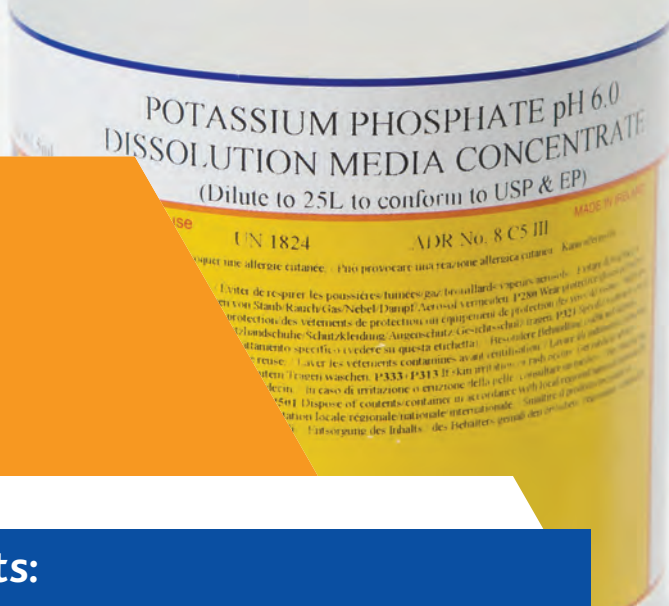


# Dissolution Media - Concentrates



## Summary of Features & Benefits:

### Commercial Benefits

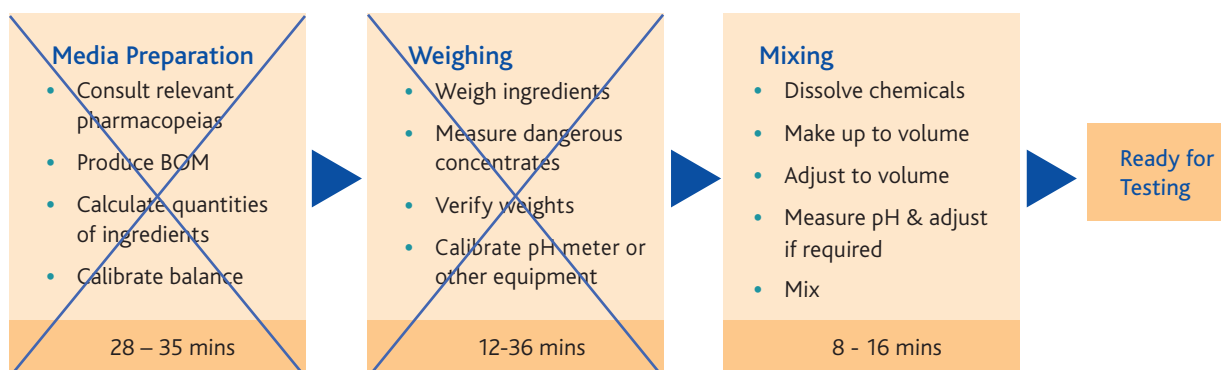
- Reduce preparation time
- Free up resources for core activities
- Save valuable bench space

### Technical Benefits

- Consistency of product
- Full regulatory & labelling compliance
- Certificates of Analysis & Safety Data Sheets available online

Reagecon has added a new range of Dissolution Media Concentrates to its manufactured product portfolio.

With Reagecon's dissolution media concentrates you take out all preparation steps up to the final mixing, simply add purified water and mix, allowing you to run your dissolution test without delay and at a reduced cost.



### Save valuable time per batch!

Allow Reagecon to offer you major savings and improved efficiencies in your dissolution testing by having products which are:-

- Prepared according to relevant pharmacopoeia requirements
- Without deviations on materials and methodology from pharmacopoeia
- Guaranteed Accuracy and Stability
- 2 year Shelf Life
- Certificates of Analysis and Safety Data Sheets available online
- Consistency of Product, Independent, Traceable, Certified

## Dissolution Media - Concentrates

Product No.	Compliant Pharm	Concentration	Pack Size
<b>Potassium Phosphate pH 5.8</b>			
DBC01-230	USP & Ph. Eur.	230.8ml of conc. dilutes to 6L	Pack of 12
DBC01-250	USP & Ph. Eur.	250ml of conc. dilutes to 10L	Pack of 12
DBC01-960	USP & Ph. Eur.	961.5ml of conc. dilutes to 25L	Pack of 6
<b>Potassium Phosphate pH 6.0</b>			
DBC02-230	USP & Ph. Eur.	230.8ml of conc. dilutes to 6L	Pack of 12
DBC02-250	USP & Ph. Eur.	250ml of conc. dilutes to 10L	Pack of 12
DBC02-960	USP & Ph. Eur.	961.5ml of conc. dilutes to 25L	Pack of 6
DBC02-1L	USP & Ph. Eur.	1L of conc. dilutes to 40L	Pack of 6
<b>Potassium Phosphate pH 6.8</b>			
DBC03-230	USP & Ph. Eur.	230.8ml of conc. dilutes to 6L	Pack of 12
DBC03-250	USP & Ph. Eur.	250ml of conc. dilutes to 10L	Pack of 12
DBC03-960	USP & Ph. Eur.	961.5ml of conc. dilutes to 25L	Pack of 6
<b>Potassium Phosphate pH 7.2</b>			
DBC04-230	USP & Ph. Eur.	230.8ml of conc. dilutes to 6L	Pack of 12
DBC04-250	USP & Ph. Eur.	250ml of conc. dilutes to 10L	Pack of 12
DBC04-960	USP & Ph. Eur.	961.5ml of conc. dilutes to 25L	Pack of 6
DBC04-1L	USP & Ph. Eur.	1L of conc. dilutes to 40L	Pack of 6
<b>Potassium Phosphate pH 7.5</b>			
DBC05-230	USP & Ph. Eur.	230.8ml of conc. dilutes to 6L	Pack of 12
DBC05-250	USP & Ph. Eur.	250ml of conc. dilutes to 10L	Pack of 12
DBC05-960	USP & Ph. Eur.	961.5ml of conc. dilutes to 25L	Pack of 6
DBC05-1L	USP & Ph. Eur.	1L of conc. dilutes to 40L	Pack of 6
<b>Acetate Buffer pH 4.5</b>			
DBC06-230	USP & Ph. Eur.	230.8ml of conc. dilutes to 6L	Pack of 12
DBC06-250	USP & Ph. Eur.	250ml of conc. dilutes to 10L	Pack of 12
DBC06-960	USP & Ph. Eur.	961.5ml of conc. dilutes to 25L	Pack of 6
<b>Sodium Lauryl Sulphate 0.50%</b>			
DBC07-400	USP	400ml of conc. dilutes to 6L	Pack of 12
DBC07-500	USP	500ml of conc. dilutes to 10L	Pack of 12
<b>Potassium Phosphate pH 7.4</b>			
DBC08-230	USP & Ph. Eur.	230.8ml of conc. dilutes to 6L	Pack of 12
DBC08-250	USP & Ph. Eur.	250ml of conc. dilutes to 10L	Pack of 12
DBC08-960	USP & Ph. Eur.	961.5ml of conc. dilutes to 25L	Pack of 6

## Dissolution Media - Concentrates

Product No.	Compliant Pharm	Concentration	Pack Size
<b>Sodium Phosphate pH 6.8</b>			
DBC09-230	USP	230.8ml of conc. dilutes to 6L	Pack of 12
DBC09-250	USP	250ml of conc. dilutes to 10L	Pack of 12
DBC09-960	USP	961.5ml of conc. dilutes to 25L	Pack of 6
<b>Hydrochloric Acid 0.01N</b>			
DBC10-230	USP & Ph. Eur.	230.8ml of conc. dilutes to 6L	Pack of 12
DBC10-250	USP & Ph. Eur.	250ml of conc. dilutes to 10L	Pack of 12
DBC10-960	USP & Ph. Eur.	961.5ml of conc. dilutes to 25L	Pack of 6
DBC10-1L	USP & Ph. Eur.	1L of conc. dilutes to 40L	Pack of 6
<b>Hydrochloric Acid 0.1N</b>			
DBC11-230	USP & Ph. Eur.	230.8ml of conc. dilutes to 6L	Pack of 12
DBC11-250	USP & Ph. Eur.	250ml of conc. dilutes to 10L	Pack of 12
DBC11-960	USP & Ph. Eur.	961.5ml of conc. dilutes to 25L	Pack of 6
DBC11-1L	USP & Ph. Eur.	1L of conc. dilutes to 40L	Pack of 6
<b>Simulated Gastric Fluid without enzyme</b>			
DBC12-230	USP & Ph. Eur.	230.8ml of conc. dilutes to 6L	Pack of 12
DBC12-250	USP & Ph. Eur.	250ml of conc. dilutes to 10L	Pack of 12
DBC12-960	USP & Ph. Eur.	961.5ml of conc. dilutes to 25L	Pack of 6
<b>Simulated Intestinal Fluid without enzyme</b>			
DBC13-230	USP & Ph. Eur.	230.8ml of conc. dilutes to 6L	Pack of 12
DBC13-250	USP & Ph. Eur.	250ml of conc. dilutes to 10L	Pack of 12
DBC13-960	USP & Ph. Eur.	961.5ml of conc. dilutes to 25L	Pack of 6
<b>Phosphate Buffer pH 6.8</b>			
DBC14-500	JP	500ml of conc. dilutes to 10L	Pack of 12
DBC14-960	JP	961.5ml of conc. dilutes to 25L	Pack of 6
<b>2nd Dissolution Fluid</b>			
DBC15-250	JP	250ml of conc. dilutes to 10L	Pack of 12
DBC15-960	JP	961.5ml of conc. dilutes to 25L	Pack of 6
<b>Potassium Phosphate pH 4.5</b>			
DBC20-960	USP & Ph. Eur.	961.5ml of conc. dilutes to 25L	Pack of 6
<b>Potassium Chloride 0.05M</b>			
DBC25-400	USP & Ph. Eur.	400ml of conc. dilutes to 10L	Pack of 12
DBC25-960	USP & Ph. Eur.	961.5ml of conc. dilutes to 25L	Pack of 6

Product No.	Compliant Pharm	Concentration	Pack Size
<b>Potassium Phosphate pH 4.5</b>			
DBC40-1L	USP & Ph. Eur.	1L of conc. dilutes to 40L	Pack of 6
<b>Potassium Phosphate pH 7.1</b>			
DBC41-1L	USP & Ph. Eur.	1L of conc. dilutes to 40L	Pack of 6
DBC41-960	USP & Ph. Eur.	961.5ml of conc. dilutes to 25L	Pack of 6
<b>Potassium Phosphate pH 8.0</b>			
DBC42-1L	USP & Ph. Eur.	1L of conc. dilutes to 40L	Pack of 6
DBC42-960	USP & Ph. Eur.	961.5ml of conc. dilutes to 25L	Pack of 6
<b>Buffered Sodium Dodecyl Sulphate, pH 7</b>			
DBC43-500	USP & Ph. Eur.	500ml of conc. dilutes to 10L	Pack of 12
<b>Potassium Phosphate pH 6.8 + 1.0% SDS(Sodium Dodecyl Sulphate)</b>			
DBC44-960	USP & Ph. Eur.	961.5ml of conc. dilutes to 25L	Pack of 12
<b>Potassium Phosphate pH 6.8 + 0.5% SDS(Sodium Dodecyl Sulphate)</b>			
DBC45-960	USP & Ph. Eur.	961.5ml of conc. dilutes to 25L	Pack of 6
<b>Acetate Buffer pH 4.5 + 1.0% SDS(Sodium Dodecyl Sulphate)</b>			
DBC46-960	USP & Ph. Eur.	961.5ml of conc. dilutes to 25L	Pack of 6
<b>Acetate Buffer pH 4.5 + 0.5% SDS(Sodium Dodecyl Sulphate)</b>			
DBC47-960	USP & Ph. Eur.	961.5ml of conc. dilutes to 25L	Pack of 6
<b>0.1N HCl+1.0% SDS (Sodium Dodecyl Sulphate)</b>			
DBC48-960	USP & Ph. Eur.	961.5ml of conc. dilutes to 25L	Pack of 6
<b>0.1N HCl+0.5% SDS (Sodium Dodecyl Sulphate)</b>			
DBC49-960	USP & Ph. Eur.	961.5ml of conc. dilutes to 25L	Pack of 6

# Dissolution Media - Ready To Use



## Summary of Features & Benefits:

### Commercial Benefits

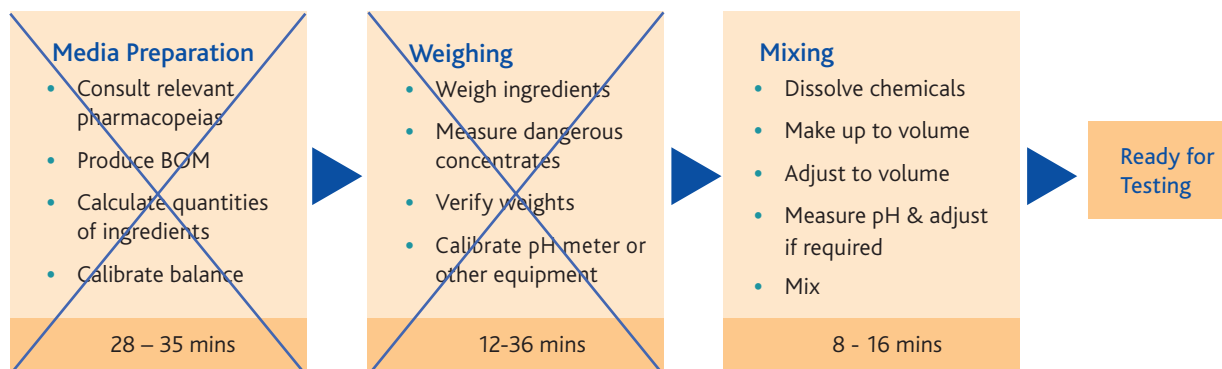
- Reduce preparation time
- Free up resources for core activities
- Save valuable bench space

### Technical Benefits

- Consistency of product
- Full regulatory & labelling compliance
- Certificates of Analysis & Safety Data Sheets available online

Reagecon has added a new range of Ready to Use Dissolution Media to its manufactured product portfolio.

Reagecon's dissolution media eliminates all preparation steps allowing you to run your dissolution test without delay and at a reduced cost.



### Save valuable time per batch!

Allow Reagecon to offer you major savings and improved efficiencies in your dissolution testing by having products which are:-

- Prepared according to relevant pharmacopoeia requirements
- Without deviations on materials and methodology from pharmacopoeia
- Guaranteed Accuracy and Stability
- 2 year Shelf Life
- Certificates of Analysis and Safety Data Sheets available online
- Consistency of Product, Independent, Traceable, Certified

## Dissolution Media - Ready to Use

Product No.	Description	Compliant Pharmacopoeia	Pack Size
DB10-121	Hydrochloric Acid 0.01N	USP & Ph. Eur.	12 x 1L
DB10-25L	Hydrochloric Acid 0.01N	USP & Ph. Eur.	25L
DB11-121	Hydrochloric Acid 0.1N	USP & Ph. Eur.	12 x 1L
DB11-10	Hydrochloric Acid 0.1N	USP & Ph. Eur.	10L (Bag in Box)
DB11-10L	Hydrochloric Acid 0.1N	USP & Ph. Eur.	10L
DB11-20	Hydrochloric Acid 0.1N	USP & Ph. Eur.	20 L
DB11-25L	Hydrochloric Acid 0.1N	USP & Ph. Eur.	25L
DB06-121	Acetate Buffer pH 4.5	USP & Ph. Eur.	12 x 1L
DB06-10	Acetate Buffer pH 4.5	USP & Ph. Eur.	10L
DB06-20	Acetate Buffer pH 4.5	USP & Ph. Eur.	20 L
DB01-121	Potassium Phosphate pH 5.8	USP & Ph. Eur.	12 x 1L
DB02-121	Potassium Phosphate pH 6.0	USP & Ph. Eur.	12 x 1L
DB03-121	Potassium Phosphate pH 6.8, R	USP & Ph. Eur.	12 x 1L
DB03-10	Potassium Phosphate pH 6.8, R	USP & Ph. Eur.	10L
DB09-121	Sodium Phosphate pH 6.8	USP	12 x 1L
DB04-121	Potassium Phosphate pH 7.2	USP & Ph. Eur.	12 x 1L
DB04-10L	Potassium Phosphate pH 7.2	USP & Ph. Eur.	10L
DB08-121	Potassium Phosphate pH 7.4	USP & Ph. Eur.	12 x 1L
DB08-10L	Potassium Phosphate pH 7.4	USP & Ph. Eur.	10L
DB08-25L	Potassium Phosphate pH 7.4	USP & Ph. Eur.	25L
DB05-121	Potassium Phosphate pH 7.5	USP & Ph. Eur.	12 x 1L
DB05-10L	Potassium Phosphate pH 7.5	USP & Ph. Eur.	10L
DB07-121	Sodium Lauryl Sulphate 0.50%	USP	12 x 1L
DB07-121-25L	Sodium Lauryl Sulphate 0.50%	USP	25L
DB12-121	Simulated Gastric Fluid, without enzyme	USP & Ph. Eur.	12 x 1L
DB12-07	Simulated Gastric Fluid, without enzyme	USP & Ph. Eur.	7 L
DB12-10	Simulated Gastric Fluid, without enzyme	USP & Ph. Eur.	10L
DB13-121	Simulated Intestinal Fluid, without enzyme	USP & Ph. Eur.	12 x 1L
DB14-121	Potassium Phosphate pH 6.80	JP	12 x 1L
DB14-10L	Potassium Phosphate pH 6.80	JP	10L
DB18-121	1st Dissolution Fluid	JP	12 x 1L
DB18-10	1st Dissolution Fluid	JP	10L
DB15-121	2nd Dissolution Fluid	JP	12 x 1L
DB15-10L	2nd Dissolution Fluid	JP	10L
DB16-121	Acetate Buffer pH 5.5	Ph. Eur.	12 x 1L
DB17-121	Acetate Buffer pH 5.8	Ph. Eur.	12 x 1L
DB19-10	HCl/NaCl, pH 1.2	Ph. Eur.	10L
DB20-10	Phosphate Buffer pH 4.5	Ph. Eur.	10L
DB21-10	Citrate Buffer 0.05M	USP & Ph. Eur.	10L

## Dissolution Media - Ready to Use

Product No.	Description	Compliant Pharmacopoeia	Pack Size
DB22-10	Phosphate Buffer pH 7.5	USP & Ph. Eur.	10L
DB27-121	Buffered Sodium Dodecyl Sulphate, pH 7	USP & Ph. Eur.	12 x 1L
DB27-10	Buffered Sodium Dodecyl Sulphate, pH 7	USP & Ph. Eur.	10L
DB28-10L	Di Sodium Phosphate 55.3g + Citric Acid 4.8g, adjust to pH 6.8	USP & Ph. Eur.	10L
DB24-10	Phosphate Buffer pH 7.00	USP & Ph. Eur.	10L

## Dissolution FaSSIF

Biorelevant intestinal media, first proposed by Galia et al in 1998, are media that simulate intestinal fluids secreted under both fasting or feed state conditions <sup>(1)</sup>. These laboratory prepared solutions share physiochemical properties with corresponding fluids found in-vivo and are used to mimic the properties of the in-vivo fluids for drug solubility and dissolution characteristics.

Such media contain the bile salt Sodium Taurocholate and Lecithin dissolved in a slightly acid phosphate buffer which is tested for pH, osmolality and buffer capacity, which simulates the in-vivo solution in the upper small intestinal region, which is where the majority of drugs are absorbed <sup>(2)</sup>.

Reagecon offers the buffering system in a number of formulations and pack sizes, which are dependent on whether the medium under test is simulating fasting or feed state conditions.

<sup>(1)</sup> Galia, E.; Nicolaidis, E.; Hörter, D.; Löbenberg, R.; Reppas, C.; Dressman, J. B. Evaluation of Various Dissolution Media for Predicting In Vivo Performance of Class I and II Drugs. *Pharm. Res.* 1998, 15 (5), 698-705.

<sup>(2)</sup> Leigh, M.; Kloefer, B.,; and Schaich, M. Comparison of the Solubility and Dissolution of Drugs in Fasted-State Biorelevant Media (FaSSIF and FaSSIF-V2), *Dissolution Technologies*, August 2013, 44-50.

Product No.	Description	Pack Size
FASSIF5	Dissolution Media FaSSIF pH 6.5 (without enzyme)	5L
FASSIFV21	Dissolution Media FaSSIF V2 - pH 6.5 - (without enzyme)	12 x 1L
FASSIFV210	Dissolution Media FaSSIF V2 - pH 6.5 (without enzyme)	10L
FESSIFV21	Dissolution Media FeSSIF V2 - pH 5.8 - (without enzyme)	12 x 1L
FESSIFV210	Dissolution Media FeSSIF V2 - pH 5.8 (without enzyme)	10L