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United States Patent [19]

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Chien et al.

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[54] **TRANSDERMAL ABSORPTION DOSAGE UNIT FOR POSTMENOPAUSAL SYNDROME TREATMENT AND PROCESS FOR ADMINISTRATION**

4,693,887 8/1987 Shah 424/80 X
4,906,169 3/1990 Chien et al. 424/448

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[57] ABSTRACT

[21] Appl. No.: **320,570**

[22] Filed: **Mar. 8, 1989**

Transdermal absorption dosage units have been developed for treatment of postmenopausal syndrome which comprise a backing layer, an adjoining adhesive polymer layer in which at least minimum effective daily doses of an estrogen is microdispersed. Presently preferred is use of the natural estrogen, 17-beta-estradiol, or ethinyl estradiol or combinations thereof together with an amount of a natural progestogen or a progestin to minimize any potential side effects. The units use bioacceptable adhesive and polymers. An additional polymer layer in intimate contact with the estrogen-containing layer can be used. Also, a separating layer can optionally be used in making the dosage units, which separate the two adhesive polymer layers, which permits estrogen transmission from the first adhesive polymer layer during treatment. Dosage units are provided which transdermally deliver at least minimum daily doses of the estrogen for at least one day or for multiple days, such as for one week. The invention also provides a process for postmenopausal syndrome treatment using the novel dosage units.

Related U.S. Application Data

[63] Continuation-in-part of Ser. No. 868,709, May 30, 1986, Pat. No. 4,883,669.

[51] Int. Cl.⁵ **A61F 13/02**

[52] U.S. Cl. **424/448; 424/447; 424/449**

[58] Field of Search **424/448, 449, 447**

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20 Claims, 18 Drawing Sheets

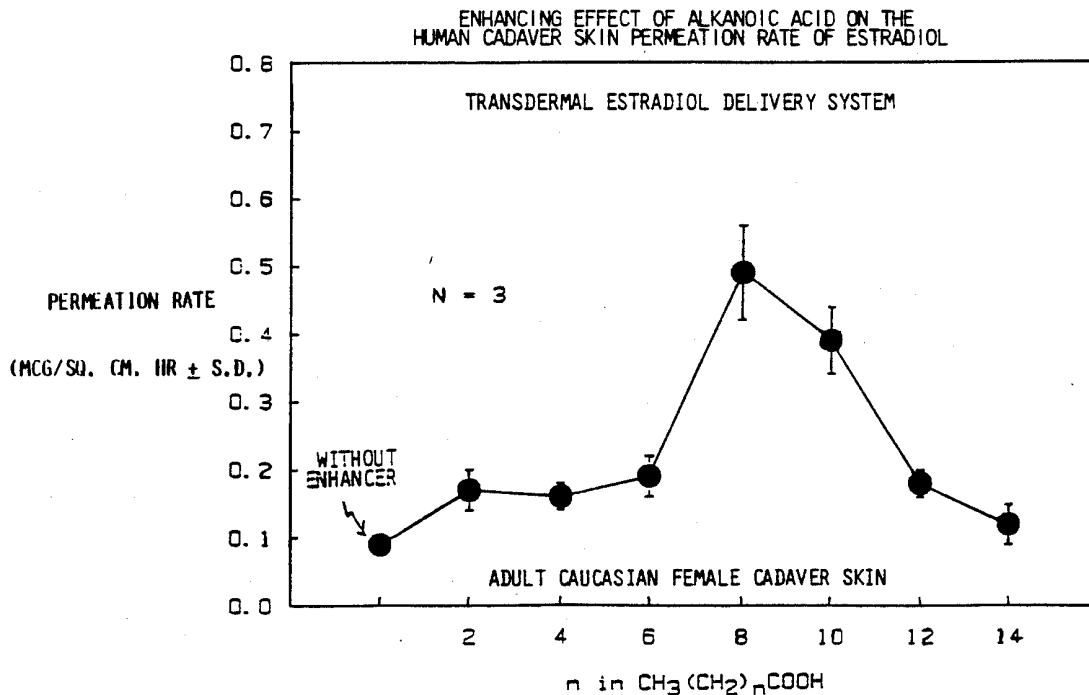


FIG. 1

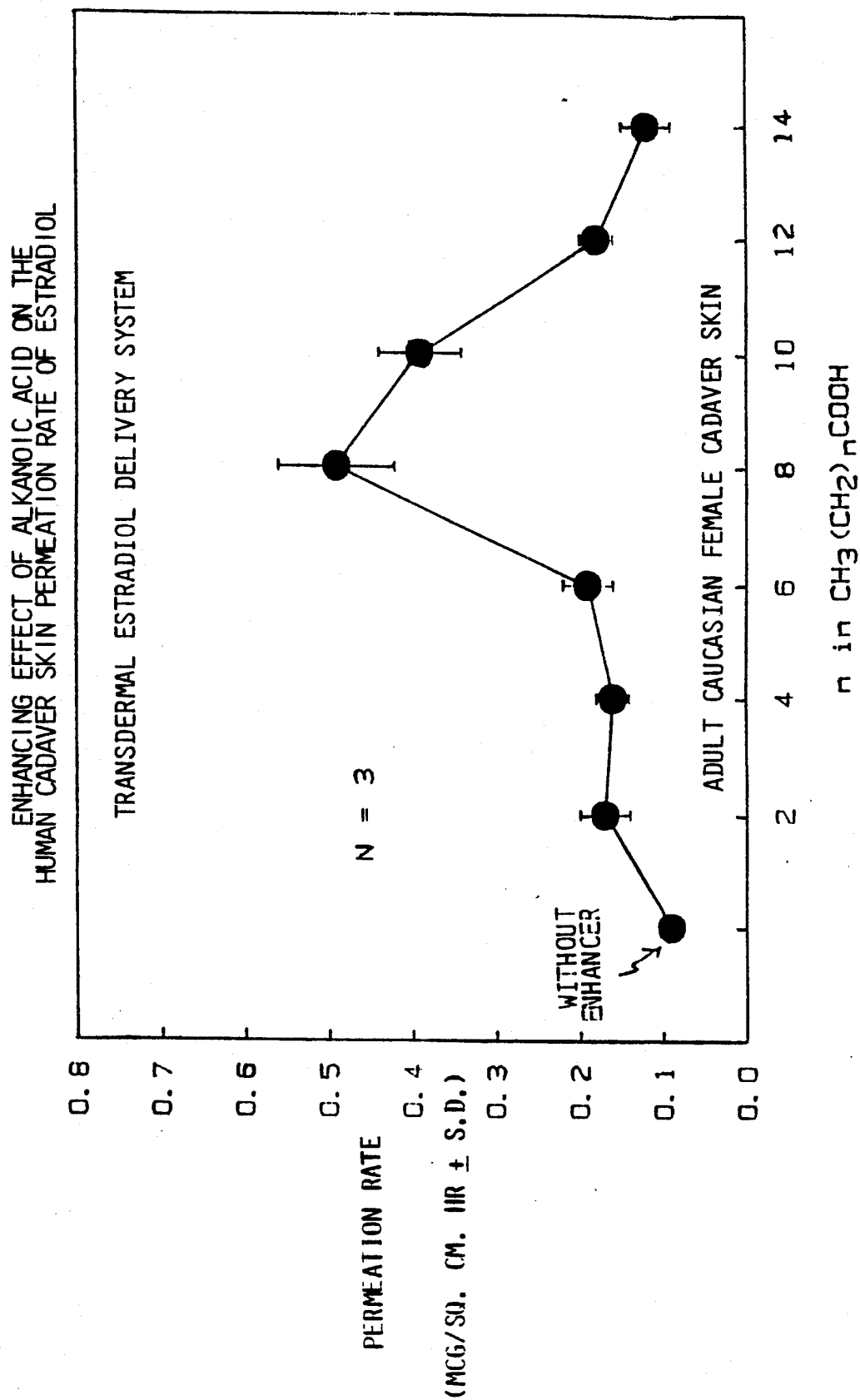


FIG. 2

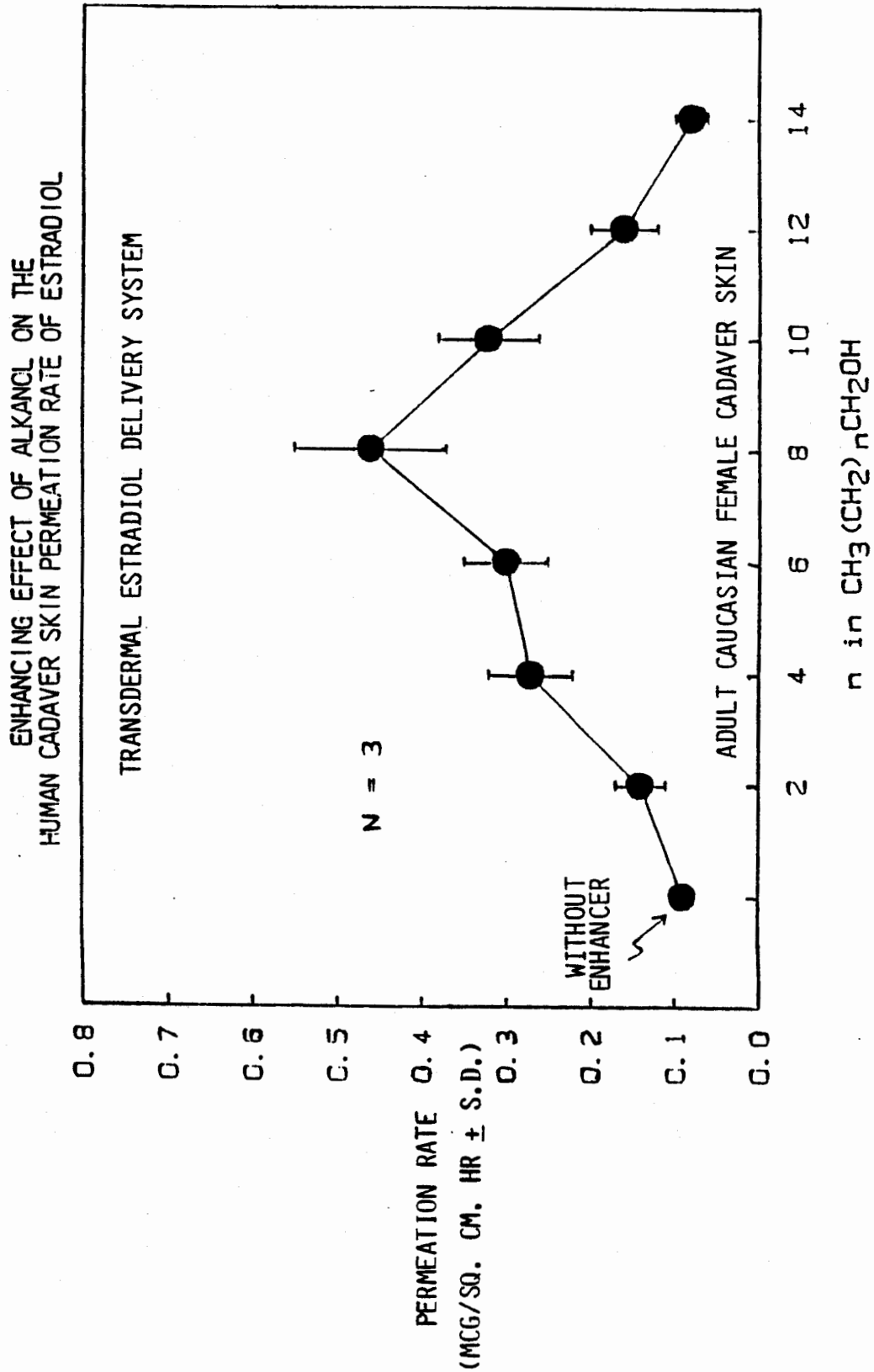


FIG. 3

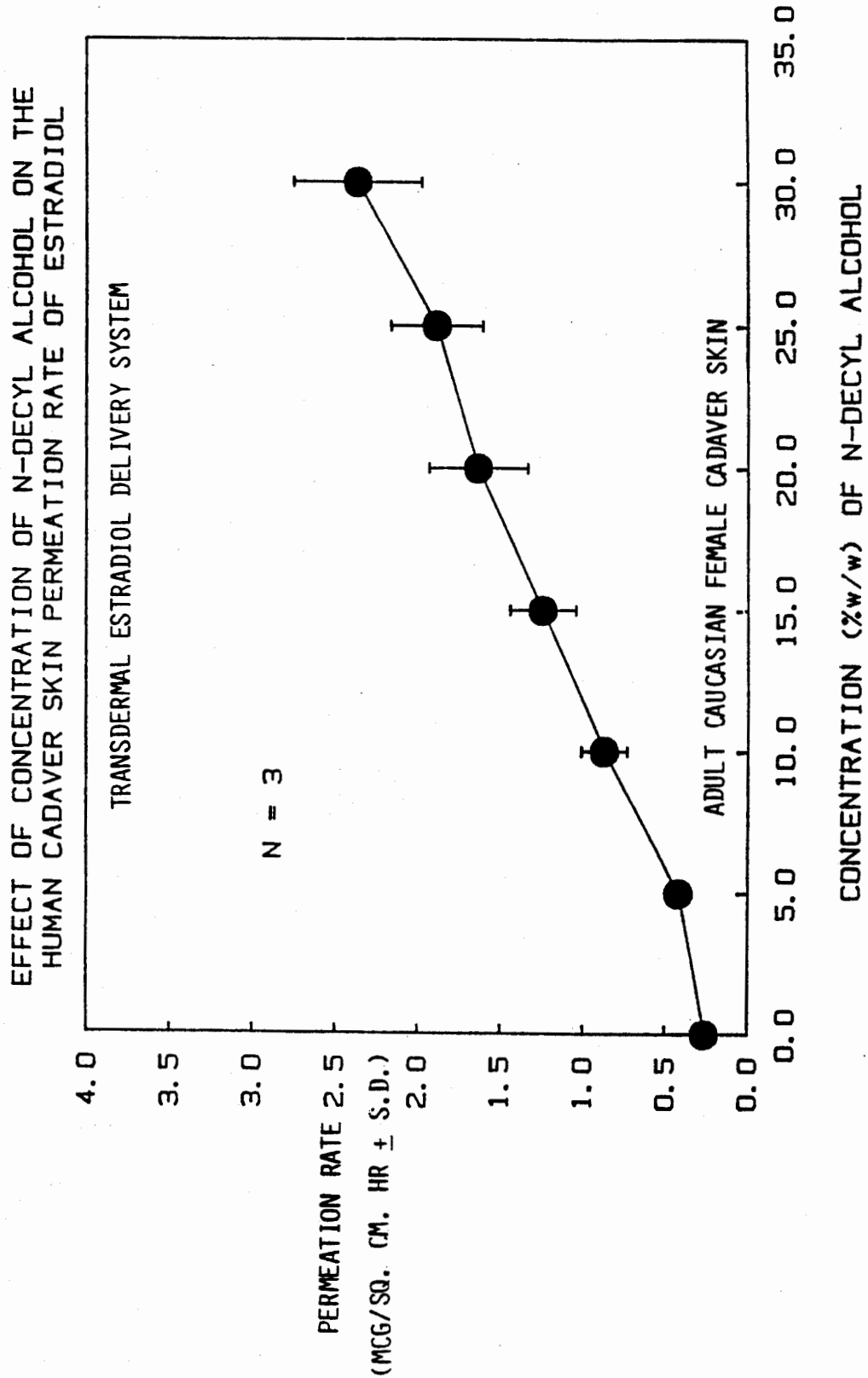
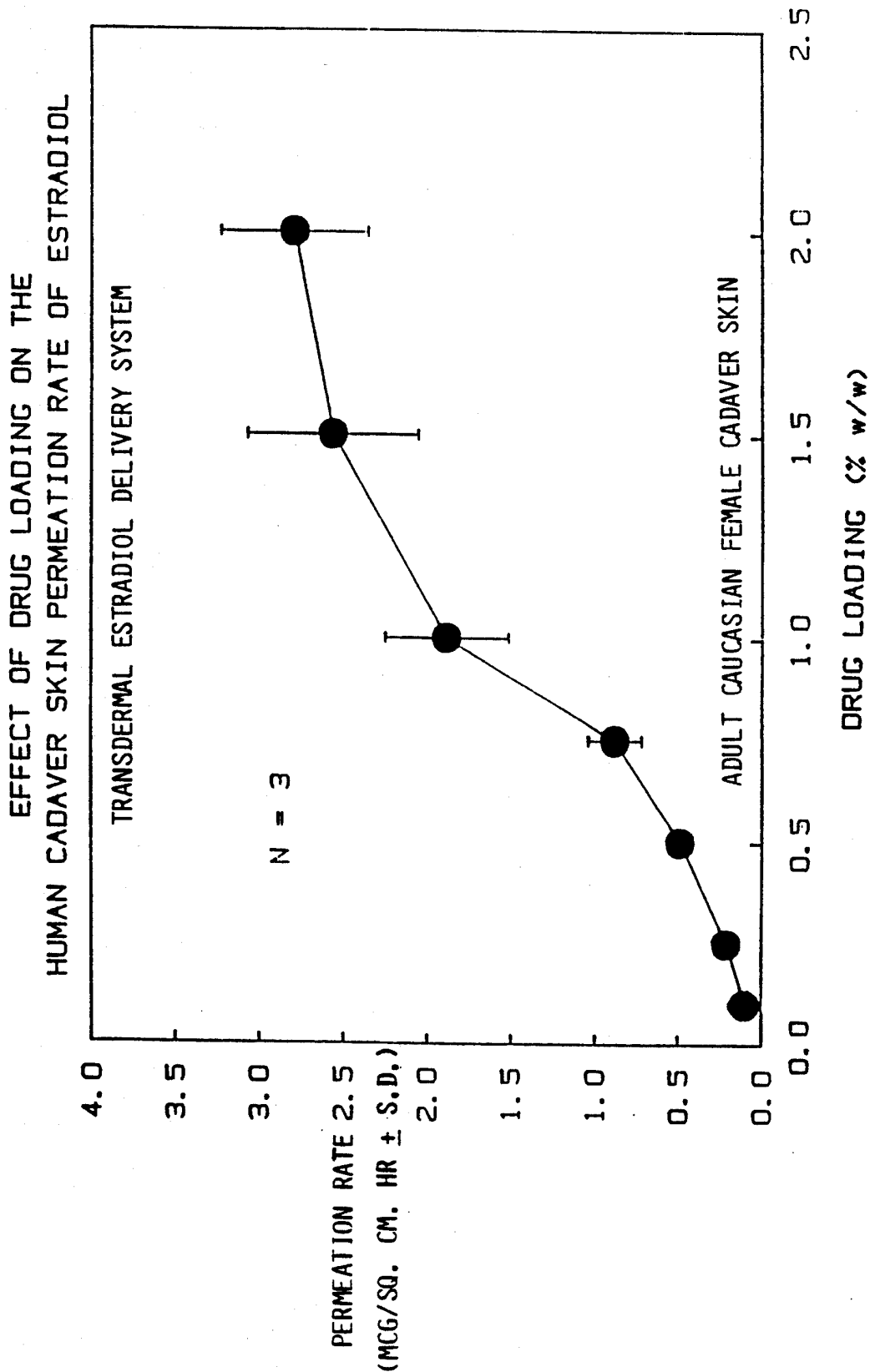


FIG. 4



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