability and Intermediate Precision)

- Range

- Detection Limit (LOD)

- Quantitation Limit (LOQ)

- Robustness

2.2 EXCLUDED FROM SCOPE

- HPLC instrument qualification (covered separately: IQ/OQ/PQ-HPLC-01)

- System suitability tests (defined but not validated here)

- Method transfer to other laboratories

Prerequisite: HPLC instrument must be qualified (IQ/OQ/PQ completed) before method validation begins.

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3. RESPONSIBILITIES

3.1 QC MANAGER

- Prepare and finalize this protocol

- Ensure HPLC instrument is qualified and calibrated

- Coordinate validation activities

- Compile and analyze validation data

- Prepare Analytical Method Validation Report (AMVR-HPLC-001)

3.2 QC ANALYSTS

- Prepare samples and standards

- Execute validation experiments per protocol

- Record all data accurately (ALCOA+ principles)

- Report any deviations immediately

3.3 QA MANAGER

- Review and approve this protocol

- Review validation data and report

- Approve method for routine use

3.4 VALIDATION MANAGER

- Review protocol and report

- Ensure compliance with validation master plan (MVP-001)

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4. PRODUCT DESCRIPTION

Product Name: Fampridin (INN)

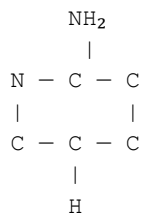
Chemical Name: 4-Aminopyridine

Molecular Formula: $C_5H_6N_2$

Molecular Weight: 94.11 g/mol

CAS Number: 504-24-5

Chemical Structure:



(Pyridine ring with amino group at position 4)

Appearance: White to off-white crystalline powder

Solubility: Freely soluble in water, soluble in ethanol

Specification (Relevant to this Method):

- **Assay:** 99.0 - 101.0% (on anhydrous basis)

- **Impurities:** Any single impurity ≤0.10%, Total impurities ≤0.50%

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5. ANALYTICAL METHOD DESCRIPTION

5.1 PRINCIPLE

Method: Reversed-Phase High-Performance Liquid Chromatography (RP-HPLC)

Detection: UV detection at 254 nm

Assay (Content):

- Quantitative determination of Fampridin by comparing peak area of sample to reference standard

Related Substances (Impurities):

- Detection and quantification of impurities by peak area relative to Fampridin main peak

5.2 CHROMATOGRAPHIC CONDITIONS

Parameter	Specification
Column	C18, 250 mm × 4.6 mm, 5 µm particle size (e.g., Waters Symmetry C18)
Mobile Phase	**A:** 0.1% Phosphoric acid in water **B:** Acetonitrile **Gradient:** (see Table 5.2.1)
Flow Rate	1.0 mL/min
Column Temperature	25°C
Injection Volume	10 µL
Detection	UV at 254 nm
Run Time	30 minutes

Table 5.2.1: Gradient Profile

Time (min)	% Mobile Phase A	% Mobile Phase B
0	95	5
5	95	5
20	60	40
25	60	40
26	95	5
30	95	5

5.3 SAMPLE PREPARATION

Assay:

- Accurately weigh approximately 25 mg of Fampridin API

- Transfer to 50 mL volumetric flask

- Dissolve in mobile phase A, dilute to volume

- **Sample Concentration:** 0.5 mg/mL

Related Substances:

- Accurately weigh approximately 50 mg of Fampridin API

- Transfer to 50 mL volumetric flask

- Dissolve in mobile phase A, dilute to volume

- **Sample Concentration:** 1.0 mg/mL

Standard Preparation:

- Fampridin Reference Standard (≥99.5% purity)

- Prepare at same concentration as sample

5.4 SYSTEM SUITABILITY REQUIREMENTS

Before each analytical run, the system must meet the following criteria:

Parameter	Acceptance Criteria
Tailing Factor	≤2.0 for Fampridin peak
Theoretical Plates (N)	≥2000 for Fampridin peak
Repeatability (RSD)	≤2.0% for 5 replicate injections of standard
Resolution	≥2.0 between Fampridin and closest impurity (if present)

If system suitability fails: Investigate and correct before proceeding with sample analysis.

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6. VALIDATION PARAMETERS (ICH Q2(R1))

6.1 SPECIFICITY

Definition: Ability to assess unequivocally the analyte in the presence of components that may be expected to be present (e.g., impurities, degradation products, matrix components).

Objective: Demonstrate that the method can separate Fampridin from impurities, degradation products, and excipients (if applicable).

Procedure:

1. **Blank:** Inject mobile phase (no peak at Fampridin retention time)

2. **Placebo:** (If applicable for formulation; for API: not applicable)

3. **Reference Standard:** Inject Fampridin reference standard (main peak identified)

4. **Sample:** Inject Fampridin API sample

5. **Stressed Samples (Forced Degradation):**

   - **Acid stress:** 1N HCl, 80°C, 2 hours

   - **Base stress:** 1N NaOH, 80°C, 2 hours

   - **Oxidative stress:** 3% H_2O_2, room temperature, 24 hours

   - **Thermal stress:** 80°C, 24 hours (solid state)

   - **Photolytic stress:** UV light, 24 hours

Acceptance Criteria:

- Fampridin peak is well-separated from impurities and degradation products (Resolution ≥2.0)

- No interference at Fampridin retention time in blank

- Stressed samples show degradation products separated from main peak

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6.2 LINEARITY

Definition: Ability of the method to obtain test results directly proportional to concentration of analyte.

Objective: Demonstrate linear relationship between peak area and concentration over the specified range.

Procedure:

1. Prepare **6 concentration levels** of Fampridin reference standard:

- **Level 1:** 50% of target concentration (0.25 mg/mL for Assay)
- **Level 2:** 70%
- **Level 3:** 80%
- **Level 4:** 100% (target: 0.5 mg/mL)
- **Level 5:** 120%
- **Level 6:** 150%

2. Inject each level in duplicate

3. Plot peak area (Y-axis) vs. concentration (X-axis)

4. Calculate linear regression:

- Slope
- Y-intercept
- Correlation coefficient (R^2)

Acceptance Criteria:

- **Correlation coefficient (R^2):** ≥0.999
- **Y-intercept:** Should be close to zero (within ±2% of response at 100%)
- Visual inspection: Data points fit the regression line

6.3 ACCURACY (RECOVERY)

Definition: Closeness of test result to the true value.

Objective: Demonstrate that the method can accurately determine the known amount of Fampridin.

Procedure:

1. **Spiking:** Add known amounts of Fampridin reference standard to placebo or pre-analyzed sample

2. Prepare **3 concentration levels** (in triplicate each = 9 determinations):

- **Level 1:** 80% of specification (e.g., 0.4 mg/mL)
- **Level 2:** 100% (0.5 mg/mL)
- **Level 3:** 120% (0.6 mg/mL)

3. Analyze each sample

4. Calculate % Recovery:

```
% Recovery = (Amount Found / Amount Added) × 100
```

Acceptance Criteria:

- **Mean Recovery:** 98.0 - 102.0% at each level
- **RSD:** ≤2.0% at each level

6.4 PRECISION

Definition: Degree of agreement among individual test results when the method is applied repeatedly.

6.4.1 REPEATABILITY (INTRA-DAY PRECISION)

Objective: Demonstrate precision under the same operating conditions over a short time interval.

Procedure:

1. Prepare **6 independent sample preparations** at 100% target concentration (0.5 mg/mL)

2. Analyze all samples on the **same day, same instrument, same analyst**

3. Calculate:

- Mean

- Standard Deviation (SD)

- Relative Standard Deviation (RSD%)

Acceptance Criteria:

- **RSD:** ≤2.0%

6.4.2 INTERMEDIATE PRECISION (INTER-DAY PRECISION)

Objective: Demonstrate precision under varied conditions (different days, analysts, equipment).

Procedure:

1. Prepare **6 independent sample preparations** at 100% target concentration

2. Analyze samples on:

- **Day 2** (different day)

- **Different analyst** (if possible)

- **Same or different HPLC instrument** (if available)

3. Calculate RSD for combined data (Day 1 + Day 2 = 12 determinations)

Acceptance Criteria:

- **RSD (combined):** ≤2.5%

6.5 RANGE

Definition: Interval between upper and lower concentration levels for which the method has been demonstrated to have suitable precision, accuracy, and linearity.

Objective: Establish the concentration range over which the method is validated.

Range:

- **For Assay:** 80-120% of target concentration (0.4 - 0.6 mg/mL)

- **For Impurities:** LOQ to 150% of specification limit (e.g., LOQ to 0.15% if specification is 0.10%)

Verification:

Range is verified through:

- Linearity (Section 6.2): 50-150%

- Accuracy (Section 6.3): 80-120%

- Precision (Section 6.4): 100%

Acceptance Criteria:

- Linearity, Accuracy, Precision meet acceptance criteria across the defined range

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6.6 DETECTION LIMIT (LOD)

Definition: Lowest concentration of analyte that can be detected, but not necessarily quantified.

Objective: Determine LOD for impurities.

Procedure:

Method 1: Signal-to-Noise Ratio (Preferred)

1. Prepare dilute solutions of Fampridin (e.g., 0.01, 0.005, 0.001 mg/mL)

2. Inject and measure signal-to-noise (S/N) ratio

3. LOD = concentration where S/N ≥ 3:1

Method 2: Based on Standard Deviation of Response and Slope

```
LOD = 3.3 × (SD / Slope)
```

Where:

- SD = Standard deviation of Y-intercept from linearity study

- Slope = Slope of linearity curve

Acceptance Criteria:

- **LOD:** Typically 0.02-0.05% (relative to sample concentration of 1.0 mg/mL)

6.7 QUANTITATION LIMIT (LOQ)

Definition: Lowest concentration of analyte that can be quantitatively determined with suitable precision and accuracy.

Objective: Determine LOQ for impurities.

Procedure:

Method 1: Signal-to-Noise Ratio (Preferred)

1. Prepare dilute solutions of Fampridin

2. Inject and measure S/N ratio

3. LOQ = concentration where S/N ≥ 10:1

Method 2: Based on Standard Deviation of Response and Slope

```
LOQ = 10 × (SD / Slope)
```

Verification:

- Prepare 6 replicates at LOQ concentration

- Calculate RSD

- **RSD should be ≤10%**

Acceptance Criteria:

- **LOQ:** Typically 0.05-0.10% (relative to sample concentration of 1.0 mg/mL)

- **RSD at LOQ:** ≤10%

6.8 ROBUSTNESS

Definition: Capacity of the method to remain unaffected by small but deliberate variations in method parameters.

Objective: Demonstrate method is robust to minor variations in operating conditions.

Procedure:

Test the following parameter variations:

Parameter	Normal Condition	Variation 1	Variation 2
Flow Rate	1.0 mL/min	0.9 mL/min	1.1 mL/min
Column Temperature	25°C	23°C	27°C
pH of Mobile Phase A	pH 2.5 (0.1% H_3PO_4)	pH 2.3	pH 2.7
Detector Wavelength	254 nm	252 nm	256 nm

Procedure:

1. Prepare Fampridin sample at 100% concentration (0.5 mg/mL)

2. Analyze under normal conditions (reference)

3. Analyze with one parameter varied (keep others constant)

4. Compare results (Assay %, Resolution, Tailing Factor)

Acceptance Criteria:

- **Assay difference:** ≤2.0% from reference

- **Resolution:** ≥2.0 maintained

- **Tailing Factor:** ≤2.0 maintained

- System suitability criteria still met

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7. EQUIPMENT AND MATERIALS

7.1 EQUIPMENT

Equipment	Model/Specification	Qualification Status
HPLC System	[e.g., Agilent 1260 Infinity II]	Qualified (IQ/OQ/PQ-HPLC-01)
Detector	UV-Vis, variable wavelength	Part of HPLC qualification
Column	C18, 250 × 4.6 mm, 5 µm	Performance verified (System Suitability)
Analytical Balance	Readability 0.01 mg	Calibrated (CAL-BAL-001)
Volumetric Flasks	Class A, 50 mL, 100 mL	Calibrated/verified
Micropipettes	10-100 µL, 100-1000 µL	Calibrated

7.2 MATERIALS

Reference Standards:

- **Fampridin Reference Standard:** CAS 504-24-5, Purity ≥99.5% (Certificate of Analysis on file)

- Supplier: [e.g., European Pharmacopoeia Reference Standard]

Reagents:

- Acetonitrile (HPLC grade, ≥99.9%)

- Phosphoric Acid (≥85%, analytical grade)

- Purified Water (Ph. Eur., Conductivity ≤1.3 µS/cm)

Stressed Sample Preparation:

- Hydrochloric Acid (1N)

- Sodium Hydroxide (1N)

- Hydrogen Peroxide (3%)

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8. VALIDATION PROCEDURES

8.1 SPECIFICITY (Section 6.1)

Step 1: Blank Injection

- Prepare mobile phase (no sample)

- Inject

- **Record:** No peak at Fampridin retention time (~12 min)

Step 2: Reference Standard

- Prepare Fampridin reference standard (0.5 mg/mL)

- Inject

- **Record:** Retention time, peak area

Step 3: Sample

- Prepare Fampridin API sample (0.5 mg/mL)

- Inject

- **Record:** Retention time, peak area, impurity peaks (if any)

Step 4: Forced Degradation Studies

- Prepare stressed samples:

  - **Acid:** Fampridin + 1N HCl, 80°C, 2h → neutralize, dilute

  - **Base:** Fampridin + 1N NaOH, 80°C, 2h → neutralize, dilute

  - **Oxidative:** Fampridin + 3% H_2O_2, RT, 24h → dilute

  - **Thermal:** Fampridin solid, 80°C, 24h → dissolve, dilute

  - **Photolytic:** Fampridin solid, UV light, 24h → dissolve, dilute

- Inject each stressed sample

- **Record:** Chromatograms, degradation peaks, resolution

Data Recording: Appendix A, Table A1

8.2 LINEARITY (Section 6.2)

Step 1: Prepare Linearity Standards

- Prepare 6 concentrations (50%, 70%, 80%, 100%, 120%, 150% of 0.5 mg/mL)

- Inject each in duplicate

Step 2: Plot and Calculate

- Plot Peak Area (Y) vs. Concentration (X)

- Calculate linear regression (R^2, slope, Y-intercept)

Data Recording: Appendix A, Table A2

8.3 ACCURACY (Section 6.3)

Step 1: Spiking

- Prepare spiked samples at 80%, 100%, 120% (triplicate each)

- Known amount added, measure amount found

Step 2: Calculate Recovery

```
% Recovery = (Amount Found / Amount Added) × 100
```

Data Recording: Appendix A, Table A3

8.4 REPEATABILITY (Section 6.4.1)

Step 1: Prepare 6 Independent Samples

- Weigh 6 separate samples (~25 mg each)

- Dilute to 50 mL (0.5 mg/mL)

Step 2: Analyze on Same Day

- Inject all 6 samples

- Calculate Assay (%) for each

Step 3: Calculate Statistics

- Mean, SD, RSD%

Data Recording: Appendix A, Table A4

8.5 INTERMEDIATE PRECISION (Section 6.4.2)

Step 1: Repeat Repeatability on Different Day

- Different day, different analyst (if possible)

- Prepare 6 new samples

Step 2: Combine Data

- Combine Day 1 + Day 2 (12 determinations total)

- Calculate combined RSD%

Data Recording: Appendix A, Table A5

8.6 LOD / LOQ (Sections 6.6 & 6.7)

Step 1: Prepare Dilute Solutions

- Dilute Fampridin to 0.01, 0.005, 0.002, 0.001 mg/mL

Step 2: Inject and Measure S/N

- Identify LOD (S/N ≥ 3) and LOQ (S/N ≥ 10)

Step 3: Verify LOQ Precision

- Prepare 6 replicates at LOQ

- Calculate RSD (should be ≤10%)

Data Recording: Appendix A, Table A6

8.7 ROBUSTNESS (Section 6.8)

Step 1: Establish Reference Conditions

- Analyze sample under normal conditions

- Record Assay, Resolution, Tailing Factor

Step 2: Vary Parameters One at a Time

- Flow Rate: 0.9 and 1.1 mL/min

- Temperature: 23°C and 27°C

- pH: 2.3 and 2.7

- Wavelength: 252 and 256 nm

Step 3: Compare Results

- Calculate % difference from reference

Data Recording: Appendix A, Table A7

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9. ACCEPTANCE CRITERIA

Summary of Acceptance Criteria (per ICH Q2(R1)):

Validation Parameter	Acceptance Criteria
Specificity	Fampridin peak separated from impurities (Resolution ≥2.0) No interference at Fampridin RT in blank
Linearity	R^2 ≥0.999 over range 50-150%
Accuracy	Mean Recovery: 98.0-102.0% at each level (80%, 100%, 120%) RSD ≤2.0%

Repeatability	RSD ≤2.0% (n=6)
Intermediate Precision	RSD ≤2.5% (n=12)
Range	80-120% of target concentration validated
LOD	S/N ≥ 3 (typically 0.02-0.05%)
LOQ	S/N ≥ 10 (typically 0.05-0.10%) RSD at LOQ ≤10%
Robustness	Assay difference ≤2.0% from reference Resolution ≥2.0, Tailing ≤2.0 maintained

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10. DATA RECORDING AND EVALUATION

10.1 DATA RECORDING

All validation data must be recorded in:

- Appendix A: Data Tables (completed during validation execution)

- Raw chromatograms (printed or saved electronically)

- HPLC system audit trail (21 CFR Part 11 compliant, if applicable)

Data Integrity (ALCOA+):

- **Attributable:** Analyst signature and date

- **Legible:** Clear, readable entries

- **Contemporaneous:** Recorded at time of activity

- **Original:** First recording (or certified true copy)

- **Accurate:** Error-free, verified

10.2 DATA EVALUATION

After all validation experiments are completed:

1. Validation Manager and QC Manager review all data

2. Verify all acceptance criteria are met

3. Investigate any Out-of-Specification (OOS) results

4. Prepare Analytical Method Validation Report (AMVR-HPLC-001)

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11. CONCLUSION AND APPROVAL

11.1 VALIDATION REPORT

After validation is complete, the Analytical Method Validation Report (AMVR-HPLC-001) will include:

- Summary of results for each validation parameter

- Statistical evaluation

- Deviations (if any) and impact assessment

- Conclusion: **Method is validated** or **Additional testing required**

- Recommendations (e.g., method improvements, revalidation triggers)

11.2 APPROVAL

The method is validated when:

- All acceptance criteria met (Section 9)

- Validation report approved by:

  - QC Manager

  - QA Manager

  - Validation Manager

After approval:

- Method can be used for routine testing of Fampridin API

- Method documented in SOP (e.g., SOP-HPLC-FAM-001)

- Included in API specification (SPEC-FAM-001)

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12. APPENDICES

APPENDIX A: DATA RECORDING TABLES

(To be completed during validation execution)

TABLE A1: SPECIFICITY

Sample	Retention Time (min)	Peak Area	Resolution (from nearest peak)	Comments
Blank	N/A	0	N/A	No peak at Fampridin RT
Reference Standard			N/A	
Sample (Unstressed)				
Acid Stressed				Degradation peaks:
Base Stressed				Degradation peaks:
Oxidative Stressed				Degradation peaks:
Thermal Stressed				Degradation peaks:
Photolytic Stressed				Degradation peaks:

Conclusion: Specificity Pass/Fail: _____

TABLE A2: LINEARITY

Level	Concentration (mg/mL)	Injection 1 (Peak Area)	Injection 2 (Peak Area)	Mean Peak Area
1 (50%)	0.25			
2 (70%)	0.35			
3 (80%)	0.40			
4 (100%)	0.50			
5 (120%)	0.60			
6 (150%)	0.75			

Linear Regression:

- Slope: _____

- Y-intercept: _____

- Correlation Coefficient (R^2): _____

Conclusion: Linearity Pass/Fail: _____

TABLE A3: ACCURACY (RECOVERY)

Level	Amount Added (mg)	Amount Found (mg)	% Recovery	Mean Recovery (%)	RSD (%)
80% - Rep 1					
80% - Rep 2					
80% - Rep 3				[Mean]	[RSD]
100% - Rep 1					
100% - Rep 2					
100% - Rep 3				[Mean]	[RSD]
120% - Rep 1					
120% - Rep 2					

120% - Rep 3				[Mean]	[RSD]

Conclusion: Accuracy Pass/Fail: _____

TABLE A4: REPEATABILITY (PRECISION)

Sample	**Assay (%)**
Rep 1	
Rep 2	
Rep 3	
Rep 4	
Rep 5	
Rep 6	
Mean	
SD	
RSD (%)	

Conclusion: Repeatability Pass/Fail: _____

TABLE A5: INTERMEDIATE PRECISION

Sample	**Day 1 Assay (%)**	**Day 2 Assay (%)**
Rep 1		
Rep 2		
Rep 3		
Rep 4		
Rep 5		
Rep 6		

Combined Statistics (n=12):

- Mean: _____

- SD: _____

- RSD (%): _____

Conclusion: Intermediate Precision Pass/Fail: _____

TABLE A6: LOD / LOQ

Concentration (mg/mL)	Signal-to-Noise (S/N)	LOD or LOQ?
0.001		
0.002		
0.005		
0.01		

LOD (S/N ≥ 3): _____ mg/mL (_____ %)

LOQ (S/N ≥ 10): _____ mg/mL (_____ %)

LOQ Precision Verification (6 replicates at LOQ):

- Mean: _____

- RSD: _____ % (Acceptance: ≤10%)

Conclusion: LOD/LOQ Pass/Fail: _____

TABLE A7: ROBUSTNESS

Parameter Varied	Condition	Assay (%)	Resolution	Tailing Factor	Pass/Fail
Reference	Normal				Reference
Flow Rate	0.9 mL/min				
Flow Rate	1.1 mL/min				
Temperature	23°C				
Temperature	27°C				
pH	2.3				
pH	2.7				
Wavelength	252 nm				
Wavelength	256 nm				

Conclusion: Robustness Pass/Fail: _____

APPENDIX B: EXAMPLE CHROMATOGRAM

(To be attached after validation execution)

- Representative chromatogram of Fampridin reference standard

- Representative chromatogram of Fampridin sample

- Chromatograms of stressed samples (forced degradation)

APPENDIX C: ABBREVIATIONS

- ALCOA: Attributable, Legible, Contemporaneous, Original, Accurate

- HPLC: High-Performance Liquid Chromatography

- ICH: International Council for Harmonisation

- IQ: Installation Qualification

- LOD: Limit of Detection

- LOQ: Limit of Quantitation

- OOS: Out-of-Specification

- OQ: Operational Qualification

- PQ: Performance Qualification

- QA: Quality Assurance

- QC: Quality Control

- RSD: Relative Standard Deviation

- RT: Retention Time

- SD: Standard Deviation

- S/N: Signal-to-Noise Ratio

- SOP: Standard Operating Procedure

- UV: Ultraviolet

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13. REFERENCES

Regulatory Guidelines:

- ICH Q2(R1): Validation of Analytical Procedures: Text and Methodology

- ICH Q7: Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients

- EU GMP Annex 15: Qualification and Validation

- USP General Chapter <1225>: Validation of Compendial Procedures

- Ph. Eur. General Chapter 2.2.46: Chromatographic Separation Techniques

Internal Documents:

- QM-001: Quality Manual

- MVP-001: Master Validation Plan

- SPEC-FAM-001: Specification – Fampridin API

- IQ/OQ/PQ-HPLC-01: HPLC Instrument Qualification

REVISION HISTORY

Version	Date	Author	Description of Changes	Approved By
1.0	04.12.2025	QC Department	Initial Protocol	[Pending Approval]

APPROVAL SIGNATURES

Prepared by:

[Name, Title: QC Manager]

Signature: _____

Date: _____

Reviewed by:

[Name, Title: QA Manager]

Signature: _____

Date: _____

Reviewed by:

[Name, Title: Validation Manager]

Signature: _____

Date: _____

Approved by:

[Name, Title: Management Representative]

Signature: _____

Date: _____

END OF ANALYTICAL METHOD VALIDATION PROTOCOL

Protocol Status: Draft – Pending Approval

Effective Date: Upon approval and signature

Supersedes: N/A (New document)