P1TR
11978

Bio Analytical Method Validation Parameter for Alfuzosin Hydrochloride		
Sr. No.	**Parameter**	**Acceptance Criteria**
1	Calibration curve range	0.150 ng/ml to 25.000 ng/ml
2	Specificity	Area response at the RT of Alfuzosin in blank plasma should be ≤ 20% of LLOQ area response and area response at RT of IS in blank plasma should be ≤ 5% of IS area response.
3	Sensitivity (at LLOQ)	Area response of Alfuzosin at LLOQ should be five times compared to blank plasma area response. % CV should be ≤ 20 % Nominal concentration should be 80 - 120
4	Linearity	r ≥ 0.9900
5	Within-batch or intra-batch accuracy	% Nominal concentration: For LLOQ : 80 -120 For LQC : 85 -115 For MQC : 85 -115 For HQC : 85 -115
6	Between-batch or inter-batch accuracy	% Nominal concentration: For LLOQ : 80 -120 For LQC : 85 -115 For MQC : 85 -115 For HQC : 85 -115
7	Within-batch or intra-batch precision	% CV : For LLOQ ≤ 20 For LQC ≤ 15 For MQC ≤ 15 For HQC ≤ 15
8	Between-batch or inter-batch precision	% CV : For LLOQ ≤ 20 For LQC ≤ 15 For MQC ≤ 15 For HQC ≤ 15
9	Recovery of Alfuzosin	Recovery should be consistent % CV within the QC level should be ≤ 15 % CV across the QC level should be ≤ 20
10	Recovery of Internal Standard.	% CV of Unextracted and Extracted sample area across QC level should be ≤ 15

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11	Dilution integrity.	% Nominal concentration: For ¼ of 2ULOQ: 85-115 For ½ of 2ULOQ: 85-115 % CV: For ¼ of 2ULOQ ≤ 15 For ½ of 2ULOQ ≤ 15
12	Matrix effect.	% Nominal concentration: For LQC : 85-115 For HQC : 85-115
13	Stock solution stability of Alfuzosin For 26 hrs. at room temp For 3 Days and 33 days at 2-8°C	% Mean change at ULOQ should be within ± 10
14	Internal standard Stock Solution stability. For 26 hrs. at room temp For 3 Days and 33 days at 2-8°C	% Mean change at IS concentration should be within ± 10
15	Bench top stability for 8.0 hrs. at room temperature	% Mean change : For LQC : ± 15 For HQC : ± 15
16	Process stability of sample at 5°C for 50 hrs	% Mean change : For LQC : ± 15 For HQC : ± 15
17	Freeze and thaw stability After 3rd cycle After 4th cycle	% Mean change : For LQC : ± 15 For HQC : ± 15
18	Long Term Stability (43 days and 126 days at -70°C)	% Mean change : For LQC : ± 15 For HQC : ± 15

Abbreviations:

RT	Retention Time
QC	Quality Control
LQC	Lower Quality Control
MQC	Medium Quality Control
HQC	Higher Quality Control
LLO	Lower Limit of Quantification
ULOQ	Upper Limit of Quantification
CV	Coefficient of Variation
IS	Internal Standard