

Supporting information

Appendix 1: Method validation Summary for the used HPLC analytical method

PARAMETER	STATISTICAL MEASURE	RESULT		LIMITS
Specificity	None	Complies		No interference between the active material peak and any other peaks
Accuracy	For 100%	100.02		96.00 - 104.00 %
Precision	Coefficient of variation	0.38		Max 2.0 (CV)
Linearity	Correlation Coefficient	0.99976		Min 0.995 (R ²)
Ruggedness	RSD	Different analyst	Different elapsed	Max 3.0 (RSD)
		0.005	0.09	

Appendix 2: Method validation summary for the used dissolution method

PARAMETER	STATISTICAL MEASURE	RESULT	LIMITS
Accuracy	% of Recovery	104.7	Not Less than 75.0% of stated amount dissolved in 30 min
Precision	Coefficient of Variation	0.74	Maximum 2.00
Linearity	Correlation Coefficient Y-Intercept	0.99994 0.03	Minimum 0. 995 ± 5.0 % of the average area

Appendix 3: Assessment of results against acceptance criteria for impurity A1

Parameter	Statistical Measure	Result		Limits
Specificity	None	Complies		No interference between the active material peak and any other peaks.
Accuracy	For 100%	99.81		96.0 - 104.0
Precision	Coefficient of variation	0.31		Max 3.0
Linearity	Correlation Coefficient	0.99899		Min 0.995
Ruggedness	RSD	Different analyst	Different elapsed	Max 5.0
		0.55	0.59	

Appendix 4: Assessment of results against acceptance criteria system suitability

Parameter	Statistical Measure	Result	Limits
Resolution	For Impurity A3	3.5	NLT 1.5 Between CR and A3
Tailing Factor	For Impurity B	1.02	NMT 1.5 for Impurity B
RSD	For Standard Solution (1)	1.10	NMT 2.0%

Appendix 5: Assessment of results against acceptance criteria for impurity A2

Parameter	Statistical Measure	Result		Limits
Specificity	None	Complies		No interference between the active material peak and any other peaks.
Accuracy	For 100%	100.05		96.0 - 104.0
Precision	Coefficient of variation	0.62		Max 3.0
Linearity	Correlation Coefficient	0.99808		Min 0.995
Ruggedness	RSD	Different analyst	Different elapsed time	Max 5.0
		1.42	0.95	

Appendix 6: Assessment of results against acceptance criteria for impurity A3

Parameter	Statistical Measure	Result		Limits
Specificity	None	Complies		No interference between the active material peak and any other peaks.
Accuracy	For 100%	99.36		96.0 - 104.0
Precision	Coefficient of variation	2.13		Max 3.0
Linearity	Correlation Coefficient	0.99809		Min 0.995
Ruggedness	RSD	Different analyst	Different elapsed time	Max 5.0
		2.16	1.18	

Appendix 7: Assessment of results against acceptance criteria for impurity A4

PARAMETER	STATISTICAL MEASURE	RESULT		LIMITS
Specificity	None	Complies		No interference between the active material peak and any other peaks.
Accuracy	For 100%	100.06		96.0 - 104.0
Precision	Coefficient of variation	1.77		Max 3.0
Linearity	Correlation Coefficient	0.99865		Min 0.995
Ruggedness	RSD	Different analyst	Different elapsed time	Max 5.0
		1.43	1.36	

Appendix 8: Assessment of results against acceptance criteria for impurity B

Parameter	Statistical Measure	Result		Limits
Specificity	None	Complies		No interference between the active material peak and any other peaks.
Accuracy	For 100%	99.50		96.0 - 104.0
Precision	Coefficient of variation	0.61		Max 3.0
Linearity	Correlation Coefficient	0.99986		Min 0.995
Ruggedness	RSD	Different analyst	Different elapsed time	Max 5.0
		0.53	0.26	
Detection and Quantitation Limit	RSD	1.53		Max 5.0%