

Natural, Synthetic and Bio-Identical Hormones

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Significant confusion may arise in the minds of both health care professionals and patients in regard to the terms “natural,” “synthetic” and “bio-identical” as applied to hormone replacement therapy (HRT). This white paper is an attempt to clarify the origin of commercially available active hormone ingredients utilized by compounding pharmacists in compounding hormone replacement therapy products.

natural

- **adjective 1** existing in or derived from nature; not made, caused by, or processed by humankind.¹

The use of the word “Natural” in relation to HRT may be somewhat misleading since the word might imply that hormone components of HRT are naturally occurring, unaltered hormones which are incorporated into HRT preparations like topical creams, sublingual tablets, capsules, etc. Natural hormones include the estrogens derived from pregnant mare’s urine found in Premarin[®] Tablets (Estrone, Equilin, 17- - Dihydroequilin, 17- - Estradiol, 17- - Dihydroequilin, 17- - Dihydroequilenin, 17- - Dihydroequilenin, 17- - Estradiol, 8,9-Dehydroestrone, Equilenin).²

synthetic /sinthetik/

- **adjective 1** made by chemical synthesis, especially to imitate a natural product.³

The term “synthetic” has also been used to designate hormone replacement products containing hormone ingredients not found in human tissues. Examples of synthetic hormones would include progestins (medroxyprogesterone, norethindrone, norgestimate, levonorgestrel, desogestrel, etc.) and estrogen analogs (ethinyl estradiol, diethylstilbestrol, etc.).

biological (Bio)

- **adjective 1** relating to biology or living organisms.⁴

— DERIVATIVES **biologically** adverb.

identical

- **adjective 1** exactly alike or the same.⁵

— DERIVATIVES **identically** adverb.

hormone replacement therapy

- **noun** treatment with certain hormones to alleviate menopausal symptoms or osteoporosis.⁶

Bio-Identical Hormone Replacement Therapy

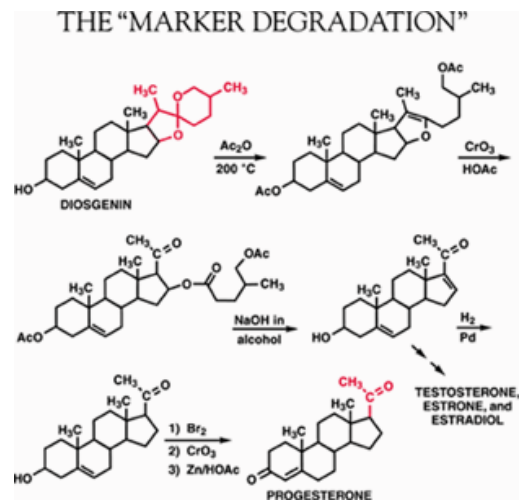
Relating to biology or living organisms exactly alike or the same pertaining to treatment with certain hormones to alleviate menopausal symptoms or osteoporosis.

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The term "bio-Identical" has been used in recent years to attempt to clarify hormone replacement products which are chemically identical to human hormones. This designation has been applied to 17 - Estradiol, Estrone, Estriol, Testosterone, Dehydroepiandrosterone, Melatonin, Pregnenolone and Progesterone. All of which are found in human tissues. Strictly speaking, hormones referenced in bio-Identical HRT are chemically synthesized from precursor compounds found in nature. These naturally occurring base compounds are similar - not identical - to human hormones.

In 1941, Russell E. Marker, a Pennsylvania State College biochemist, discovered a practical method of synthesizing progesterone beginning with diosgenin, a sapogenin molecule closely related to all of the human steroid sex hormones. This chemical process is diagrammed here. The Marker Degradation provided a commercially viable source for progesterone, namely the diosgenin molecule found in Mexican yams (Dioscorea).⁷ The diosgenin molecule is not a human hormone molecule, but is similar in structure to many human hormone molecules. Progesterone had been available at a cost of \$8.00 per gram (\$117.10 in 2007 dollars) before Marker discovered this process to synthesize it.⁸ Human steroid hormones can now be easily and economically synthesized from the readily available precursor compounds found in nature.



Chemical manufacturers of bio-identical hormones utilize diosgenin from *Dioscorea* in the Marker Degradation to synthesize progesterone and other hormones. Diosgenin may also be obtained from other plant sources (agave, crape ginger, soy etc.). The majority of commercially available bio-identical steroid hormones are produced with this process. Chemical manufacturing companies utilize United States Pharmacopeia-National Formulary (USP-NF) monographs to test each hormone for which USP-NF monographs are available. Reputable chemical manufacturers and distributors can provide compounding pharmacies with Certificates of Analysis based on USP-NF standards certifying that hormone ingredients are not adulterated or misbranded and that the hormone meets or exceeds a rigid set of monograph specifications, which vary by molecule.⁹

¹ From *The Compact Oxford English Dictionary* http://www.askoxford.com/concise_oed/natural?view=ge
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² From FDA Web Site. <http://www.fda.gov/cder/present/NIHWHI102302/tsld018.htm>

³ From *The Compact Oxford English Dictionary* http://www.askoxford.com/concise_oed/synthetic
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⁴ From *The Compact Oxford English Dictionary* http://www.askoxford.com/concise_oed/biological?view=uk
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⁵ From *The Compact Oxford English Dictionary* http://www.askoxford.com/concise_oed/identical?view=uk
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⁶ From *The Compact Oxford English Dictionary* http://www.askoxford.com/concise_oed/hormonereplacementtherapy?view=uk

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⁷ From American Chemical Society Web Site <http://acswebcontent.acs.org/landmarks/marker/decade.html>

⁸ Pharmacognosy Tyler, Varro E., Brady, Lynn R., Robbers, James E., Lea & Febiger, 1981.

⁹ From United States Pharmacopeia Web Site <http://www.usp.org/USPNF/faq.html>

Disclaimer: MedQuest Pharmacy is not endorsing the use of the term Bio-Identical, Natural, or Synthetic in relation with describing Hormone Replacement Therapies.

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