Journal of Pharmaceutical Research and Technology
Journal homepage: https://journalprt.com/
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Research Article

Analytical Method Development and Validation for Estimation of Dexrabeprazole and Domperidone in Bulk and Tablet Dosage Form by RP-HPLC

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Article Info

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Received: 18/04/2025
Revised: 01/05/2025
Published: 14/05/2025

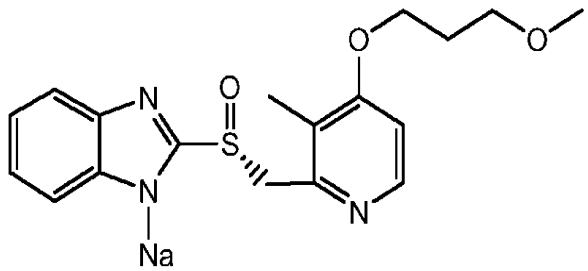
Keywords:
RP-HPLC, Dexrabeprazole, Domperidone, Simultaneous estimation, Method Development.

Abstract:

This study presents the development and validation of an analytical method for the simultaneous estimation of Dexrabeprazole and Domperidone in bulk and tablet dosage forms using Reverse Phase High-Performance liquid chromatography (RP-HPLC). The method was optimized and validated to ensure its accuracy, precision, and reliability. A Waters HPLC system with an auto- sampler and PDA detector (model 996) was utilized for the analysis. The chromatographic separation was achieved using an Altima C18 (4.6 *150 mm,5µm) with a mobile phase composed of methanol and acetone in a ratio of 65:35 (v/v). The flow rate was set at 1 ml/min, and detection was performed at a wavelength of 240 nm. The injection volume was 10 µl, and the total run time for the analysis was 14 min. The method demonstrated suitable performance in terms of resolution, peak shape, and retention time, making it a reliable approach quantification of dexrabeprazole and domperidone in both bulk and tablet formulations. The developed method complies with the regulatory requirements for analytical methods, ensuring its application in routine quality control and stability studies.

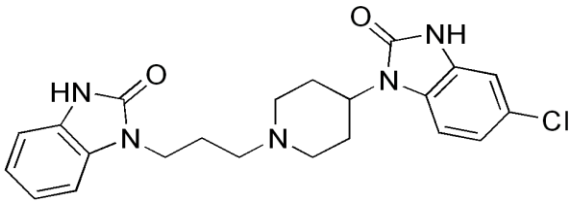
Introduction:

Dexrabeprazole



Dexrabeprazole is a proton pump inhibitor (PPI). It works by reducing the amount acid in stomach which helps in relief of acid related indigestion and heartburn. It is used in the treatment of acidity, gastroesophageal reflux disease (acid reflux) and peptic ulcer disease. (1-8)

Domperidone



Domperidone is an anti-sickness medicine. It helps you to stop feeling or being sick (nausea or vomiting). It works by causing the muscles at the top of your stomach to relax. This makes you less likely to be sick (vomit). (10-15)

MATERIALS AND METHODS (16-19):

Instruments(equipment): Compact HPLC system from WATERS Alliance 2695 separation module, Software: Empower 2996 PDA Detector.

Chemicals used: Methanol for HPLC, Buffer for HPLC (KH_2POH)

Raw materials: Dexrabeprazole and Domperidone are the working standards.

METHOD DEVELOPMENT (20-22):

Mobile phase: Methanol that has been degaussed to its purest form.

Chromatography conditions:

The volumetric flow rate	: 1ml/min.
Column	: Altima C18 (4.6 ×150mm,5µ)
Mobile phase	: Methanol: Acetone (65:35v/v)
Wavelength	: 240nm
Injection volume	: 10 µl

Trails

Trail 1:

Mobile phase	: Methanol: Water (80: 20%v/v)
Column	: ODS C18 (4.6 ×150mm, 5 µm particle size) make; waters
Flow rate	: 0.6 ml /min
Wavelength	: 240nm
Column temp	: 28℃

Injection volume : 10 µl

Run time : 10 minutes

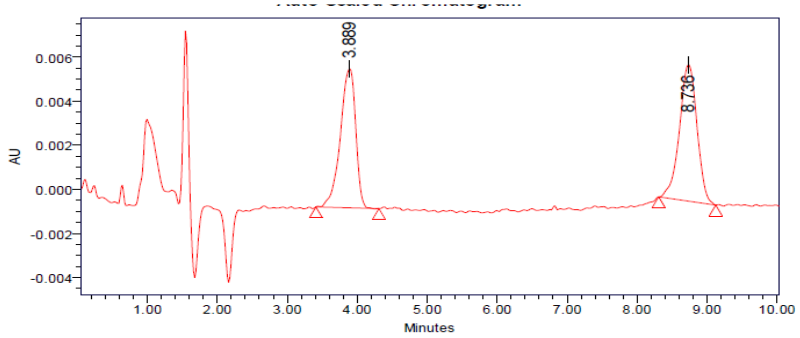


Fig. 1: Chromatogram for trail 1

Table 1: Peak results for trail 1

Sr. No.	Peak name	Rt	Area	Height	USP resolution	USP Tailing	USP plate count
1.	Dexrabeprazole	3.889	96377	6320	-	0.81	1642
2.	Domperidone	8.736	107991	6192	11.26	0.94	6110

Observation:

This trail shows improper base line in the chromatogram, so more trails were required for obtaining good peaks.

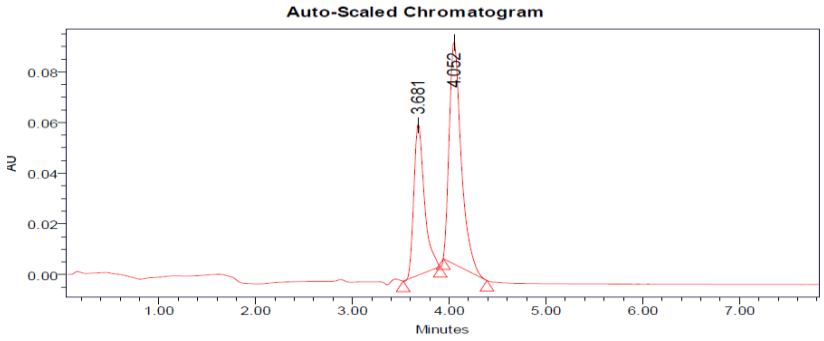


Fig. 2: Chromatogram For Trail 2

Trail 2:

Mobile Phase : Water (pH 3): Acetonitrile (65%-35%v/v)

Column : Zodiac C18 (4.6 x 250 mm)5µ

Flow Rate : 0.7ml/min

Wave Length : 240nm

Column Temp : 40 ℃

Injection Volume : 10 µl

Run Time : 7 minutes

Table 2: Peak Results for Trail 2

Sr. No.	Peak name	Rt	Area	Height	USP Resolution	USP Tailing	USP Plate Count
1.	Dexrabeprazole	3.681	453159	59898		1.42	5843
2.	Domperidone	4.052	755096	87984	1.72	1.64	5346

Observation: This Trail Show Very Less Plate Count, and Show improper base line in The Chromatogram, so more Trails Were Required for obtaining good Peaks.

Trail 3:

Mobile Phase : Methanol: ACN (70:40%v/v)

Column : Zodiac C18 (4.6 x 250mm 5 µm)

Flow Rate : 0.8 nm/min

Wave length : 240 nm

Column Temp : 40 ℃

Injection Volume : 10 µl

Run Time : 10 minutes

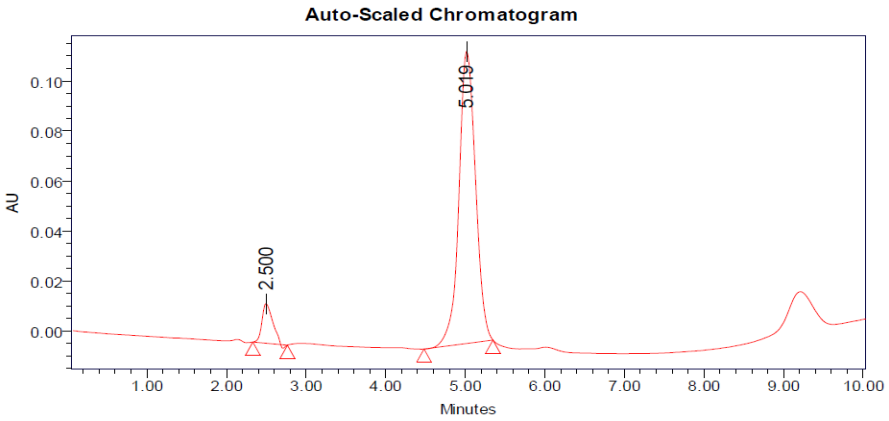


Fig. 3: Chromatogram For trail 3

Table 3: Peak Results for trail 3

Sr. No.	Peak Name	Rt	Area	Height	USP Resolution	USP Tailing	USP Plate Count
1.	Dexrabeprazole	2.500	152465	15939	-	1.24	1465
2.	Domperidone	5.019	163743	17063	7.85	0.97	1202

OBSERVATION:

This trial shows improper baseline and shows less plate count in the chromatogram, so more trials were required for obtaining peaks.

RESULTS AND DISCUSSIONS:

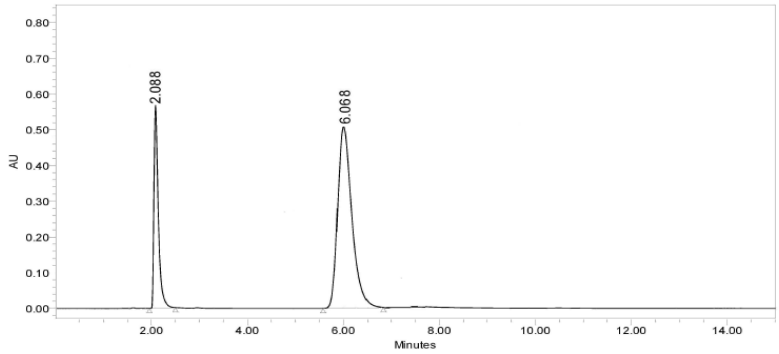


Fig. 4: Chromatogram showing assay of standard

Table 4: Peak results for assay standard

Sr. No.	Name	Rt	Area	Height	USP Resolution	USP Tailing	USP Plate count	Injection
1	Dexrabeprazole	2.087	3465681	567917		1.0	5568.0	1
2	Domperidone	6.067	1623594	517719	2.5	1.1	5359.2	1
3	Dexrabeprazole	2.088	346541	567933		1.0	5565.5	2
4	Domperidone	6.068	16298543	517733	2.5	1.1	5355.2	2
5	Dexrabeprazole	2.088	3465423	567933		1.0	5545.5	3
6	Domperidone	6.068	16265213	517733	2.5	1.1	5352.1	3

ACCURACY:

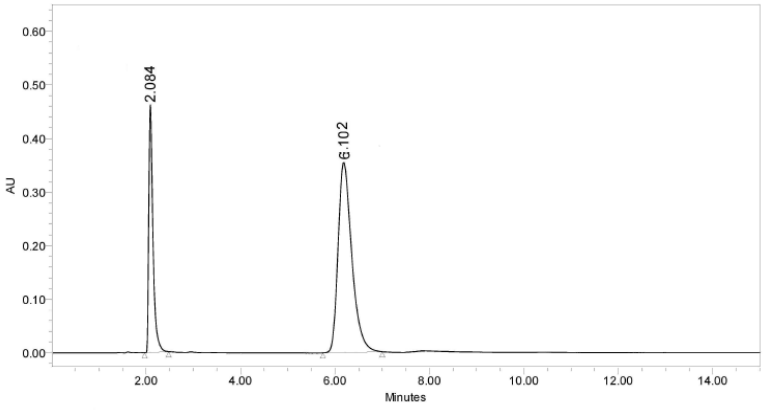


Fig. 5: Chromatogram showing accuracy-100% injection

Table 5: The accuracy results for Dexrabeprazole

% Concentration (at specification level)	Area	Amount Added (ppm)	Amount Found (ppm)	% Recovery	Mean Recovery
50%	154793	37.5	37.52	101.5	100.9%
100%	4035883	75	75.1	101.4	
150%	4451005	112.5	112.47	99.4	

Table 6: The accuracy results for Domperidone

% concentration(at specification Level)	Area	Amount Added (ppm)	Amount found (ppm)	%Recovery	Mean recovery
50%	1084420	15	15.07	100.2	99.6%
100%	2096069	40	29.6	99.4	
150%	3112684	45	44.8	99.5	

PRECISION

The precision of an analytical procedure expresses the closeness of agreement between a series of measurements obtained from multiple sampling of the same homogeneous sample under the prescribed conditions.

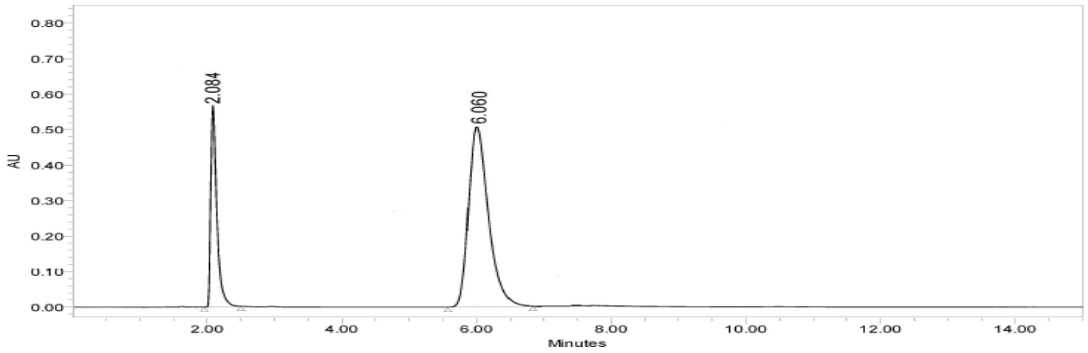


Fig. 6: Chromatogram showing precision injection

Table 7: Result of repeatability for Dexrabeprazole

Sr. No.	Name	Rt	Area	Height	USP plate count	USP Tailing
1	Dexrabeprazole	2.084	3569412	567917	5568.0	1.0
2	Dexrabeprazole	2.083	3465125	517719	5359.2	1.1
3	Dexrabeprazole	2.082	3598154	567933	5565.5	1.0
4	Dexrabeprazole	2.081	3586491	517733	5355.2	1.1
5	Dexrabeprazole	2.080	3582694	567917	5568.0	1.0
Mean			3560375			
Std. Dev			54225.61			
% RSD			1.524031			

Table 8: Results of method precision for domperidone

Sr. No.	Name	Rt	Area	Height	USP plate count	USP Tailing	USP Resolution
1	Domperidone	6.056	1582264	567917	5568.0	1.0	2.5
2	Domperidone	6.057	1586491	517719	5359.2	1.1	2.5
3	Domperidone	6.058	1598154	567933	5565.5	1.0	2.5
4	Domperidone	6.059	1564125	157733	5355.2	1.1	2.5
5	Domperidone	6.060	1569412	562173	5568.0	1.0	2.5
Mean			1580089				
Std. Dev			13609.81				
%RSD			0.861332				

LINEARITY:

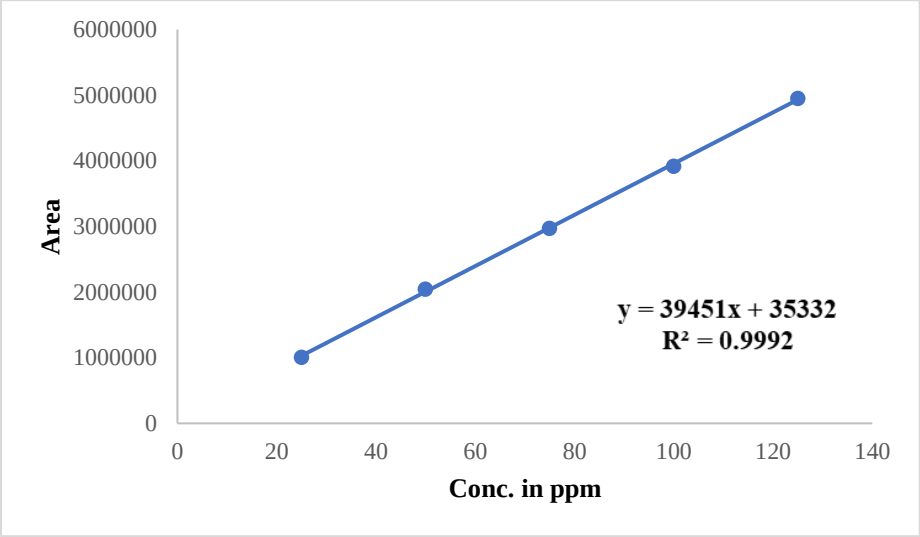
CHROMATOGHIC DATA FOR LINEARITY STUDY:

DEXRABEPRAZOLE

Table 9: Chromatographic data for linearity study of Dexrabeprazole

Concentration µg/ml	Average Peak Area
25	1010252
50	2049374
75	2972706
100	3921068
125	4952813

Fig. 7: Calibration graph for Dexrabeprazole

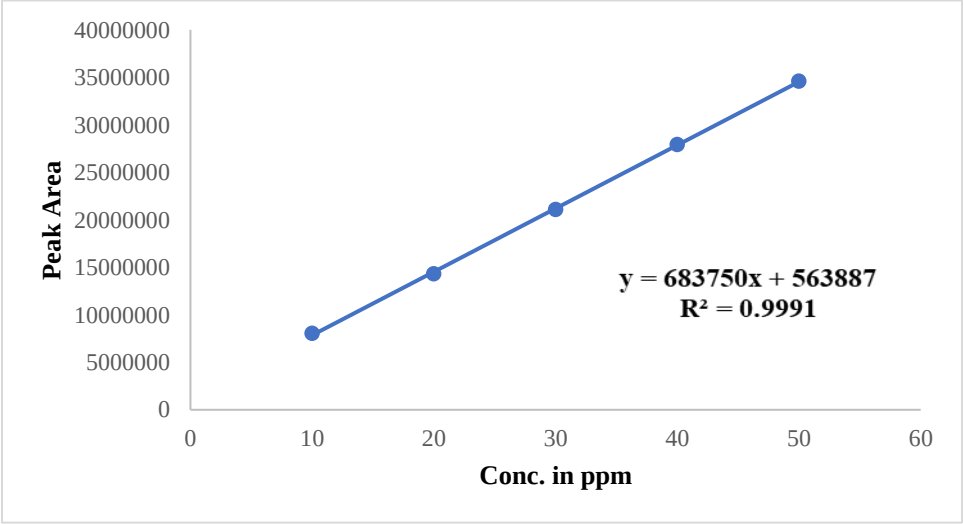


Domperidone:

Table 10: Chromatographic data for linearity study of Domperidone

Concentration µg/ml	Average Peak Area
10	8040807
20	14318417
30	21087985
40	27913928
50	34584741

Fig. 8: Calibration graph for Domperidone



System Suitability:

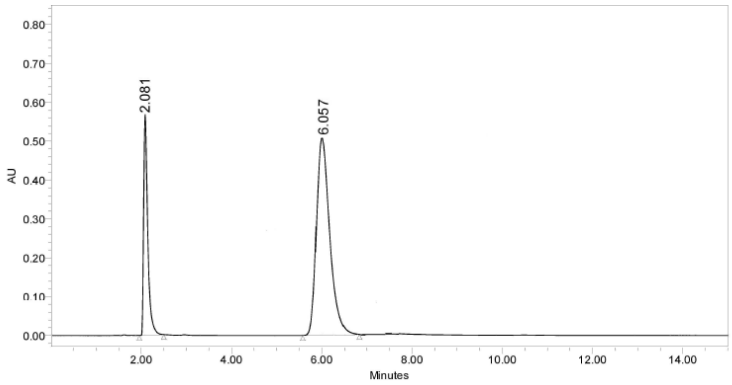


Fig 9: Chromatogram system suitability

Table 9: Results of System Suitability for Dexrabeprazole

Sr. No.	Name	Rt	Area	Height	USP Plate Count	USP Tailing
1	Dexrabeprazole	2.080	3569412	567917	5568.0	1.0
2	Dexrabeprazole	2.080	3465125	517719	6359.2	1.1
3	Dexrabeprazole	2.080	3598154	567933	5565.5	1.0
4	Dexrabeprazole	2.081	3586491	517733	5355.2	1.1
5	Dexrabeprazole	2.081	3582694	567917	6348.0	1.0
Mean			3560375			
Std.Dev			54225.61			
% RSD			1.524031			

Table 10: Results of System Suitability for Domperidone

Sr. No.	Name	Rt	Area	Height	USP Plate Count	USP Tailing	USP Resolution
1	Domperidone	2.080	3582264	567917	5568.0	1.0	2.5
2	Domperidone	2.080	3586491	517719	5359.2	1.1	2.5
3	Domperidone	2.080	3598154	567933	5565.5	1.0	2.5
4	Domperidone	2.081	3564125	517733	5355.2	1.1	2.5
5	Domperidone	2.081	3569412	562173	5568.0	1.0	2.5
Mean			3580089				
Std. Dev			13609.81				
%RSD			0.380153				

ROBUSTNESS:

Table 11: Results For Robustness of dexrabeprazole

Parameter Used for Sample Analysis	Peak Area	Retention Time	Theoretical Plates	Tailing Factor
Flow Rate of 1.0mL/min	342541	2.088	5568.2	1.0
Flow Rate of 0.9mL/min	3425282	3.111	5922.2	1.2
Flow Rate of 1.1mL/min	3517879	1.880	5868.8	1.2
Less aqueous phase	3175487	3.101	5836.2	1.2
More aqueous phase	3365431	1.881	5282.6	1.1

Table 12: Results For Robustness domperidone

Parameter used for sample analysis	Peak Area	Retention Time	Theoretical Plates	Tailing Factor
Flow rate of 1.0ml/min	2029854	6.068	5359.2	1.1
Flow rate of 0.9ml/min	1738319	7.101	5999.1	1.2
Flow rate of 1.1 ml/min	1638404	5.007	5989.2	1.1
Less aqueous phase	1973724	7.108	5387.2	1.1
More aqueous phase	2102838	5.008	5938.1	1.1

CONCLUSION:

The RP-HPLC Method developed and validated in this study provides a robust and reliable approach for the simultaneous quantification of Dex rabeprazole and Domperidone in bulk and tablet dosage forms. The use of a waters HPLC system with a PDA detector, coupled with the optimized chromatographic conditions, ensured accurate and precise measurement of both compounds. The method demonstrated excellent resolution, peak symmetry, and reproducibility, which are critical for quality control in pharmaceutical manufacturing. Compliance with regulatory requirements confirms the method's suitability for routine application in quality control

and stability testing. Overall, the method is effective for ensuring quality and consistency of Dex rabeprazole and Domperidone in various formulations

ACKNOWLEGEMNT:

The authors are thankful to Dr. M. Venkataramana, Principal of Surabhi Dayakar Rao College of Pharmacy for providing necessary facilities to carry out the entire research work.

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