

GMP Grade – Your Insurance Policy

Taq DNA Polymerase, GMP Grade

Taq DNA Polymerase, GMP Grade belongs to the family of high-performance amplification enzymes supplied by Roche Applied Science (Table 1). In view of the current and future importance of “good manufacturing practice” (GMP), our GMP-Grade Taq DNA Polymerase is produced to meet the high quality and documentation requirements of research and development in the pharmaceutical and biotechnology industries, while providing convenient packaging options. Consistent results can be obtained with our Taq DNA Polymerase, GMP Grade:

- ➔ Outstanding lot-to-lot consistency that allows incorporation into your standard operating procedures without concern for product variability
- ➔ Minimized risk of interference caused by contamination due to stringent quality control, product segregation, and GMP manufacturing
- ➔ Fully validated Taq DNA Polymerase manufactured using validated production, quality control, and filling procedures

Table 1: **Specifications Taq DNA Polymerase, GMP Grade**

Origin	Thermus aquaticus BM, recombinant in <i>E. coli</i>
Appearance	clear, colorless solution
Content	≥ 5 units/μl
Purity (SDS-PAGE)	> 98%
Specific activity (protein determination: E _{280 nm})	≥ 130,000 U/mg
Ribonucleases (up to 10 units, 1 hour at 37°C)	not detectable
Endonucleases (up to 30 units, 16 hours at 65°C)	not detectable
Nicking activity (up to 30 units, 16 hours at 65°C)	not detectable
Bioburden	≤ 50 cfu/ml
1st Performance test: PCR on lambda DNA	0.5 kb fragment positive down to 0.01 ng
2nd Performance test: LightCycler on human genomic DNA (β-globin)	corresponds
3rd Performance test: LightCycler on plasmid DNA (β-globin)	corresponds
Stability	24 months (-15 to -20°C) from date of manufacture
Animal-derived additives	none
Quality	GMP manufactured

- ➔ Convenient packaging options to meet your research needs. Taq DNA Polymerase, GMP Grade comes with 10x concentrated PCR buffer with MgCl₂ in 5 ml vials.

Benefit From the High-Quality Standards Provided by GMP

The general rules for “good manufacturing practice” (GMP) are valid for regulated products. Manufacturers of raw materials are also encouraged to follow these guidelines. What we at Roche Applied Science have established from these guidelines is as follows:

- ➔ Raw materials must meet highest quality and regulatory standards.
- ➔ All manufacturing processes are clearly defined, systematically reviewed, and shown to be consistently capable of producing products of the required quality and complying with their specifications.
- ➔ Materials having direct contact with the product are sterilized and used only once. Equipment in direct contact with the product is dedicated for a single product or parameter.
- ➔ Employment of a strict “one room, one product” policy in an area specifically dedicated to the production of enzymes for molecular biology.
- ➔ The production areas are access controlled and class 100,000 with reference to the non-viable particle counts (< 0.5 μm) and less than 200 cfu/m³. The filling of bulk solutions takes place in a laminar-flow box (class 100).
- ➔ Defined flow of personnel, material, and equipment.
- ➔ Manufacturing processes and significant changes to the process are validated.

Taq DNA Polymerase, GMP Grade eliminates the quality and production documentation issues of other amplification enzymes for research and development in the pharmaceutical and biotechnology industries. At Roche Applied Science, quality assurance is a top priority; this commitment ensures that our customers receive the best molecular biochemicals available.



Product	Pack Size	Cat. No.
Taq DNA Polymerase, GMP Grade*	1,000 U	03 734 927 001
	5,000 U	03 734 935 001

*Supplied with 10x concentrated PCR Buffer with MgCl₂