

Cat# 2B-FDA01

# Formulations of Developed Antibodies<sup>®</sup>

The ready-to-use antibody buffer-optimization and pre-formulation tool

Simplifies and speeds-up the discovery of antibody-stabilizing buffer conditions and helps finding the optimal starting point for antibody formulation development and buffer optimization.

## FEATURES

- 96 buffer conditions from FDA- and EMA-approved formulations of therapeutic antibodies.
- Ready-to-use 5x stock solutions (0.2 mL).
- Wide range of different buffer compositions (1x at 25 °C):
  - pH: 4.6 – 8.0 (acetate, citrate, glycine, histidine, phosphate)
  - Salts: 3 – 200 mM (potassium chloride, sodium chloride)
  - Amino acids: 1 – 300 mM (glycine, glutamate, methionine, proline)
  - Sugars: 12 – 300 mM (maltose, mannitol, sorbitol, sucrose, trehalose)
  - Detergents: 0 – 1.6% (polysorbate 20, polysorbate 80)

## AREAS OF USE

- Ideal for antibody stability screening and unfolding analysis.
- Allows for rapid characterization of buffer influence on chemical, thermal, colloidal, and conformational stability.
- Enables quick-and-easy buffer optimization and pre-formulation.
- Use with your biophysical or biochemical read-out of choice (e.g. DSF, nanoDSF, DSC, DLS, LC-MS, SEC-HPLC, ELISA, etc.).
- Can just as well be used for stability analysis and buffer optimization of any kind of protein.

## INTRODUCTION

The 2bind plate “Formulations of Developed Antibodies” allows for rapid characterization of your antibody of choice in 96 pre-made buffer conditions, derived from the formulations of therapeutic antibodies approved by the FDA (Food and Drug Administration, USA) and the EMA (European Medicines Agency, EU). The buffer conditions can be used for studying important antibody parameters such as chemical, thermal, colloidal, and conformational stability, long-term storage stability, forced-degradation resistance, as well as biochemical activity and antigen-binding.

The buffer conditions have two main benefits over other pre-formulation tools:

- They only comprise already FDA- and EMA-approved substance combinations.
- They have already shown to have positive effects on antibody stability and formulation.

Thus, these conditions provide optimal starting points for developing pre-formulations for therapeutic and diagnostic antibody candidates.

## CONTENT

- “Formulations of Developed Antibodies” buffer screen in a 96 deep-well plate.
- The “Formulations of Developed Antibodies” buffer screen is for research use only.
- The plate contains 96 5x buffer stock solutions (200  $\mu$ L each).
- Instruction manual.

## STORAGE

- Upon receipt, store the plate at 4 °C.
- During use keep at room temperature.
- Expiry date: See inside of box lid.

## REQUIRED EQUIPMENT AND MATERIAL

- Plate centrifuge with variable speed
- Target antibody or protein
- Ultrapure water
- Self-adhesive 96-well plate seal

## FORMULATION NOTES

The 2bind "Formulations of Developed Antibodies" buffers are formulated using high-purity chemicals and ultrapure water (>18.0 MΩ) and are sterile-filtered using 0.22 μm filters. No preservatives are added. Prepared at room temperature. Please note that the storage buffer of the target antibody or protein may affect the final pH and/or buffer composition of the buffers. It is thus recommended to work with highly-concentration target antibody or protein stock solutions in order to generate a maximum dilution effect when diluting the target antibody or protein into the buffers.

## PROTOCOL

Before using the plate, check the seal for any defects. In case of a defect, please contact us under [support@2bind.com](mailto:support@2bind.com).

1. Let the plate adjust to room temperature.
2. Centrifuge the plate at 1000 x g for 20 seconds.
3. Carefully remove seal and avoid spilling buffers into adjacent wells.
4. Check all wells for possible precipitations. In case of visible precipitates, carefully resuspend the respective buffers by pipetting up and down. Buffers in rows G and H and buffer A12 can be more susceptible to precipitation. Ensure proper resuspension before using. In case a 5x-stock solution of a buffer cannot be resuspended completely, dilution of the buffer to its final 1x concentration will ensure proper solving of buffer components. This does not impair buffer quality and the buffer can still be used normally.
5. Prepare the assay samples by diluting your target antibody or protein to the final required assay concentration while also bringing the buffers to 1x final concentration.  
Example: Antibody stock concentration 8 mg/mL, required antibody assay concentration 1 mg/mL, final assay volume of 50 μL:
  - Mix 10 μL of each 5x buffer stock with 33.75 μL ultrapure water.
  - Add 6.25 μL antibody.
  - The antibody will then be at 1 mg/mL in the final 1x buffer.
6. Alternatively, in order to generate 1x buffer solutions, add 800 μl of ultrapure water to each well and mix carefully by pipetting up and down.

## APPLICATION GUIDELINES

Usage of the “Formulations of Developed Antibodies” plate could give rise to liability for patent infringement, because the use of the provided buffers with their corresponding original product/antibody as listed in the following table is protected by patents. Purchase of the “Formulations of Developed Antibodies” plate grants no right for use of these antibodies with the supplied patent-protected buffers.

Well	Product	Antibody	Well	Product	Antibody	Well	Product	Antibody
A01	Actemra	Tocilizumab	C09	Emgality	Galcanezumab-Gnim	F05	Simponi	Golimzumab
A02	Adcetris	Brentuximab Vedotin	C10	Ilaris	Canakinumab	F06	Simponi Aria	Golimzumab
A03	Aimovig	Erenumab-Aooe	C11	Ilumya	Tildrakizumab-Asmn	F07	Soliris	Eculizumab
A04	Amjevita	Adalimumab-Atto	C12	Imfinzi	Durvalumab	F08	Stelara	Ustekinumab
A05	Anthim	Obiltoximab	D01	Inflectra	Infliximab-Dyyb	F09	Stelara	Ustekinumab
A06	Arzerra	Ofatumumab	D02	Ixifi	Infliximab-Qbtx	F10	Synagis	Palivizumab
A07	Avastin	Bevacizumab	D03	Kadcyla	Ado-Trastuzumab Emtansine	F11	Taltz	Ixekizumab
A08	Arcalyst	Rilonacept	D04	Kevzara	Sarilumab	F12	Ultomiris	Ravulizumab-Cwvz
A09	Benlysta	Belimumab	D05	Keytruda	Pembrolizumab	G01	Tremfya	Guselkumab
A10	Besponsa	Inotuzumab Ozogamicin	D06	Lemtrada	Alemtuzumab	G02	Trogarzo	Ibalizumab-Ulyk
A11	Eylea	Aflibercept	D07	Mvasi	Bevacizumab-Awwb	G03	Tysabri	Natalizumab
A12	Bexxar	Tositumomab	D08	Gamifant	Emapalumab-Lzsq	G04	Unituxin	Dinutuximab
B01	Ajovy	Fremanezumab-Vfrm	D09	Skyrizi	Risankizumab-Rzaa	G05	Vectibix	Panitumumab
B02	Blinicyto	Blinatumomab	D10	Libtayo	Cemiplimab-Rwic	G06	Xgeva	Denosumab
B03	Campath	Alemtuzumab	D11	Ocrevus	Ocrelizumab	G07	Xgeva	Denosumab
B04	Cimzia	Certolizumab Pegol	D12	Ogivri	Trastuzumab-Dkst	G08	Cosentyx	Secukinumab
B05	Evenity	Romosozumab-Aqgg	E01	Trazimera	Trastuzumab-Qyyp	G09	Darzalex	Daratumumab
B06	Cinqair	Reslizumab	E02	Skyrizi	Alirocumab	G10	Gazyva	Obinutuzumab
B07	Cosentyx	Secukinumab	E03	Praluent	Alirocumab	G11	Humira	Adalimumab
B08	Crysvisa	Burosumab-Twza	E04	Praxbind	Idarucizumab	G12	Lartruvo	Olaratumab
B09	Cyltezo	Adalimumab-Adbm	E05	Takhzyro	Lanadelumab	H01	Lucentis	Ranibizumab
B10	Cyramza	Ramucirumab	E06	Prostascint	Capromab Pendetide	H02	Opdivo	Nivolumab
B11	Dupixent	Dupilumab	E07	Prostascint	Capromab Pendetide	H03	Portrazza	Necitumumab
B12	Empliciti	Elotuzumab	E08	Raptiva	Efalizumab	H04	Poteligeo	Mogamulizumab-Kpkc
C01	Enbrel	Etanercept	E09	Raxibacumab	Raxibacumab	H05	Simulect	Basiliximab
C02	Entyvio	Vedolizumab	E10	Remicade	Infliximab	H06	Sylvant	Siltuximab
C03	Erbitux	Cetuximab	E11	Renflexis	Infliximab-Abda	H07	Xolair	Omalizumab
C04	Fasenra	Benralizumab	E12	Reopro	Abciximab	H08	Yervoy	Ipilimumab
C05	Hemlibra	Emicizumab-Kxwh	F01	Repatha	Evolocumab	H09	Zenapax	Daclizumab
C06	Herciptin	Trastuzumab	F02	Repatha	Evolocumab	H10	Nulojix	Belatacept
C07	Cablivi	Caplacizumab-Yhdp	F03	Rituxan	Rituximab	H11	Zimbryta	Daclizumab
C08	Erelzi	Etanercept-Szsz	F04	Siliq	Brodalumab	H12	Zimlavya	Bezlotoxumab

## TECHNICAL SUPPORT

Our technical support helps with any questions regarding the “Formulations of Developed Antibodies” plate. Please e-mail your request to [support@2bind.com](mailto:support@2bind.com).

## FAQs

- ❖ Why are there 85 antibodies in the patent right list, when the plate provides 96 buffer conditions?
  - Some therapeutic antibodies are provided in more than one formulation.
- ❖ How should I store the plate upon arrival?
  - The plate should be stored at 4 °C until usage.
- ❖ Why do I have to resuspend the buffers before use?
  - The plate provides high-concentration buffer stocks (5x) in order to enable a variety of measurements for the customer. Due to the high stock concentration, some components may precipitate over time. In order to avoid inaccuracy during measurements, resuspend the 5x buffer stock solutions by pipetting up and down. After proper resuspension, there are no negative effects from any precipitates.
- ❖ How many samples can be analyzed with one plate?
  - Depending on the applied analysis method, the plate can serve for many experiments. The plate contains 200 µl of 5x stock solutions, so 1 ml of 1x buffers can be prepared.
- ❖ Is it possible to purchase individual buffers?
  - Yes. Individual buffers can be purchased in 50 ml batches and will be supplied with a Certificate of Analysis. Please contact us at [orders@2bind.com](mailto:orders@2bind.com).
- ❖ Where do I find information of the identity of a buffer in a specific well?
  - A buffer composition document is provided with this product. Alternatively, check our homepage <https://2bind.com> for more information on buffer composition.
- ❖ I have another question; how can I contact the support?
  - Our technical support is happy to provide you with any additional advice. Please e-mail your question to [support@2bind.com](mailto:support@2bind.com) or call us under +49 941 2000 0890. Thank you very much.

## SAFETY INFORMATION

Relevant hazard statements, GHS-pictograms and precautionary statements of product components:

### Hazard statements

H226	Flammable liquid and vapor.
H290	May be corrosive to metals.
H302	Harmful if swallowed.
H314	Causes severe skin burns and eye damage.
H318	Causes serious eye damage.
H319	Causes serious eye irritation.
H332	Harmful if inhaled.
H361d	Suspected of damaging the unborn child.
H373	May cause damage to organs through prolonged or repeated exposure.

### Precautionary statements

P210	Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
P260	Do not breathe dust/ fume/ gas/ mist/ vapors/ spray.
P264	Wash skin thoroughly after handling.
P280	Wear protective gloves/ protective clothing/ eye protection/ face protection.
P301+P312+P330	If swallowed: Call a poison center/doctor if you feel unwell. Rinse mouth.
P303+P361+P353	If on skin (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower.
P304+P340+P310	If inhaled: Remove person to fresh air and keep comfortable for breathing. Immediately call a poison center/doctor.
P305+P351+P338+P310	If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a poison center/doctor.
P337+P313	If eye irritation persists: Get medical advice/ attention.
P370+P378	In case of fire: Use dry powder or dry sand to extinguish.



For more information, please consult the respective Safety Data Sheets (SDS), which are available on request from [support@2bind.com](mailto:support@2bind.com).

## WARRANTY AND LIABILITY

2bind GmbH warrants that the "Formulations of Developed Antibodies" plate is free from defects in material and workmanship until the expiration date printed on the label only if the plate is used according to the guidelines and instructions set of this leaflet.

2bind GmbH assumes no liability when:

- A product-defect resulted through material or workmanship not provided by 2bind GmbH.
- A product-defect is caused by misuse or use contrary to the supplied instructions.
- The product is contaminated by improper storage or handling.
- The product is incidentally or consequentially damaged.

## PURCHASER NOTIFICATION

2bind GmbH grants the buyer the non-transferable right to use the purchased product for research conducted by the buyer only. The buyer cannot sell or otherwise transfer this product or its components for commercial purposes.

## CONTACT

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