

OBJECTIVE

Perspectives on Common Formulations and Use of BHRT Preparations

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International Journal of Pharmaceutical Compounding
Remington: The Science and Practice of Pharmacy
www.CompoundingToday.com

POINTS TO ADDRESS

- Common formulations for BHRT preparations published in IJPC
- Special populations of patients highlighted in IJPC
- Sources for data on use and effectiveness

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- **Common formulations for cBHRT preparations published in IJPC**
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Common formulations for BHRT preparations published in IJPC

- Commercially available BHRT drug products
- Compounded BHRT drug preparations
- Variables for patient use
 - Drug (Single and Combinations)
 - Dose (Depends on each patient)
 - Esthetics (Flavor, odor, texture, consistency, appearance, etc.)
 - Route of administration (Convenience factor)
 - Compliance and Availability
 - Other

Commercial Product Dosage Forms

- Oral
 - Capsules (Powder filled)
 - Capsules (Oil-based)
 - Tablets
- Vaginal
 - Gel
 - Creams
 - Inserts
 - Rings
 - Tablets

Commercial Product Dosage Forms

- Topical/Transdermal
 - Gels
 - Patches
 - Mini-Patches (Dots)
 - Topical Emulsion
 - Spray Solution
- Injection
 - Aqueous
 - Oils (Sesame oil, Castor oil)

Compounded Dosage Forms

- Oral
 - Capsules (Powder filled)
 - Capsules (Lactose-free)
 - Capsules, Semi-Solid Filled
 - Capsules, Oil-Filled
 - Tablet Triturates
 - Troches and Mini-Troches, Soft
 - Troches and Mini-Troches, Hard
 - Buccal Tablets
 - Soft Linguets
 - Liquids (Syrups, Suspensions, Emulsions)
 - Sublingual Drops (Oil)

Compounded Dosage Forms

- Topical/Transdermal
 - Creams
 - Gels
 - Microemulsion Gels
 - Lotions, Clear
 - Lotions, Opaque
 - Lotions (Aqueous, Nonaqueous)
 - Suspensions

Compounded Dosage Forms

- Nasal
 - Drops
 - Sprays
 - Solutions
 - Suspensions
- Injections
 - Aqueous
 - NonAqueous (Sesame Oil, Castor Oil, CoSolvents)

Compounded Dosage Forms

- Vaginal
 - Suppositories/Inserts
 - Water-Soluble
 - Lipid-Soluble
 - Crams
 - Solutions (Poloxamer, etc)
- Rectal
 - Enema
 - Gels
 - Suspensions
 - Emulsions

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Special populations of patients highlighted in IJPC

- Lactose Intolerant
- Preservative Intolerant
- Difficulty swallowing oral solids
- Prefer topical/transdermal
- Prefer oral dissolving flavored solids
- Convenience important for compliance
 - Individualize flavors
 - Ease of transporting, administration
 - Combination preparations
 - Easily modified for each patient

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Sources for data on use and effectiveness

- Dosage forms and strengths vary with physicians and patients
- Physicians and patients are the “drivers” for BHRT
- Pharmacists serves as consultant for both

Sources for data on use and effectiveness-Compounding Occurs:

- Local, neighborhood pharmacies
- Chain Pharmacies, Local
- Chain Pharmacies, Central Fill
- Mail Order Compounding Pharmacies
- Mail Order Chain Pharmacies
- Clinical Setting Pharmacies (Pharmacy separate)
- Combination Practices (Physicians and Pharmacists Together)
- Specialty Compounding Pharmacies
- Limited extent in hospitals for BHRT

Sources for data on use and effectiveness-Data Difficult, Why?

- No centralized data collection site (Costs time and money-Who will pay?)
- No single organization represents all compounding facilities
 - APhA, ASHP, IACP, NCPA, ACA, ASPEN, AMCP, ACCP, ASCP, etc.
- Numerous Compounding Support Companies
 - PCCA, Medisca, Letco, Fagron, Spectrum, Humco, B&B, etc. for ingredients. Dozens of others for specialty supplies, equipment, facilities support, software, testing, etc.
- Private/Privileged information in some facilities.
- Insurance generally does not cover.

Sources for data on use and effectiveness-Conclusion

- Data is not readily available.
- Variation between geographical areas of US
- If data was available, several questions arise:
 - How does one report it:
 - # or weight/volume of Units prepared,
 - # of prescriptions compounded?
 - Cost or dollar value?
 - # of Patients served, etc?
 - What constitutes a “single prescription” for length of treatment per prescription? (week, month, 3-months supply? This affects all the above.
- Even “guesstimates” are difficult.

SUMMARY

- Looked at Commercial and Compounded Dosage Forms
- Listed some special populations
- Sources for data

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- Compounding is concerned with “Individualizing Dosage Forms” for each patient to enhance compliance and effective therapy.
- Too many variables and insufficient data sources make it difficult to obtain “valid numbers” on its extent of use.