

NEW PRODUCT EVALUATION SHEET

Product Name :

Manufacturing Block:

Active Ingredient:

DATA ON ACTIVE DRUG MOLECULE

A) SOLUBILITY IN WATER (1 gm of the substance in ml of water.

- | | |
|---------------|-----------------|
| 1. < 1 | 2. 1 – 10 |
| 3. 10 – 30 | 4. 30 – 100 |
| 5. 100 – 1000 | 5. 1000 – 10000 |
| 6. > 10000 | |

B) TOXICITY DATA

LD 50 (ORAL; RAT / MOUSE).....

ADE/PDE Value:

C) Strength / Potency:

Smallest Recommended Daily Dose (SRDD)

D) Largest recommended daily dose (LRDD).....

E) DIFFICULT TO CLEAN

As recommended by Production.

Recommendation regarding worst case rating.

F) MAXIMUM ALLOWABLE CARRYOVER (MACO) CALCULATION:

- i) Batch size :
- ii) Largest Recommended Daily Dose (LRDD):.....
- iii) Smallest recommended Daily Dose (SRDD).....

Details of major equipment required in the manufacturing of the product:

- | | |
|----|----|
| 1. | 2. |
| 3. | 4. |

- 5.
- 6.
- 7.
- 8.
- 9.
- 10.

Total product contact Area in cm²:

1. Dose Based criteria:

a) MACO calculation for swab sample

$$\text{MACO (mg/swab)} = \frac{\text{S.F X [SRDD (A) in mg] X [MBS (B) mg] X [Swab Area cm}^2\text{]}}{\text{[LRDD (B) in mg] X [shared equipment surface area between products cm}^2\text{]}}$$

$$= \text{-----} =$$

b) MACO calculation for rinse sample

$$\text{MACO (Total equipments in mg)} = \frac{\text{S.F x [SRDD (A) in mg] x [MBS (B) in mg]}}{\text{[LRDD (B)] in mg}}$$

$$= \text{-----} =$$

$$\text{MACO (one equipment in mg)} = \frac{\text{[MACO for total equipments in mg] x [Equipment surface area cm}^2\text{]}}{\text{Total equipment product contact shared surface area cm}^2}$$

$$= \text{-----} =$$

$$\text{MACO (mg/ml)} = \frac{\text{[MACO value for equipment in mg]}}{\text{Rinse volume used for equipment in ml}}$$

$$= \text{-----} =$$

2. Toxicity Based criteria (LD50 value):

NOEL shall be calculated by following equation:

$$\text{NOEL} = \frac{\text{LD}_{50} \text{ (mg / kg) x 50 (kg a person)}}{2000}$$

$$= \text{-----} =$$

a) MACO calculation for swab sample

$$\text{MACO (mg/swab)} = \frac{\text{S.F X [NOEL (A)] in mg X [MBS (B) mg] X [Swab Area in cm}^2\text{]}}{\text{[LRDD (B) in mg] X [shared equipment surface area between products cm}^2\text{]}}$$

$$= \frac{\text{-----}}{\text{-----}} =$$

b) MACO calculation for rinse sample

$$\text{MACO (For total equipments in mg)} = \frac{\text{S.F X [NOEL (A) in mg] X [MBS (B) in mg]}}{\text{[LRDD (B) in mg]}}$$

$$= \frac{\text{-----}}{\text{-----}} =$$

$$\text{MACO (one equipment in mg)} = \frac{\text{[MACO for total equipments in mg]} \times \text{[Equipment surface area in cm}^2\text{]}}{\text{Total equipment product contact shared surface area}}$$

$$= \frac{\text{-----}}{\text{-----}} =$$

$$\text{MACO (mg/ml)} = \frac{\text{[MACO value for equipment in mg]}}{\text{Rinse volume used for equipment in ml}}$$

$$= \frac{\text{-----}}{\text{-----}} =$$

3. Toxicity Based criteria(ADE/PDE value) :

$$\text{MACO} = \frac{\text{PDE x BS (mg)}}{\text{LRDD (mg)}}$$

a) MACO calculation for swab sample

$$\text{MACO (mg /swab)} = \frac{\text{MACO (mg) x Surface area of swab (cm}^2\text{)}}{\text{Shared equipment contact surface area (cm}^2\text{)}}$$

$$= \frac{\text{-----}}{\text{-----}} =$$

Recommendation

www.guideline-sop.com