

## DESIGN, PREPARATION, AND EVALUATION OF SELF-MICROEMULSIFYING DRUG DELIVERY SYSTEM OF BAMBUTEROL HYDROCHLORIDE

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### ABSTRACT

**Objective:** The self-micro-emulsifying drug delivery system (SMEDDS) of bambuterol hydrochloride was designed, prepared, and evaluated to overcome the problem of poor bioavailability.

**Methods:** The designing of the formulation included the selection of oil phase, surfactant, and cosolvent/cosurfactant based on the saturated solubility studies. Pseudoternary phase diagram was constructed using aqueous titration method, to identify the self-emulsifying region. Different ratios of the selected surfactant and cosolvent/cosurfactant (Smix) were also studied and used to construct the ternary phase diagram. The prepared formulations of the SMEDDS were evaluated for drug content, morphology, globule size, robustness to dilution, emulsification time, optical clarity, and stability.

**Results:** The formulation containing 10 mg bambuterol hydrochloride, triacetin (12.50% w/w), Tween 80 (43.75% w/w), and ethanol (43.75% w/w) was concluded to be optimized. The optimized SMEDDS not only showed optimum globule size, zeta potential, and drug content but was also found to be robust to dilution, formed emulsion spontaneously, and was stable. The optimized SMEDDS showed increased permeability of the drug across the intestinal membrane in *ex vivo* studies.

**Conclusion:** The results suggest that bambuterol hydrochloride can be formulated as self-microemulsifying drug delivery system, and further, SMEDDS can be used to improve the oral bioavailability of bambuterol hydrochloride.

**Keywords:** Self-microemulsifying drug delivery system, Bambuterol hydrochloride, Phase diagram, Zetasizer, Everted gut technique.

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### Old Table-

Table 1: Selected Composition at different % w/w of oil, surfactant and co-surfactant for bambuterol SMEDDS

| Composition Code | Smix   | Smix Ratio | Pre-concentrate |                  |                 | Oil:Smix | Precon.:water (for stability studies) |
|------------------|--------|------------|-----------------|------------------|-----------------|----------|---------------------------------------|
|                  |        |            | Oil (parts)     | Tween 80 (parts) | Ethanol (parts) |          |                                       |
| F 1              |        | 1:1        | 12.50           | 43.75            | 43.75           | 1:7      | 1:1.5                                 |
| F 2              | Smix 1 | 1:1        | 13.80           | 43.10            | 43.10           | 1:6.25   | 1:0.724                               |
| F 3              |        | 1:1        | 15.38           | 42.31            | 42.31           | 1:5.5    | 1:0.538                               |
| F 4              |        | 2:1        | 12.50           | 58.33            | 29.17           | 1:7      | 1:1.5                                 |
| F 5              | Smix 2 | 2:1        | 13.80           | 57.47            | 28.73           | 1:6.25   | 1:0.724                               |
| F 6              |        | 2:1        | 15.38           | 56.41            | 28.20           | 1:5.5    | 1:0.538                               |
| F 7              |        | 1:2        | 12.50           | 29.17            | 58.33           | 1:7      | 1:1.5                                 |
| F 8              | Smix 3 | 1:2        | 13.80           | 28.73            | 57.47           | 1:6.25   | 1:0.724                               |
| F 9              |        | 1:2        | 15.38           | 28.20            | 56.41           | 1:5.5    | 1:0.538                               |
| F 10             | Smix 4 | 1:2        | 9.09            | 30.30            | 60.60           | 1:10     | 1:0.818                               |
| F 11             |        | 1:2        | 14.30           | 28.57            | 57.13           | 1:6      | 1:0.428                               |
| F 12             | Smix 5 | 1:1        | 9.09            | 45.45            | 45.45           | 1:10     | 1:0.818                               |
| F 13             |        | 1:1        | 14.30           | 42.85            | 42.85           | 1:6      | 1:0.428                               |

Precon: pre-concentrate; P.G.: propylene glycol

### New Table-

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|                  |        |            | Oil (parts)     | Tween 80 (parts) | P.G. (parts)    |          |                                       |
| F 10             | Smix 4 | 1:2        | 9.09            | 30.30            | 60.60           | 1:10     | 1:0.818                               |
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