

Development and Validation of an HPLC Method for the Determination of Meloxicam and Pantoprazole in a Combined Formulation

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1. Compatibility Tests

The compatibility of meloxicam and pantoprazole was checked; the samples were analyzed on Fourier Transform Infrared (FTIR) and Differential Scanning Calorimeter (DSC) devices for this purpose.

FTIR is an essential analytical technique for determining compatibility. The analysis is based on the exact functional group change during the interaction between the drug and the drug excipients.

On the other hand, DSC is a thermal analysis device that measures physical properties and temperature change over time.

All of the excipients used in the formula were compatible with both drugs in IR and DSC studies.

2. Dissolution Test

According to the US Pharmacopeia, the following procedures were done during the experiment. A 1000 mL of dissolution media was placed in a dissolution vessel. Next, one tablet was introduced into the vessel of the dissolution apparatus, taking care to exclude air bubbles from the tablet's surface.

Immediately operate the apparatus at 50 rpm. The vessel was kept covered for the test duration and verified the mixture's temperature under test at the beginning, mid, and end.

After 30 minutes, 10 mL was withdrawn from a region midway between the surface of the dissolution medium and the top of the rotating paddle, not less than 1 cm from the vessel wall, and filtered through a 0.7- μ m glass syringe filter.

The operating conditions were: the medium: HCl; 1000 mL, speed: 50 rpm, time: 30 minutes, apparatus: II, and filter type: 0.7 μ m glass filter.

Table 1A. Assay test details of meloxicam.

Sample ID	AUC	Conc actual ppm (mg/L)	Conc theoretical ppm (mg/L)	Av.	ASSAY %	Assay B#	RSD%
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Pantoprazole (10mg) Meloxicam (15) mg Sample 1 Rep1	1892959	147.8			99		
Pantoprazole (10mg) Meloxicam (15) mg Sample 1 Rep2	1957959	152.9	150.0	151.8	102	101.2	
Pantoprazole (10mg) Meloxicam (15) mg Sample 1 Rep3	1982207	154.7			103		
Pantoprazole (10mg) Meloxicam (15) mg Sample 2 Rep1	1921804	150.0			100		
Pantoprazole (10mg) Meloxicam (15) mg Sample 2 Rep2	1937167	151.2	150.0	152.7	101	101.8	101
Pantoprazole (10mg) Meloxicam (15) mg Sample 2 Rep3	2010235	156.9			105		
Pantoprazole (10mg) Meloxicam (15) mg Sample 3 Rep1	1939649	151.4			101		1
Pantoprazole (10mg) Meloxicam (15) mg Sample 3 Rep2	1923402	150.1	150.0	150.4		100.2	
Pantoprazole (10mg) Meloxicam (15) mg Sample 3 Rep3	1915415	149.5			100		

Table 1B. Assay test details of pantoprazole.

Sample ID	AUC	Conc. actual ppm (mg/L)	Conc theoretical ppm (mg/L)	Av.	ASSAY %	Assay B#	RSD%
Pantoprazole (10mg) Meloxicam (15) mg Sample 1 Rep1	2506851	96.7			97		
Pantoprazole (10mg) Meloxicam (15) mg Sample 1 Rep2	2645242	102.1	100.0	99.1	102	99.1	
Pantoprazole (10mg) Meloxicam (15) mg Sample 1 Rep3	2554882	98.6			99		101
Pantoprazole (10mg) Meloxicam (15) mg Sample 2 Rep1	2654845	102.5			102		
Pantoprazole (10mg) Meloxicam (15) mg Sample 2 Rep2	2605418	100.6	100.0	101.4	101	101.4	2

Pantoprazole (10mg) Meloxicam (15) mg Sample 2 Rep3	2618783	101.1			101	
Pantoprazole (10mg) Meloxicam (15) mg Sample 3 Rep1	2687895	103.7			104	
Pantoprazole (10mg) Meloxicam (15) mg Sample 3 Rep2	2597561	100.2	100.0	102.1		102.1
Pantoprazole (10mg) Meloxicam (15) mg Sample 3 Rep3	2648562	102.2			100	

Table 2A. Dissolution of meloxicam.

Sample ID	Area	Conc. Actual ppm(mg/l)	Conc. Theoretical ppm(mg/l)	Accuracy	Av.	RSD%
Dissolution V1	198456	15.2	15.0	102	100.09	0.01
Dissolution V2	199546	15.3	15.0	102		
Dissolution V3	194756	15.0	15.0	100		
Dissolution V4	193564	14.9	15.0	99		
Dissolution V5	193564	14.9	15.0	99		
Dissolution V6	193413	14.8	15.0	99		

Table 2B. Dissolution of Pantoprazole.

Sample ID	Area	Conc. Actual ppm(mg/l)	Conc. Theoretical ppm(mg/l)	Accuracy	Av.	RSD%
Dissolution V1	274566	10.3	10.0	103	102.04	0.03
Dissolution V2	270155	10.1	10.0	101		
Dissolution V3	268745	10.1	10.0	101		
Dissolution V4	261548	9.8	10.0	98		
Dissolution V5	268954	10.1	10.0	101		
Dissolution V6	287565	10.8	10.0	108		

Table 3A. Stability of meloxicam.

Sample ID	AUC	Conc. Actual ppm(mg/l)	Conc. Theoretical ppm(mg/l)	Av.	Assay%
Meloxicam (15) mg Sample1 initial	971088	75.7			101
Meloxicam (15) mg Sample1 12 hr.	969443	75.5			101
Meloxicam (15) mg Sample1 24 hr.	9656587	75.2	75.0	75.5	100

Table 3B. Stability of pantoprazole.

Sample ID	AUC	Conc. Actual ppm(mg\l)	Conc. Theoretical ppm(mg\l)	Av.	Assay%
Pantoprazole (10mg) Sample1 Initial	1277454	49.1	50.0	48.8	98
Pantoprazole (10mg) Sample1 12 hr.	1272398	48.9			98
Pantoprazole (10mg) Sample1 24 hr.	1254686	48.3			97
