

	ORA LABORATORY PROCEDURE Food and Drug Administration	Document No.:	Version No.: 1.7
		ORA- LAB.5.4.5	Page 15 of 19
Title: ATTACHMENT B – VALIDATION FORM EXAMPLE		Effective Date: 10-01-03 Revised: 08-29-14	

REPORT FOR: _____ REQUEST #: _____

ANALYST(S) NAME AND DATE: _____

METHOD NAME: _____

RESULTS:

ACCURACY: ___ PASS ___ FAIL ___ N/A (Criteria – Define)

PRECISION: ___ PASS ___ FAIL ___ N/A (Criteria – Define)

DETECTION LEVEL: ___ PASS ___ FAIL ___ N/A (Criteria-Define)

INTERFERENCE(S): ___ PASS ___ FAIL ___ N/A (Criteria – Pass=interferences resolved; Fail=interferences not resolved)

t TEST: ___ PASS ___ FAIL ___ N/A F TEST: ___ PASS ___ FAIL ___ N/A
(Criteria = < t Critical; < F Critical)

ADDITIONAL PERFORMANCE MEASUREMENTS (i.e. linearity, corr.coef..)

___ PASS ___ FAIL ___ N/A

COMMENTS: _____

ANALYST(S) SIGNATURE AND DATE: _____

FIT FOR INTENDED USE: ___ YES ___ NO

CONCURRENCES:

SUPERVISOR: ___ YES ___ NO

SIGNATURE AND DATE: _____

QMS MANAGER: ___ YES ___ NO

SIGNATURE AND DATE: _____

LABORATORY DIRECTOR: ___ YES ___ NO

SIGNATURE AND DATE: _____