



Review protocol below and find evidence of poor compliance with GDP:

1. SPRAY BALL COVERAGE TEST

1.1 PROCEDURE

- a. Identify all critical spots and mark them up on a drawing.
- b. Dismantle the equipment / system and spray the aqueous dye solution (Riboflavin) on all critical spots.
- c. Set up the equipment and connect it to the water supply through a pump.
- d. Supply Demineralized Water to the spray ball.
- e. Dismantle the equipment and visually check all the critical spots inside the vessel using UV lamp.
- f. Check absence of Riboflavin.

1.2 MATERIALS

| Material | Manufacturer | Batch No | Dye powder weight | Concentration |
|-------------------|--------------|----------|-------------------|---------------|
| RIBOFLAVIN POWDER | | | 200mg | 200 mg/l |

1.3 RESULTS

| Verification | Acceptance Criteria | Observation (OK/Not OK/NA) | Deviations |
|--|--|----------------------------|------------|
| All critical spots are cleaned of rinsing when sprayed | No trace of remaining fluorescence detectable under UV light | | |

COMMENTS:

| | | |
|-------------|-------------------------------|-------------------------------|
| TEST RESULT | <input type="checkbox"/> PASS | <input type="checkbox"/> FAIL |
|-------------|-------------------------------|-------------------------------|

Performed by/Date: