

Ntensify[®] reagent mixes

HQG · HIGH QUALITY GRADEMixes of reagents for GMP manufacturing — Packaging content
saRNA – process 6.3

WHAT HQG MEANS

High Quality Grade (HQG) reagents are manufactured under Quantom's documented quality management system, in controlled and segregated production areas, against defined release specifications. Every lot is produced to a batch record, fully traceable, and released with a Certificate of Analysis. Raw materials are animal-origin-free and qualified suppliers are bound by change notification.

Because these are raw materials, HQG reagents are suitable for use as starting materials in the **GMP manufacturing of RNA drug substance** — as well as for process development, engineering runs, and preclinical and toxicology material. The documentation supplied with each lot is built to support qualification of the reagent under your quality system.

One grade, from bench to clinic.

Each HQG lot carries the traceability and documentation — CoA, TSE/BSE and animal-origin-free statements, change notification — that a GMP manufacturer needs to qualify a raw material. The same reagents carry you from process development into GMP drug-substance production, with no change of source or specification along the way.

GRADE SCOPE AT A GLANCE

	R&D	HQG
Quality system	Documented QMS	Documented QMS
Lot release	Internal control	Specification + CoA
Traceability	Full batch record	Full batch record
Change notification	✗	✓
Documentation supplied	Product datasheet & CoC	CoA, CoC, TSE/BSE & AOF statement
Intended use	Research use only	Process development, toxicity studies, preclinical & raw material for GMP manufacturing

Ntensify® reagents mixes – HQG – process 6.3

NAME	DESCRIPTION	GRADE	20 mL Kit	200 mL Kit	STORAGE
			Vol mL	Vol mL	
ATP	Adenosine triphosphate	HQG	2,56	26,02	-20 °C
CTP	Cytidine triphosphate	HQG	3,25	33,35	-20 °C
GTP	Guanosine triphosphate	HQG	3,02	30,91	-20 °C
Cap analog	CleanCap® Trilink® AU	HQG	1,46	16,24	-20 °C
Uridine	rUTP	HQG	2,33	23,57	-20 °C
Mix 2	Enzymes	HQG	3,52	39,60	-20 °C
Mix 3	IVT buffer	HQG	4,53	50,72	-20 °C
Mix 4	DNA removal	HQG	3,18	34,65	-20 °C
Mix 5	Quenching	HQG	3,69	45,15	RT
Mix 6	Purification (high-salt buffer + beads)	HQG	21	21	RT
Mix 7	High-salt buffer	HQG	153	321	RT
Mix 8	Ethanol 100 %, Ph. Eur. / USP, ≥ 99.5 %, non-denatured	HQG	1000 <i>off-the-shelf bottle</i>	1000 <i>For 400 / 600 / 800: supplied in a 2500 mL bottle</i>	RT
Mix 9, Mix 11, Mix 13	Water for injection, Ph. Eur.*	HQG	500 <i>off-the-shelf bottle</i>	500 <i>For 400 / 600 / 800: 500, 500 and 2000 mL</i>	RT

KIT SPECIFICATION

STORAGE

-20 °C ± 5 °C or RT, per component

Shipped on dry ice; excursions ≤ 72 h acceptable*

SHELF LIFE

24 months*

From date of manufacture, in original container

QUALITY & DOCUMENTATION

- ✓ Endotoxin — ≤ 1 EU/mL*
- ✓ Bioburden — ≤ 10 CFU/mL*
- ✓ RNase / DNase — not detected*
- ✓ Identity & purity — per component spec
- ✓ Certificate of Analysis — per lot, per component
- ✓ Certificate of Compliance — per kit
- ✓ TSE/BSE & animal-origin-free — all components
- ✓ Safety data sheets — all components

For further manufacturing use as a raw material. Not a finished drug product; not for direct administration to humans or animals, and not for diagnostic use.

* Placeholder information, to be updated. · TK — to be provided. ·

CleanCap® and Trilink® are registered trademarks of Trilink BioTechnologies. Cap analog supplied under licence, including rights for commercial use. Ethanol is included in the kit as supplied. Uridine analogs are supplied as a set of three; the user selects the analog required for their construct.