



Dissolution Media Concentrates

Pure Simplicity



Product	8oz Bottle with 200mL Case of 12 Yields 6L Media/Bottle	12oz Bottle with 333.3mL Case of 12 Yields 10L Media/Bottle	24oz Bottle with 666.6mL Case of 6 Yields 20L Media/Bottle	32oz Bottle with 833.25mL Case of 6 Yields 25L Media/Bottle
0.01N HCl	DMC-001-6	DMC-001-10	DMC-001-20	DMC-001-25
0.10N HCl	DMC-002-6	DMC-002-10	DMC-002-20	DMC-002-25
pH 4.5 Acetate Buffer	DMC-003-6	DMC-003-10	DMC-003-20	DMC-003-25
pH 5.8 Potassium Phosphate	DMC-004-6	DMC-004-10	DMC-004-20	DMC-004-25
pH 6.0 Potassium Phosphate	DMC-005-6	DMC-005-10	DMC-005-20	DMC-005-25
pH 6.8 Potassium Phosphate	DMC-006-6	DMC-006-10	DMC-006-20	DMC-006-25
pH 7.0 Potassium Phosphate	DMC-007-6	DMC-007-10	DMC-007-20	DMC-007-25
pH 7.2 Potassium Phosphate	DMC-008-6	DMC-008-10	DMC-008-20	DMC-008-25
pH 7.4 Potassium Phosphate	DMC-009-6	DMC-009-10	DMC-009-20	DMC-009-25
pH 7.5 Potassium Phosphate	DMC-010-6	DMC-010-10	DMC-010-20	DMC-010-25
Sodium Lauryl Sulfate 0.5%	DMC-011-6*	NA	NA	NA
Simulated Gastric Fluid - TS (No Enzymes)	DMC-012-6*	NA	NA	NA
Simulated Intestinal Fluid - TS (No Enzymes)	DMC-013-6*	NA	NA	NA

*400 mL solution yielding 6L of prepared media.

Key Features and Benefits

Really Easy and Fast To Use

To use media concentrates, the chemist simply shakes the unopened bottle briefly and transfers the entire contents with one rinsing to the appropriate volume with USP purified water. No weighing or pipeting is necessary and a 5 minute mix is all that is required after dilution. Compared to weighing neat chemicals, mixing until dissolution and generating required documentation, media concentrates offer a distinct time savings advantage.

Economical and Efficient

Media concentrates materially reduce dissolution media preparation time and level of effort allowing chemists to focus upon other, more productive activities.

Detailed product documentation simplifies regulatory and audit compliance.

Because dissolution media concentrates are highly concentrated:

- They are easier to handle than bulky bags and drums of typical pre-mixed media.
- They are smaller than typical pre-mixed dissolution requiring much less storage space.
- Dissolution media concentrates are much cheaper to ship than bulky pre-mixed media. A 20L drum of pre-mixed media can weigh more than 40 lbs while an equivalent concentrate weighs just 1 1/2 lbs (light enough to ship overnight if needed).
- Dissolution media concentrates are very stable with the shelf life of the phosphate buffer group exceeding 3 years. It will be fit for use for as long as you have it.

Consistent and Accurate in Use

With validated manufacturing processes and stringent critical component requirements, lot to lot and bottle to bottle variance is effectively eliminated.

Each media concentrate lot is quality tested at the user level to assure function. When you need a pH 7.2 potassium phosphate dissolution media, that's exactly what you'll get.

Flexible

Dissolution media concentrates are available off the shelf in volumes yielding 6L, 10L, 20L and 25L to meet your different requirements. Custom volumes can be prepared.

Manufacturing/Formulation Process

All NSI dissolution media concentrates are manufactured and quality tested in our ISO 9001:2000 registered facility.

- Manufactured only from USP grade neat chemicals and USP purified water following validated procedures to meet regulatory requirements.
- Masses and volumes are accurate to $< \pm 0.5\%$ to ensure function at diluted level.
- Filtered through 0.2 μM prior to bottling to enhance purity.
- Packaged in triple cleaned HDPE bottles for purity, safety and maximum long term stability.

Quality Control Process

Controlled manufacturing process supported by statistically valid sampling and technically rigorous analyses assures concentrates yield accurate and consistent media bottle to bottle and lot to lot.

- Accuracy is validated by analysis of media concentrates at diluted levels against primary reference materials (USP and NIST-SRMs), using 2 independent valid methods.
- Batch homogeneity is documented by analysis of a statistically valid number of randomly chosen media concentrate bottles.
- Purity is validated by microbial assay, and/or other analytical techniques as appropriate for the specific media.
- All NSI media concentrates are supplied with complete manufacturing and quality assurance testing records including lot manufacture bench sheets, analytical testing records with acceptance criteria and an approved Certificate of Analysis.

FAQs

Should I be concerned about the headspace above the dissolution media concentrate?

The headspace above the dissolution media concentrate has no effect on the quality of the product. After filling, the solution is blanketed with inert gas. In an effort to keep product packaging costs low, we've used routinely available, off the shelf bottle sizes.

Would you like to receive further information?
Please contact:



How do you ensure the right amount of concentrate volume is in each bottle?

Our filling process is calibrated and validated to a tolerance of $< \pm 0.5\%$. We verify and document the accuracy and reproductibility of each lot through rigorous batch homogeneity testing.

If I am using pre-mixed media or preparing it in-house, what are the major benefits to using NSI dissolution media concentrates?

If you are preparing media in-house, use of NSI dissolution media concentrate will save a lot of time, prevent re-work and greatly simplify record keeping.

If you are using pre-mixed media, you'll find that NSI dissolution media concentrates are easier to handle and much cheaper to ship because they are lighter and smaller than bags and drums of pre-mixed media. And, at 20L prepared volumes, NSI dissolution media concentrates cost 25% less than 20L pre-mixed products.

What sort of documentation accompanies NSI dissolution media concentrates?

Each box of product is supplied with every piece of product documentation we generate including:

- Batch records detailing raw material identity and specifications, chemical masses used with weigh tapes, batch volume, production data, responsible chemists, lot number, and processing details.
- Analytical quality control summary with acceptance criteria.
- Approved certificate of analysis with expiration date.
- MSDS.

How are NSI dissolution media concentrates packaged?

All of our stock dissolution media concentrates are packaged in triple rinsed HDPE bottles. They won't break and they seal tightly so that no transport leakage occurs. HDPE bottles also ensure the stability of the product.

Is there a minimum order volume?

No. The 8oz and 12oz sized bottles are supplied in cases of 12 bottles. The 24oz and 32oz bottles are supplied in cases of 6 bottles.

Can you prepare customized dissolution media concentrates?

Yes. Customized reagents and reference material manufacturing represents a significant portion of our business.

Would you like to receive further information?

Please contact:



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