This information should not be considered to represent advice or guidance on behalf of the U.S. Department of Health and Human Services or any agency or office thereof.

Example Target Product Profile (TPP) for a Small Molecule Drug

As explained in Creating a Target Product Profile for New Drug Products a TPP is a planning tool introduced by the FDA to streamline the drug development process. NIH SEED has developed the following sample TPP for a small molecule drug. It is intended to be illustrative and demonstrate potential content based on various stages of product development and a summary of the quality characteristics a drug product should possess. An actual TPP would require more detail and be based on thorough scientific, regulatory, and market research.

Sample Target Product Profile for a Small Molecule Drug

Product Type: Small Molecule Drug	Indication: Hypertension	
Attributes	**Minimal Acceptance Criteria**	**Preferred Acceptance Criteria**
Efficacy	Reduction in systolic blood pressure by at least 10 mmHg	Reduction in systolic blood pressure by at least 20 mmHg
Safety & Tolerability	Similar side effect profile to current first-line treatments	Fewer side effects than current first-line treatments
Route of Administration	Oral	Oral
Dosage Form	Tablet	Extended-release tablet
Dosage Frequency	Once daily	Once daily
Stability & Shelf Life	2 years at room temperature	3 years at room temperature

Preclinical Studies	
Pharmacodynamics (PD)	Must show clear dose-response relationship in relevant animal models.
Pharmacokinetics (PK)	Suitable half-life supporting once-daily dosing.
Toxicology	No significant organ toxicity at therapeutic doses.

Quality	
Manufacturability	Considerations regarding the ease of manufacture, scalability of the production process, and meeting the target dose number per year.
Sterility	For products that must be sterile, such as injectables.
Formulation	Acceptability and palatability of the composition of the drug product.
Cost of Goods (COGs)	Understanding the COGs is crucial for commercial viability and includes costs associated with raw materials, manufacturing, quality control, and packaging.

Clinical Trials	
Phase I	Safety, tolerability, and PK/PD in healthy volunteers.
Phase II	Dose-ranging study to determine the optimal dose for efficacy with minimal side effects.
Phase III	Large-scale, randomized controlled trials comparing the drug to the current standard of care, assessing long-term safety and effectiveness.

Market Analysis	
Competitive Landscape	Evaluate existing treatments and pipelines to identify gaps and opportunities.
Target Population	Estimate the size of the patient population and subgroups who might benefit most from the new drug.
Pricing Strategy	Based on cost-effectiveness analyses and market willingness to pay.

Regulatory Guidelines	
FDA/EMA	Compliance with guidelines for new antihypertensive drugs, including demonstrating a clinically meaningful reduction in blood pressure and cardiovascular risk.
ICH	Adherence to International Council for Harmonisation (ICH) guidelines for quality, safety, efficacy, and multidisciplinary approaches.

Additional examples:

TPP for a Biological Product

TPP for a Vaccine Product

TPP for a Cell and Gene Therapy Product