



SIMULTANEOUS ESTIMATION OF THE SULBACTAM AND DURLOBACTAM IN BULK AND TABLET DOSAGE FORM BY RP-HPLC

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ABSTRACT:

A simple, Accurate, precise method was developed for the simultaneous estimation of the Sulbactam and Durlobactam in bulk and Tablet dosage form. Chromatogram was run through phenomenexC18 250 x 4.6 mm, 5m. Mobile phase containing Buffer 0.1% OPA: Acetonitrile taken in the ratio 60:40 was pumped through column at a flow rate of 1 ml/min. Buffer used in this method was 0.1% OPA. Temperature was maintained at 30°C. Optimized wavelength selected was 270 nm. Retention of Sulbactam and Durlobactam were eluted at 2.206 min and 2.871 min. %RSD of the Sulbactam and Durlobactam were and found to be 0.8 and 0.9 respectively. %Recovery was obtained as 100.35% and 100.70% for Sulbactam and Durlobactam respectively. LOD, LOQ values obtained from regression equations of Sulbactam and Durlobactam were 0.63, 1.90 and 0.11, 0.34 respectively. Regression equation of Sulbactam is $y = 15617x + 4696.6$, and $y = 18901x + 2971$ of Durlobactam. Retention times were decreased and that run time was decreased, so the method developed was simple and economical that can be adopted in regular Quality control test in Industries.

Key Words: Sulbactam, Durlobactam, RP-HPLC

INTRODUCTION

Bacterial infections are any illness or condition caused by bacterial growth or poisons (toxins). You can get sick from getting harmful bacteria in your skin, gut (GI tract), lungs, heart, brain, blood or anywhere else in your body. Harmful bacteria from the environment, an infected person or animal, a bug bite or something contaminated (like food, water or surfaces) can cause infections. Bacteria that's not normally harmful but that gets into a place in your body where it shouldn't be can also cause infections.¹

The risk of getting a bacterial infection increases when you are in contact with flood water. Flood water can come from storms or cyclones. Touching items affected by flooding can also increase your risk of bacterial infection. You should avoid contact with flood water and practice good hand hygiene. Wash your hands with soap and clean water. If clean water isn't available, use hand sanitiser.²

Localized Symptoms:³

Pain: This is common with bacterial infections. You can experience skin pain with a bacterial infection on the skin. A lung infection can cause pain when breathing, and you can feel abdominal (stomach) pain with an intestinal (or bowel) infection.

Skin Rash: Bacterial skin infections, such as impetigo, erythrasma, folliculitis, and methicillin-resistant *Staphylococcus aureus* (MRSA), can cause a red, itchy, and painful skin rash.

Swelling and redness: You may notice redness or swelling on parts of the body that you can see, such as the skin, throat, or ears.

Problems with organ function: Internal organs can become inflamed and swollen. While you can't see it, you may feel pain or other effects in these areas. For example, pyelonephritis (a kidney infection) could worsen kidney function

Some bacterial infections are:¹

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1. Food poisoning (gastroenteritis).
2. Some skin, ear or sinus infections.
3. Some sexually transmitted infections (STIs).
4. Bacterial pneumonia.
5. Most urinary tract infections (UTIs).

Sulbactam Durlobactam medication is used to treat certain bacterial infections. This product contains 2 medications: sulbactam and durlobactam. Sulbactam is an antibiotic that works by stopping the growth of bacteria. Durlobactam is an enzyme inhibitor (beta-lactamase inhibitor) that helps sulbactam work better.⁴

In May 2023, sulbactam/durlobactam was approved in the USA for use in patients 18 years of age and older for the treatment of hospital-acquired bacterial pneumonia and ventilator-associated bacterial pneumonia (HABP/VABP) caused by susceptible isolates of *Acinetobacter baumannii*-calcoaceticus complex (ABC).⁵

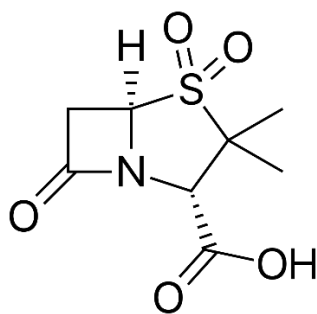


Figure.1: Structure of Sulbactam

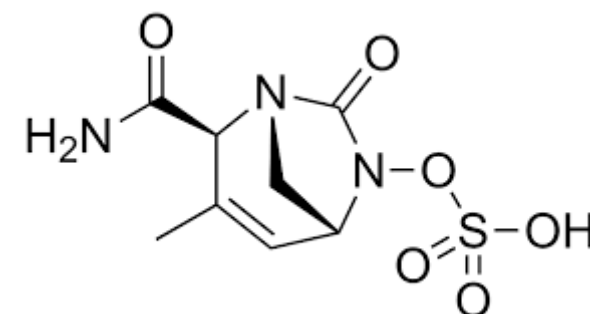


Figure.2: Structure of Durlobactam

Materials and Methods: Sulbactam and Durlobactam pure drugs (API), Combination Sulbactam and Durlobactam tablets (Xacduro), Distilled water, Acetonitrile, Phosphate buffer, Methanol, Potassium dihydrogen ortho phosphate buffer, Ortho-phosphoric acid. All the above chemicals and solvents are from Rankem.

Instrumentation: The development and method validation were conducted using a WATERS HPLC 2695 SYSTEM equipped with quaternary pumps, Photo Diode Array detector and Auto sampler integrated with Empower 2 Software.

Objective: In order to fulfill ICH standards, we need to design and test an HPLC technique that can detect Sulbactam and Durlobactam in pharmaceutical formulations at the same time.

Table:1 Chromatographic Conditions

Mobile phase	60% 0.1% OPA: 40% Acetonitrile
Flow rate	1.0 ml/min
Column	Phenomenex C18 (4.6 x 250mm, 5 μ m)
Detector wave length	270nm
Column temperature	30°C
Injection volume	10 μ L
Run time	10.0 min

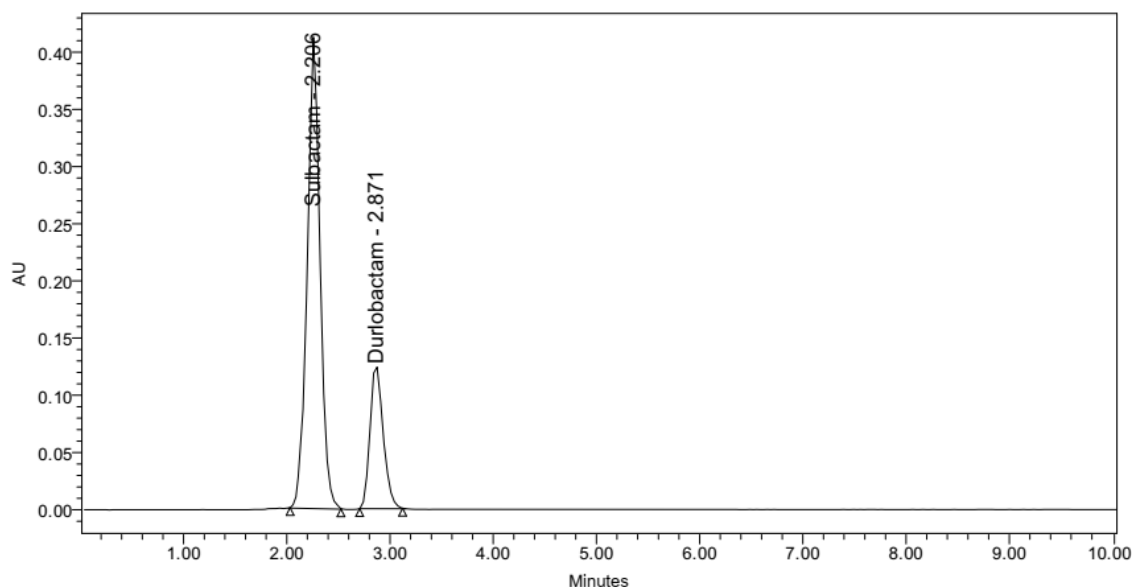


Figure.3: Optimized Chromatogram

Preparation of Standard stock solutions: Accurately weighed 10mg of Sulbactam, 5mg of Durlobactam and transferred to 10ml flasks and 3/4 th of diluents was added to these flask and sonicated for 10 minutes. Flask were made up with diluents and labeled as Standard stock solution. (1000 μ g/ml of Sulbactam and 500 μ g/ml Durlobactam).

Preparation of Sample stock solutions: 5 tablets were weighed and the average weight of each tablet was calculated, then the weight equivalent to 1 tablet was transferred into a 500ml volumetric flask, 5 ml of diluents was added and sonicated for 25 min, further the volume was made up with diluent and filtered by HPLC filters (2000 μ g/ml of Sulbactam and 1000 μ g/ml of Durlobactam).

System suitability parameters: The system suitability parameters were determined by preparing standard solutions of Sulbactam (100ppm) and Durlobactam (50ppm) and the solutions were injected six times and the parameters like peak tailing, resolution and USP plate count were determined. The % RSD for the area of six standard injections results should be not more than 2%.

Specificity: Checking of the interference in the optimized method. We should not find interfering peaks in blank and placebo at retention times of these drugs in this method. So this method was said to be specific.

Table:2 System suitability results

S no	Sulbactam			Durlobactam				
	Inj	RT(min)	USP Plate Count	Tailing	RT(min)	USP Plate Count	Tailing	Resolution
1		2.208	7732	1.28	2.869	9400	1.2	6
2		2.212	7852	1.28	2.873	9980	1.19	5.8
3		2.214	7158	1.24	2.874	10319	1.19	5.8
4		2.214	7132	1.28	2.876	11105	1.18	5.9
5		2.224	7728	1.21	2.914	9808	1.21	6.3
6		2.279	7216	1.3	2.988	9587	1.21	6

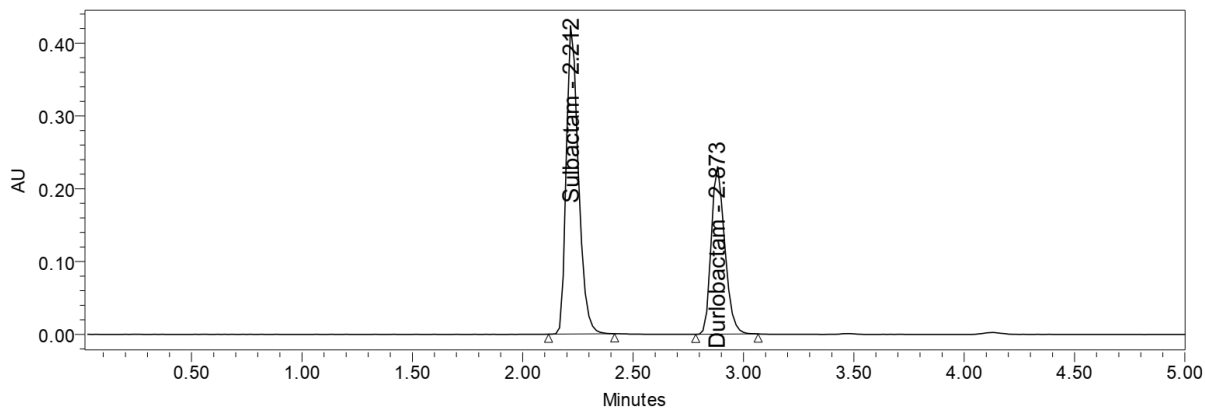


Figure.4: system suitability Chromatogram

Table:3 Specificity data

Sample name	Retention time(mins)
Sulbactam	2.206
Durlobactam	2.871

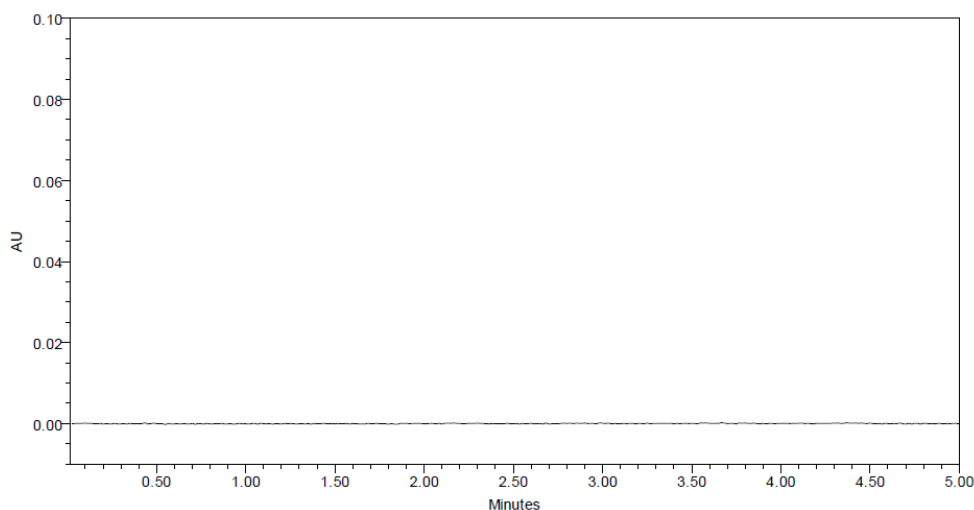


Figure.5 Blank

Linearity:

Calibration data is given in table and regression data in table 4 and calibration curve in figure 6 and 7

Table:4 Calibration data of Sulbactam and Durlobactam

Sulbactam		Durlobactam	
Conc (µg/mL)	Peak area	Conc (µg/mL)	Peak area
0	0	0	0
25	402410	12.5	241770
50	786734	25	474925
75	1165461	37.5	706333
100	1575220	50	956078
125	1957570	62.5	1192093
150	2344330	75	1411241

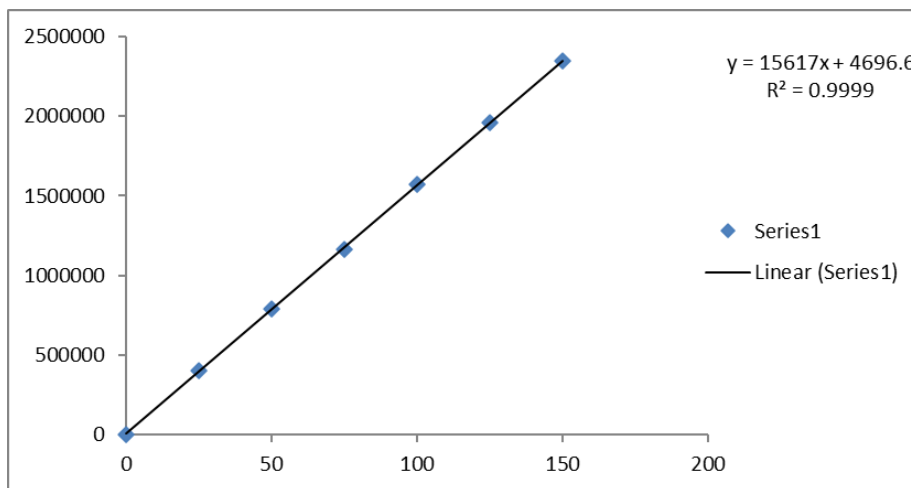


Figure.6: Calibration curve of Sulbactam

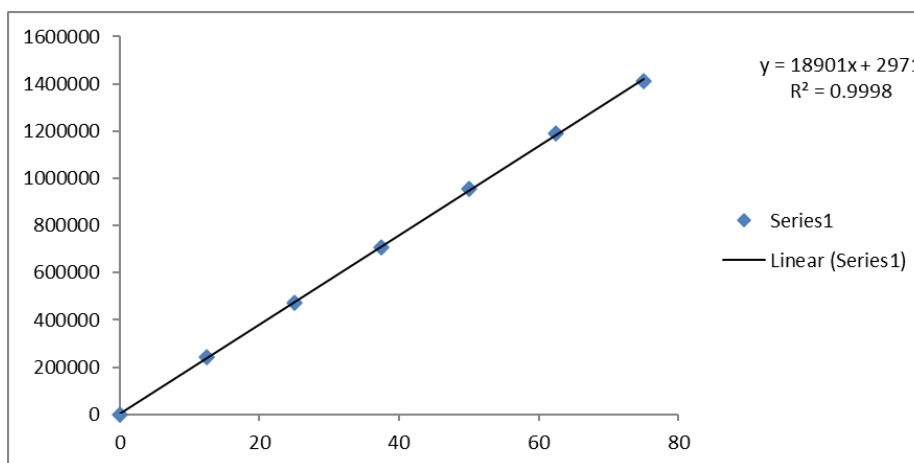


Figure.7: Calibration curve of Durlobactam

Accuracy:

Recovery data shown in table

Table:5 recovery data of Sulbactam and Durlobactam

% Level	Sulbactam			Durlobactam		
	Amount Spiked (µg/mL)	Amount recovered (µg/mL)	% Recovery	Amount Spiked (µg/mL)	Amount recovered (µg/mL)	% Recovery
50%	50	50.994	101.99	25	24.54209	98.17
	50	49.441	98.88	2	25.26216	101.05
	50	50.319	100.64	25	25.1974	100.79
100%	100	100.958	100.96	50	50.97101	101.94
	100	99.591	99.59	50	50.62367	101.25
	100	100.467	100.47	50	50.80837	101.62
150%	150	149.223	99.48	75	76.18322	101.58
	150	151.749	101.17	75	74.81758	99.76
	150	149.977	99.98	75	75.11063	100.15
% Recovery	100.35%			100.70%		

System precision was performed and the data was shown in table

Table:6 System precision of Sulbactam and Durlobactam

S. No	Area of Sulbactam	Area of Durlobactam
1.	1615103	977378
2.	1624387	985152
3.	1600006	970599
4.	1601721	971171
5.	1600097	963379
6.	1631506	983380
Mean	1611543	975177
S.D	13672.1	8340.7
%RSD	0.8	0.9

The % RSD for the peak areas of Sulbactam and Durlobactam obtained from six replicate injections of standard solution was within the limit.

Method Precision: The precision of the method was determined by analyzing a sample of Sulbactam and Durlobactam and shown in table

Table: method Precision

S. No	Area of Sulbactam	Area of Durlobactam
1.	1629420	992058
2.	1626262	984877
3.	1636635	986859
4.	1635464	990697
5.	1630581	983667
6.	1609817	976901
Mean	1628030	985843
S.D	9722.0	5456.1
%RSD	0.6	0.6

From the above results, the % RSD of method precision study was within the limit for Sulbactam and Durlobactam.

Robustness: Robustness conditions like Flow minus (0.9ml/min), Flow plus (1.1ml/min), mobile phase minus (65B:35A), mobile phase plus (55B:45A), temperature minus (25°C) and temperature plus(35°C) was maintained and samples were injected in duplicate manner. System suitability parameters were not much affected and all the parameters were passed. %RSD was within the limit.

Table:7 Robustness data for Gemcitabine and Paclitaxel.

S.no	Condition	%RSD of Sulbactam	%RSD of Durlobactam
1	Flow rate (-) 0.9ml/min	0.3	0.3
2	Flow rate (+) 1.1ml/min	0.8	0.6
3	Mobile phase (-) 65B:35A	0.2	0.2
4	Mobile phase (+) 55B:45A	0.4	0.4
5	Temperature (-) 25°C	0.4	0.4
6	Temperature (+) 35°C	1.2	1.3

CONCLUSION:

A simple, Accurate, precise method was developed for the simultaneous estimation of the Sulbactam and Durlobactam in bulk and Tablet dosage form. Retention of Sulbactam and Durlobactam were eluted at 2.206 min and 2.871 min. %RSD of the Sulbactam and Durlobactam were and found to be 0.8 and 0.9 respectively. %Recovery was obtained as 100.35% and 100.70% for Sulbactam and Durlobactam respectively. LOD, LOQ values obtained from regression equations of Sulbactam and Durlobactam were 0.63, 1.90 and 0.11, 0.34 respectively. Regression equation of Sulbactam is $y = 15617x + 4696.6$, and $y = 18901x + 2971$ of Durlobactam. Retention times were decreased and that run time was decreased, so the method developed was simple and economical that can be adopted in regular Quality control test in Industries.

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