



SUGGESTED FORMULA

Estradiol 2mg Vaginal Suppositories

Version number: 1.0

Volume or quantity: #30 Suppositories

Estradiol, USP	0.06gm
Supposi-Plex V33 Base (550-83359)	Q.S.

*It is necessary to calibrate the suppositories molds you are using and adjust formulation accordingly prior to compounding.

This preparation should be compounded in a vertical airflow hood in a biological safety cabinet or barrier isolation technology.

SUGGESTED COMPOUNDING PROCEDURES

1. Calculate the required quantity of each ingredient for the total amount to be prepared
2. Accurately weigh and/or measure each ingredient
3. Using an appropriate heat source, melt the required quantity of Supposi-Plex V33 base to about 32 to 35°C
4. Slowly sprinkle the Estradiol into the melt with stirring until a mixture is obtained
5. Cool slightly, then pour into the mold in a continuous motion, if appropriate for the mold being used
6. Cool, trim if necessary, package and label
7. Suggested Quality assessments
 - a. % variability & % deviation from theoretical <10% - (remake if >10%)
 - b. Surface appearance and feel
 - c. Melting test
 - d. Quantity
 - e. Label - auxiliary labels, storage, BUD, compounded medication

Package in air tight, light resistant containers and Store below 30°C

No claims are made as to the safety or efficacy of this preparation. This formulation is provided solely at the unsolicited request of the pharmacist.

Beyond-Use Dates of preparations are conservative estimates from reference books, peer-reviewed literature, and intended duration of therapy, formulation from commercially available products, organoleptic observations and current USP guidelines. Compounders may have stability studies performed by a reputable laboratory if they wish to extend the Beyond-Use Date. It is recommended that you follow USP <795> recommendations for potency testing.

Beyond-Use Date should be assigned as directed by the current USP <795> Standards

Precautions:

Precautions should be taken when compounding hormones, following USP Chapter <800> standards. These may be absorbed through skin, mucous membranes and lungs. Wear appropriate personal protective equipment – and inform personnel of the risk. Mix and prepare in double-HEPA filtered or filtered/vented enclosure (hood). Pregnant women and personnel with hormone related cancers should not compound hormone preparations.

Although much attention has been paid to ensure the accuracy of the formulation contained here, Spectrum Pharmacy Products accepts no liability for the loss or damage arising from reliance on the information. Compounding pharmacists using this formula take full responsibility for the formulations and hold Spectrum Pharmacy Products and Spectrum Chemical Mfg Corp. and its officers, directors and employees harmless for any claim arising from use of or reliance on information contained therein.

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