

**Standard Method Performance Requirements for Quantitative Methods for Drug Residues in Shrimp, Tilapia, Catfish, and Salmon**

Intended Use: Laboratory use by qualified analysts for analysis of tissues with maximum levels (ML) <1 mg/kg (ppm)

**1 Applicability**

*Shrimp*.—Any species of the *Palaemon* genus.

*Tilapia*.—Various species of *Oreochromis*, *Sarotherodon*, and *Tilapia*, collectively known colloquially as “tilapias.”

*Catfish*.—Species of the *Ictalurus* genus such as the channel catfish (*Ictalurus punctatus*) and blue catfish (*Ictalurus furcatus*).

*Salmon*.—Common name for several species of fish of the family *Salmonidae*.

**2 Analytical Technique**

Any analytical method that meets the method performance requirements in Table 1.

**3 Definitions**

*Limit of detection (LOD)*.—The lowest quantity of a substance that can be distinguished from the absence of that substance (a blank value) within a stated confidence limit (generally 1%). Typically calculated as 3 \* standard deviation of a series of blank readings.

*Limit of quantification (LOQ)*.—The level above which quantitative results may be obtained with a specified degree of confidence. The LOQ is mathematically defined as equal to 10 times the standard deviation of the results for a series of blank replicates. LOQ are matrix, method, and analyte specific.

**4 Method Performance Requirements**

See Table 1.

**5 Validation Guidance**

These performance requirements are intended for a single-laboratory validation (SLV).

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**Table 1. Method performance requirements<sup>a</sup>**

Performance parameter	Types of drug residues						
	Chloramphenicol	Nitrofurans [nitrofurazone, nitrofurantoin, furaltadone, fruazolidone (and marker residues, AOZ, AHD, AMOZ and SEM)]	Fluoroquinolones (ciprofloxacin, enrofloxacin, sarafloxacin, difloxacin, danaofloxacin)	Malachite green, crystal violet, leuco crystal violet, leuco malachite green	Methyltestosterone (17- $\alpha$ -methyltestosterone)	Quinolones (oxolinic acid, flumequine, nalidixic acid)	
Minimum applicable range	0.3–1.2	1.0–3.6	1.0–3.6	1.0–3.6	0.8–3.0	0.5–2.0	
LOD	0.15	0.5	0.5	0.5	0.4	0.25	
LOQ	0.3	1.0	1.0	1.0	0.8	0.5	
Precision (SD), %	54	46	46	46	54	54	
Recovery, %	40–120	60–115	60–115	60–115	40–120	40–120	

<sup>a</sup> Method performance requirements based on fitness-for-purpose criteria in CODEX CRD 19 (Revised Doc. CX/MAS 09/30/07). Reproducibility target according to CODEX CAC/GL 71-2009 (p. 22). Criteria assume confirmation criteria met 50% of time. Criteria based on what is reasonably achievable given current instrumentation capabilities.