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Development of pharmacokinetic profile of Amycordial Forte and its screening for estrogenic activity

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ABSTRACT

Background and Aim: Amycordial Forte® is a propriety Ayurvedic polyherbal formulation manufactured and marketed by AIMIL Pharmaceuticals (I) Ltd., Delhi. Its use is recommended in menstrual disorders such as dysmenorrhea, Polycystic Ovarian Syndrome (PCOS), amenorrhea, etc. It contains thirty-nine ingredients. In practice, the formulation is widely used but lacks experimental data. This study was designed to determine the role of Amycordial Forte in letrozole induced PCOS and normalization of estrous cycle in rats.

Methods: Thirty female rats were divided into five groups of six each. Group 1 received 0.5 % aqueous solution of CMC orally and acted as control. All other animals were administered letrozole (1 mg/kg) by oral gavage daily for 28 days to induce PCOS. After the induction of PCOS, animals were divided in four groups. Group 2 was not subjected to any further treatment and was designated as Negative control. Groups 3, 4 and 5 received metformin (50 mg/kg), Amycordial Forte (2.5 ml/kg) and Amycordial Forte (3.5 ml/kg) orally once a day for 21 days. Vaginal smears were observed daily to check the phase of estrous cycle. Blood serum level of estrogen, progesterone and testosterone were estimated to confirm induction of PCOS on 28th day as well as at the end of the study (on 49th day). Histological studies of ovaries from animals of each group were carried out at the end of the study.

Results: It was observed that letrozole administration resulted in gross changes in microstructure of ovaries. Treatment with Amycordial Forte for three weeks resulted in normalization of microstructure of ovaries in a dose dependent manner. The restorative effect was comparable to metformin. The beneficial effects of Amycordial Forte administration on estrogen, progesterone and testosterone levels at the end of the study were in good agreement with the outcomes of histological studies. The other aim of the study was to develop HPLC fingerprinting profile for Amycordial Forte. An HPLC method for simultaneous quantitative determination of Shatavarin IV and Withaferin A was developed and validated. HPLC fingerprinting profile was established for the Amycordial Forte. It was carried out using Prominence UFLC system with C_{18}column (250 x 4.6 mm, Shim-pack 5 µm, Shimadzu, Japan) using isocratic elution with acetonitrile-water (70:30 v/v) at a flow rate 1 ml/min. The detection was done at 254 nm. The content of Shatavarin IV and Withaferin A (constituents of ingredient herbs *Asparagus racemosus* and *Withania somnifera*) in the formulation was found out to be 422.63 ± 0.85 and 380.93 ± 0.58 µg/ml, respectively. The developed method was validated as per ICH guidelines. The method was helpful in pharmacokinetic study of Amycordial Forte.

Conclusion: Our findings clearly established the estrogenic effect of Amycordial Forte that was standardized for Shatavarin IV and Withaferin A content using a validated HPLC method.

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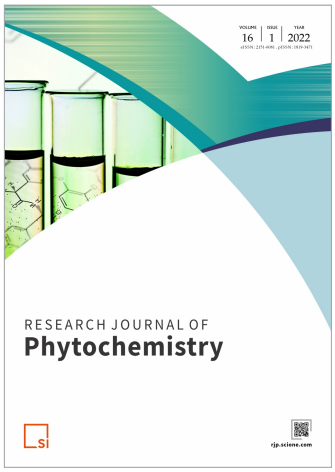

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