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(RESEARCH ARTICLE)

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QBD approach in HPLC method development and validation of furazolidone

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Abstract

QbD principles for establishment of a HPLC method for Furazolidone with improved robustness and performance. On the basis of the initial prioritization and factor screening studies, the highly influential factors were identified and subsequently optimized for improving the method robustness. The response surface mapping particularly facilitated improved understanding of the factor–response relationship and interactions associated with them. Extensive validation studies further ensured high degree of method robustness with extreme variation in the key variables influencing the method performance. In addition, the method showed improved sensitivity for the Furazolidone much beyond the values reported in the literature.

Keywords: QbD; Validation; Furazolidone; Robustness; Frequency

1. Introduction

Pharmaceutical QbD is a systematic approach to development that begins with predefined objectives and emphasizes product and process understanding and control based on sound science and quality risk management Quality by Design (QbD) allows for a systematic approach to drug development that is intended to improve quality by using analytical and risk-management methodologies for the design, development and manufacturing of new medications. The approach primarily aims to design quality into workflows from the outset. Since the introduction of Quality-by-Design (QbD) concepts, it has been accepted that quality of pharmaceutical products should be designed and built during the manufacturing process. According to Juran (1), most of quality problems are related to the way in which a pharmaceutical product was designed. A poor-designed pharmaceutical product will show poor safety and efficacy, no matter how many tests or analyses have been done to verify its quality. Thus, QbD begins with the recognition that quality will not be improved by merely increasing analyses of pharmaceutical products. In other words, quality must be built into the product.

QbD is "a systematic approach to pharmaceutical development that begins with predefined objectives and emphasizes product and process understanding and process control, based on sound science and quality risk management".

Application of QbD will provide knowledge and scientific understanding to support pharmaceutical development (2).

Pharmaceutical QbD goals may include:

- ✓ To achieve meaningful product quality specifications;
- ✓ To increase process capability and reduce product variability;
- ✓ To increase pharmaceutical development and manufacturing efficiencies; and
- ✓ To enhance cause-effect analysis and regulatory flexibility.

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2. Materials and method

2.1. Material

FURAZOLIDONE DRUG

2.2. **Method**

- Organoleptic properties
  - The colour, odour and taste of the drugs were studied.
- Particle size and shape
  - Particle size and shape of the drugs were studied by optical microscopic method.
- Melting point
  - Melting points of the drugs were confirmed by capillary tube method.
- Solubility analysis
  - Solubility is the important parameter for preformulation studies because,
    - ✓ It affects the dissolution of the drug.
    - ✓ Bioavailability of drug is directly affected by oral administration and also by dissolution.
    - ✓ Particle size, shape, surface area may affect the dissolution characteristics of drug hence it should be determined during preformulation.

Method: Weighed quantity of drug was added to the suitable volume of solvent and solubility checked.

2.3. Identification by FTIR

Infrared spectroscopy can be used to identify a compound and also to investigate the composition of the mixture. Pure drugs, polymers, excipients, drug excipients mixture was subjected to FTIR studies to investigate the drug- excipients interactions. The IR spectra of the test samples were obtained by pressed pellet technique using potassium bromide.

2.4. HPLC method development

A Waters Acquity high-performance liquid chromatographic system (M/s Waters Corporation, Ilford, UK) fitted with quaternary solvent manager, sample manager; PDA detector controlled by Empower 2 software, cooling auto sampler and column oven enabling temperature control of the analytical column was used for the method development.

3. Results and discussion

3.1. Furazolidone identification studies

Physico Chemical Characterization of Furazolidone Furazolidone raw material obtained from CIPLA Ltd. Mumbai was tested as per in house specification and the results are listed in table 10. The drug source is identified and found complying with the specifications.

Table 1 Characterization of Furazolidone

S.No	Test	Specification	Results
1	Description	Furazolidone is a white to yellowish crystalline powder	A yellowish crystalline powder
2	Solubility	Freely soluble in dichloromethane, slightly soluble in ethanol	Complies
3	Melting point	184 °C-185 °C.	181-183 °C

3.2. Drug identification by FTIR

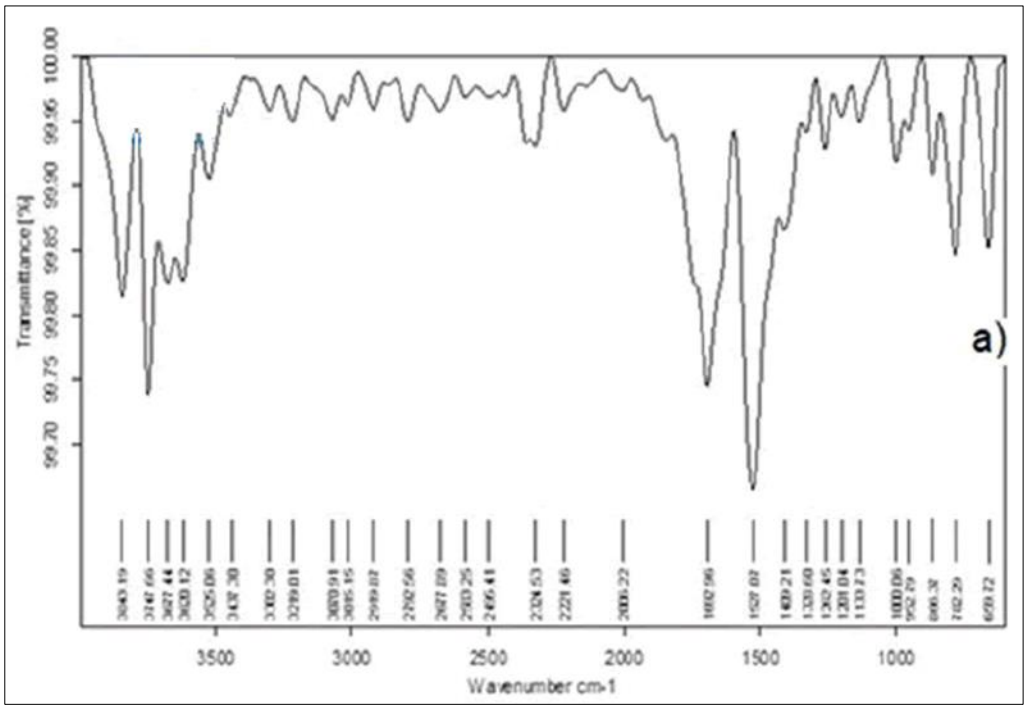

Figure 1 FTIR

3.3. Optimum chromatographic solution

The search for optimum solution was carried out by numerical optimization by "trading off" various CAAs to attain the desired goals, i.e., maximization of peak area and theoretical plates, and minimization of retention time and peak tailing to obtain desirability function close to 1 shown in figure 17. The optimized solution showed the mobile phase composition containing 55–45 mixture of acetonitrile–phosphate buffer (50 mM), buffer pH 3.5 and oven temperature 40°C yielded desirability close to 1.0 along with all the CAAs in the desired ranges.

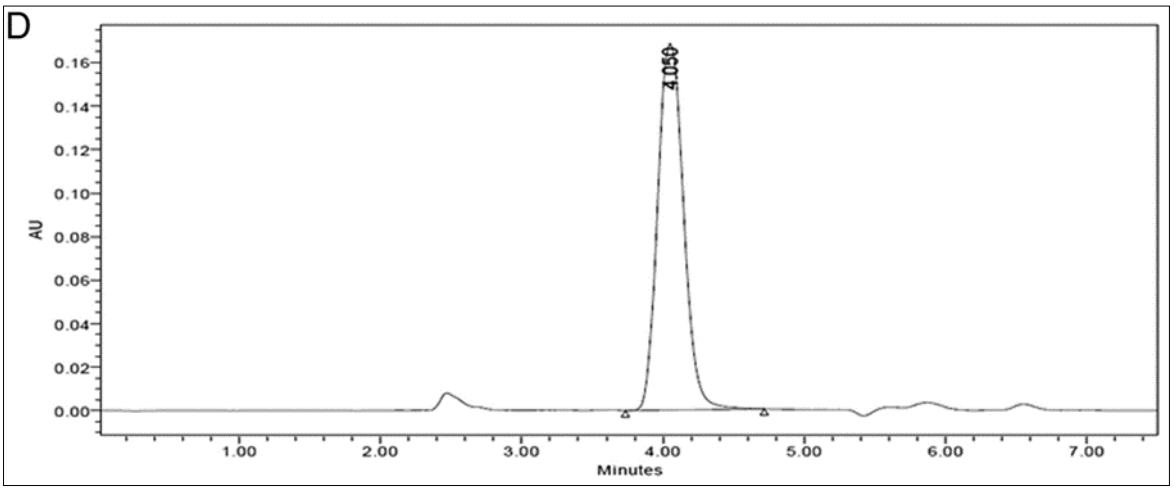

Figure 2 Chromatogram of Furazolidone at 50 ng/mL

4. Conclusion

A simple, rapid, sensitive and economic stability-indicating analytical method has been successfully developed employing the systematic QbD-based approach for quantification of Furazolidone. Application of risk assessment studies helped in prioritizing the factors, critically influencing the method parameters, while factor screening and

optimization studies employing experimental designs finally embarked upon the selection of CMPs/CPPs, thus facilitating the understanding of relationship among CMPs/CPPs with CAAs.

The optimal setting of chromatographic conditions was in the analytical design space using desirability function. Validation of the AQbD method corroborated excellent linearity, accuracy, precision, system suitability and robustness. Further, the experimentally observed values of LOD and LOQ of Furazolidone were also quite lower than those reported by other scientists till date.

Compliance with ethical standards

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Disclosure of conflict of interest

No conflict of interest to be disclosed.

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