

# **Rapidly disintegrating vagina retentive cream suppositories of progesterone: development, patient satisfaction and in vitro/in vivo studies**

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## **Abstract**

Our objective was to develop novel vagina retentive cream suppositories (VRCS) of progesterone having rapid disintegration and good vaginal retention. VRCS of progesterone were prepared using oil in water (o/w) emulsion of mineral oil or theobroma oil in hard fat and compared with conventional vaginal suppositories (CVS) prepared by hard fat. VRCS formulations were tested for content uniformity, disintegration, melting range, in vitro release and stability studies. The most stable formulation (VRCS I) was subjected to scaling-up manufacturing and patients' satisfaction test. The rapid disintegration, good retentive properties are applicable through the inclusion of emulsified theobroma oil rather than hydrophilic surfactant into the hard fat bases. The release profile of progesterone from VRCS I showed a biphasic pattern due to the formation of progesterone reservoir in the emulsified theobroma oil. All volunteers involved in patients' satisfaction test showed high satisfactory response to the tested formulation (VRCS). The in vivo pharmacokinetic study suggests that VRCS of progesterone provided higher rate and extent of absorption compared to hard fat based suppositories. Our results proposed that emulsified theobroma oil could be promising to solve the problems of poor patients' satisfaction and variability of drug absorption associated with hard fat suppositories.

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