

Target Product Profile

A Target Product Profile (TPP) is a planning tool for therapeutic candidates based on FDA *Guidance for Industry and Review Staff Target Product Profile — A Strategic Development Process Tool*.

<http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm080593.pdf>.

Below is an example worksheet based on the FDA guidance that defines the minimal/ideal profile of the final marketed product and shows the ultimate goals of the proposed therapy development effort.

Product Properties	Minimum Acceptable Result	Ideal Result
Primary Indication	Relief of pain symptoms in diabetic neuropathy	Relief of symptoms in neuropathic pain syndromes
Patient Population	Adults with diabetes who experience neuropathic pain	Adults and children with neuropathic pain
Treatment Duration	Chronic	Chronic
Delivery Mode	Oral	Oral
Dosage Form	Tablet or capsule	Tablet or capsule
Regimen	1–2x/day	1x/day
Efficacy	A 40% decrease in pain score in 30% of patients	A 70% decrease in pain score in 50% of patients.
Risks/Side Effects	Devoid of opioid side effects Devoid of GI side effects from Non-steroidal anti-inflammatory drugs (NSAIDs) Minor or moderate CNS side effects	Devoid of opioid side effects Devoid of GI side effect from NSAIDs No CNS side effects