**Introduction & Rationale**

**Physicochemical Properties**
- Fenofibrate
  - BCS class II molecule
  - Solubility related poor
  - Bioavailability: 86%

**QbD based Fenofibrate Nanosuspension**
- Quality based approach for development of Fenofibrate nanosuspension
- Development of Fenofibrate nanosuspension using Planetary Ball Mill process and PVA as stabilizer (Non-infringing Approach)

**Experimental**

**QbD Approach**
- **QTPP**
- **CQA**
- **Risk Assessment**
- **Experimental Design**
- **Control Strategy**

**QTPP**
- **Target**
- **Justification**
  - Particle Size (Nanosuspension)
    - Nanonization to develop pharmaceutical equivalent product
  - Route of administration
    - Oral
    - Pharmacological equivalent product
  - Dosage Strength
    - 145 mg
    - Pharmacological equivalent product
  - Stability
    - At least 24 month at RT
    - To maintain the therapeutic potential during storage
  - Container closure system
    - Alu-Alu blister
    - Primary packaging for powder dosage form
  - Packaging integrity
    - Suitable packaging to ensure shelf life of product
    - Efficacious and Stable formulation

**CQA**
- **Target**
- **Justification**
  - Particle size (less than 500 nm)
    - To achieve bioequivalence
  - Polydispersibility index
    - 0.1-0.3
    - To maintain stability of nanosuspension
  - Assay
    - 98-102%
    - To maintain therapeutic equivalence
  - Drug Loading
    - More than 2%
    - To reduce bulk weight
  - Cumulative Drug Release
    - More than 80% in 60 min
    - To achieve Cmax in vivo

**Result & Discussion**

**Mathematical Modelling**
- Particle size: +715.91 – 176.75 X5 – 95.97 X2

**ANOVA Results**
- **Response**
  - Particle size: [% of variance = 0.987]
  - PDI: [% of variance = 0.987]

**Model Diagnostoc Plot**
- No model transformation is required as the lambda value is 1

**Conclusion & Future Prospects**

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**References**