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could affect the drug performance and the development of a dosage form. This could provide important information for formulation design or

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In a generic setting,
preformulation studies are
mainly focused on developing
a formulation that is
bioequivalent to the
innovator's product with the

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main objective of filing an
abbreviated new...

Role of Preformulation in
Development of Solid Dosage
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a. Fundamental
preformulation studies.

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These studies are specific to candidate drug molecules and it include solubility analysis (e.g., ionization constant, partition coefficient, solubilization, thermal effect, common ion effect, dissolution etc.),

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(e.g., polymorphism,
solvated forms and amorphous
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those physicochemical...

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The development of a
pharmaceutical oral solid
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as the phase of research and development in which preformulation studies characterize physical and chemical properties of a drug molecule in order to develop safe, effective and stable dosage form.

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CHAPTER 1 Preformulation

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Chewing gum, Pellets, Films

1. Dose accuracy 2.

Stability of the drug 2.

Portability 3. Uniformity of
dose 4. Reproducibility 5.

High Mechanical strength 6.

Tamper resistance 6. Masking
of taste, odour 7. Easy to

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