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ORIGINAL ARTICLE

Development and Validation of High-Performance Thin Layer Chromatographic Method for the Simultaneous Estimation of Dapagliflozin and Vildagliptin in Fixed-Dose Combination

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ABSTRACT

Objectives: The objective of this study was to develop a simple, precise, and accurate high-performance thin-layer chromatographic (HPTLC) method for the simultaneous estimation of dapagliflozin (DAP) and vildagliptin (VIL) in a combined pharmaceutical formulation. Managing diabetes often involves using a combination of drugs to better control blood sugar levels. One such effective formulation is combination of DAP, an SGLT2 inhibitor, with VIL, a DPP-4 inhibitor, in a single formulation. To ensure the quality and consistency of these combination products, it is important to have a simple and reliable method for analyzing both drugs simultaneously.

Materials and Methods: An aluminium-backed pre-coated silica gel 60 F_{254} TLC plate was employed as the stationary phase. The mobile phase consisted of toluene, methanol, and ethyl acetate in a volumetric ratio of 5:3:2. Prior to plate development, the chamber was saturated with the mobile phase for 20 minutes. Detection was carried out at 210 nm, selected based on the isosbestic point of the analytes.

Results: The developed method successfully separated the analytes with retardation factor values of 0.57±0.02 for DAP and 0.26±0.02 for VIL. The method exhibited linearity in the concentration ranges of 0.6 to 1.4 µg per band for DAP, with a correlation coefficient (r^2) of 0.997 and 6 to 14 µg per band for VIL, with an r^2 of 0.998. The limit of detection was found to be 0.02 µg/band for DAP and 0.19 µg/band for VIL. Similarly, the limit of quantification was determined to be 0.07 µg/band for DAP and 0.58 µg/band for VIL.

Conclusion: The proposed HPTLC method allows for the simultaneous estimation of DAP and VIL with high accuracy, precision, and sensitivity. Owing to its satisfactory analytical performance, the method is suitable for routine quality control of combined dosage forms containing DAP and VIL.

Keywords: HPTLC, anti-diabetic, dapagliflozin, vildagliptin, method development

INTRODUCTION

Diabetes mellitus (DM) is a chronic, complex metabolic disorder associated with hyperglycemia. DM is primarily classified into type 1 and type 2 DM (T2DM). Type 1 DM is insulin-dependent, whereas type 2 is insulin-independent, which accounts for more than 85% of total affected patients worldwide.[1] Various therapeutic agents are available and are also being developed, targeting different pathophysiological aspects related to glycemic activity.[2] Metformin is one of the well-established oral anti-diabetic medications.[3] Early combination therapy provides more significant glycemic control than metformin monotherapy.[4]

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The fixed-dose combination (FDC) of dapagliflozin (DAP) and vildagliptin (VIL) is indicated for patients with T2DM uncontrolled by metformin monotherapy.[5]

DAP is chemically (2S,3R,4R,5S,6R)-2-[4-chloro-3-[(4-ethoxyphenyl)methyl]phenyl]-6-(hydroxymethyl)oxane-3,4,5-triol;[6,7] it provides effective glycemic control with a low-risk of hypoglycemia, lowers body weight, and has adequate control over blood pressure. Its mechanism of action is insulin-independent.[8] It acts by inhibiting sodium glucose co-transporter 2, thereby blocking the glucose reabsorption from the kidney, which in turn increases the elimination of glucose in urine.[9,10] The structure of DAP is given in Figure 1.

VIL is chemically: (2S)-1-[2-[(3-hydroxy-1-adamantyl)amino] acetyl]pyrrolidine-2-carbonitrile.[11] It acts by enhancing the incretin levels by inhibiting dipeptidyl peptidase-4, which degrades the incretin, increasing insulin sensitivity, and decreasing glucagon secretion.[12-14] The structure of VIL is given in Figure 2.

According to the literature review, there are currently few published high-performance thin-layer chromatographic (HPTLC) methods, and only one HPTLC method is available for estimating DAP and VIL simultaneously. Still, the published HPTLC method has used benzene as a component of the mobile phase.[15] A comparison table for existing methods versus the current method is given in Table 1. We developed a safe, simple, precise, and accurate HPTLC method for the simultaneous estimation of DAP and VIL in tablet and bulk dosage forms. The method mentioned in the literature incorporated the use of benzene as a component of the mobile phase, which is a class 1 solvent and is considered carcinogenic, so we have proceeded with solvents such as toluene, ethyl acetate, and methanol, which are comparatively safer. The availability

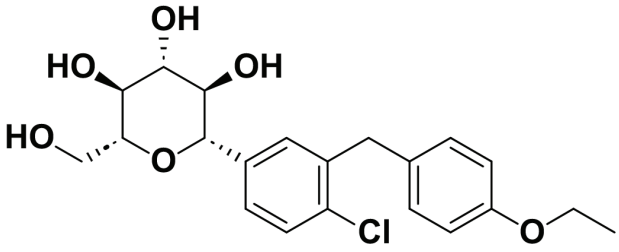

Figure 1. Structure of dapagliflozin

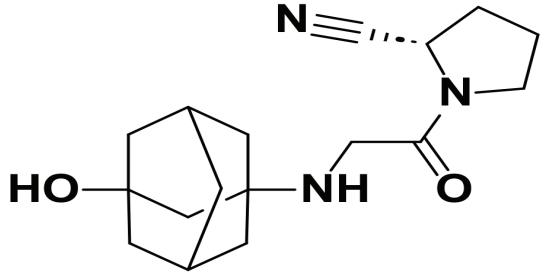

Figure 2. Structure of vildagliptin

Table 1. A comparison table for existing methods vs. the current method for simultaneous estimation of DAP and VIL

Comparison table		HPTLC		HPLC	
		Current method	Existing method	Existing method	Existing method
Stationary phase		Silica gel 60 F_{254}	Silica gel 60 F_{254}	C_{18} (250mm x 4.6mm, 5µm)	C_{18} (250mm x 4.6mm, 5µm)
Mobile phase		Toluene: ethyl acetate: methanol (5:2:3, *v/v/v*)	Acetonitrile: benzene: glacial acetic acid (9:1:2 *v/v/v*)	Methanol: 0.01% Trifluoroacetic acid (pH 2.78) (95:5% *v/v*) Isocratic mode	0.05 M KH2PO4: acetonitrile: methanol (35:10:55% *v/v/v*) Isocratic mode
Retardation factor for HPTLC	DAP	0.57	0.84	4.070 min	7.97 min
Retention time for HPLC	VIL	0.26	0.21	2.282 min	2.91 min
Linearity and range	DAP	0.6-1.4 µg/band (r^2=0.997)	0.2-2.5 µg/band (r^2=0.9931)	10-60 µg/mL (r^2=0.999)	1-5 µg/mL
	VIL	6.0-14 µg/band (r^2=0.998)	2.0-25 µg/band (r^2=0.9954)		10-50 µg/mL
LOD	DAP	0.02 µg/band	0.021 µg/band	0.3342 µg/mL	0.039 µg/mL
	VIL	0.19 µg/band	0.154 µg/band	0.9012 µg/mL	0.585 µg/mL
LOQ	DAP	0.07 µg/band	0.063 µg/band	1.0128 µg/mL	0.128 µg/mL
	VIL	0.58 µg/band	0.469 µg/band	2.7310 µg/mL	1.930 µg/mL

DAP: Dapagliflozin, HPLC: High-performance liquid chromatography, HPTLC: High-performance thin layer chromatography, LOD: Limit of detection, LOQ: Limit of quantification, VIL: Vildagliptin, min: Minimum

of robust, cost-effective, safe, and rapid analytical methods for the simultaneous estimation of these drugs in combined dosage forms remains limited. Therefore, the development and validation of an HPTLC method is essential to ensure quality control, regulatory compliance, and batch-to-batch consistency during pharmaceutical manufacturing. This study addresses this need by establishing a simple, precise, and reliable HPTLC method for the simultaneous quantification of DAP and VIL in FDCs. The developed chromatographic method was validated for multiple parameters, including linearity, accuracy, precision, limit of detection (LOD), limit of quantification (LOQ), and specificity, by ICH Q2(R1) guidelines.[16] The aim of this study is to develop a simultaneous quantitative HPTLC method for the estimation of DAP and VIL in FDCs.

MATERIALS AND METHODS

DAP and VIL pure substances were purchased from Yarrowchem (Mumbai, India) and Astitva Chemicals (Gujarat, India), respectively; the FDC tablet dosage form was procured locally; and toluene was procured from Sisco Laboratories Pvt. Ltd., Mumbai, India. Methanol (VetecTM) was obtained from Sigma-Aldrich Chemicals Pvt. Ltd., Bangalore, India. Ethyl acetate (AvantorTM) was procured from Avantor Performance Materials, Maharashtra, India. All the reagents used for this analytical work were of Analytical Reagent grade.

Instrumentation and chromatographic conditions

Chromatography was performed by spotting the sample using a CAMAG Hamilton syringe with a capacity of 100 µL (Bonaduz, Switzerland) on a precoated silica gel 60 F254 aluminium-backed TLC plate [Merck, Darmstadt, Germany]. Using the CAMAG Linomat V applicator (Switzerland), the sample was spotted onto the plate with a bandwidth of 8 mm at a constant dosage speed of 150 nL s-1. For the chromatographic development, a 20x10 cm twin trough glass chamber (CAMAG, Switzerland) was used. We performed the chromatographic separation using the stationary phase of an aluminium-backed TLC plate pre-coated with silica gel 60 F254 (20x10 cm). The mobile phase for development was toluene, methanol, and ethyl acetate (5:3:2, *v/v/v*). For 20 minutes, the mobile phase was allowed to saturate the development chamber. At room temperature, the developed plate was air-dried for 10 minutes to evaporate the mobile phase. The CAMAG TLC scanner IV was used to scan the developed plate in the absorbance mode. The slit dimension of 6x0.45 mm and the scanning speed of 10 mm s-1 were selected for processing. For detection, a deuterium lamp was selected as the radiation source; we set the detection wavelength at 210 nm. Data analysis and interpretation were performed using CAMAG VisionCATS software (V 3.1).

Preparation of standard and sample solutions

Precisely 10 mg of DAP was weighed and transferred into a 10 mL volumetric flask. The standard DAP was then dissolved and made up to 10 mL using methanol to get the standard stock solution having a concentration of 1000 µg mL^{-1}. The working solution of the mixture of DAP and VIL was prepared by adding 1 mL of DAP stock solution into a 10 mL standard flask containing 10 mg of VIL. Using methanol, we adjusted the volume to 10 mL to get the working concentration of 100 µg mL^{-1} and 1000 µg mL^{-1} of DAP and VIL, respectively.

To prepare the sample solution, twenty tablets were accurately weighed and triturated. The powder weight equivalent to 10 mg of DAP was weighed and transferred into a 100 mL standard flask. Initially, the volume was made up to 50 mL using methanol, then sonicated for 30 minutes, and filtered. The final volume was adjusted to 100 mL by using methanol.

Validation of the chromatographic method

In accordance with ICH Q2(R1) guidelines, the developed HPTLC method was validated for specificity, accuracy, intra-day, inter-day precision, repeatability, linearity of sample application, and area under the curve measurement. Further, the LOD and LOQ for DAP and VIL were determined based on the standard deviation of the slope.

Linearity

For linearity of the method, an aliquot of 6-14 µL of working standard solution (DAP 100 µg mL^{-1} and VIL 1000 µg mL^{-1}) was used to obtain 0.6-1.4 µg/band for DAP and 6-14 µg/band for VIL. TLC plates were developed under optimized conditions and scanned using a densitometer. Peak areas were noted for the corresponding concentrations of DAP and VIL. Peak areas of DAP and VIL plotted against their corresponding concentrations were used to develop the standard calibration curve.

Accuracy

The developed HPTLC method was evaluated for accuracy at three levels in the drug product (50%, 100%, 150%) by adding a known amount of pure DAP and VIL to the product, and the recovery (%) was calculated. Triplicates were performed for each level. Results obtained from this study were then compared with those of the expected value.

Precision

To demonstrate the precision of the method, parameters such as intra-day precision, inter-day precision, and repeatability studies were employed.

Repeatability

Sample application repeatability

Sample application repeatability was evaluated by spotting DAP (0.8 µg/band) and VIL (8 µg/band) six times on a precoated TLC plate. The plate was then developed by using the optimized HPTLC method and scanned. The % relative standard deviation (RSD%) of peak areas for six spots of DAP and VIL was calculated.

Sample measurement repeatability

Sample measurement repeatability was evaluated by spotting DAP (0.8 µg/band) and VIL (8 µg/band) on a precoated TLC plate. The plate was developed. After development, the corresponding spots of DAP and VIL were scanned using a scanner six times, without any change in the position of the developed TLC plate, and the RSD% of peak areas obtained for six scans of each analyte was computed.

Intra-day precision and inter-day precision

Intra-day precision and inter-day precision were studied by analyzing the responses at three different concentration levels (0.6, 0.8, 1.0 µg/band for DAP and 6, 8, and 10 µg/band for VIL), and the RSD% values were calculated.

Detection limit and quantification limit

The LOD and LOQ for DAP and VIL of this method were calculated by using the formulae LOD = (3.3× standard deviation of intercept)/slope and LOQ = (10× standard deviation of intercept)/slope, where the slope is obtained from the line equation of the calibration graph of DAP and VIL individually.

Specificity

By comparing the band's peak start, peak apex, and peak end position spectra of standard drugs and samples, the specificity of the procedure was evaluated.

RESULTS

Optimization of chromatographic conditions and mobile phase composition

Initially, individual solvents were tried as the mobile phase based on the band shape, and further optimization of the retardation factor (R_f) values was conducted. Further, different mixtures of solvents (n-hexane: methanol: toluene, toluene: methanol: ethyl acetate) have been tried as a mobile phase for chromatographic development. In the mixture of n-hexane, methanol, and toluene, the band of VIL appeared at an R_f of 0.11, which is unacceptable. The combination of Toluene, methanol, and ethyl acetate resulted in better separation of both the standard drugs. Further, different compositions of the same mixture (Toluene: methanol: ethyl acetate, 4:4:2 *v/v/v*, 5:3:2 *v/v/v*) have been tried. Toluene: methanol: ethyl acetate, 5:3:2 *v/v/v,* resulted in proper separation and compact bands, which resulted in good band shape for both the analytes. When tried with methanol at lower levels in mobile phase composition, VIL resulted in R_f less than 0.2, which is usually an unacceptable R_f. However, higher methanol levels improved the R_f of VIL, but it resulted in the poor peak shape of DAP. Finally, the mobile phase composition was optimized to be toluene: methanol: ethyl acetate in the ratio of 5:3:2 *v/v/v*. Based on the isobestic point obtained from the overlay spectrum, 210 nm was selected as the detection wavelength. Optimization of saturation time was performed by trying different saturation periods of 10, 20, and 30 minutes. Among those, saturation times of 10 minutes, the solvent front was not linear as expected. However, with 20 and 30 minutes, a linear development was observed, and there was no significant difference between them. Therefore, 20 minutes was selected as the optimized saturation time for this method. A typical chromatogram of standard DAP and VIL separated using the proposed method is presented in Figure 3. Table 2 represents the optimal conditions for chromatography.

Linearity

The linearity of this method was established by spotting nine concentrations of the drug, which was prepared using methanol in the range of 0.6-1.4 µg/band for DAP and 6-14 µg/band for VIL.

Table 2. Fixed chromatographic conditions

Stationary phase	Silica gel 60 F_{254}
Mobile phase	Toluene: ethyl acetate: methanol (5:2:3, *v/v/v*)
Chamber saturation time	20 minutes
Bandwidth	8 mm
Slit dimension	6x0.45 mm
Detection wavelength	210 nm

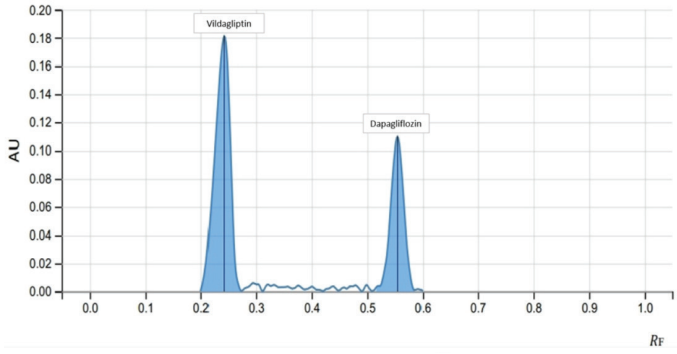

Figure 3. A typical densitogram of standard dapagliflozin and vildagliptin
AU: Absorbance unit

The calibration regression equation from the calibration plot of DAP was y = 0.0071x+0.0004, and the correlation coefficient (r^2) was 0.9972. The calibration regression equation from the calibration plot of VIL was y y = 0.0012x-0.0003, and the correlation coefficient (r^2) was 0.998. The standard calibration curves obtained for DAP and VIL are given in Figures 4 and 5.

Accuracy

The recovery (%) for DAP and VIL after spiking the known amount of standard into their pharmaceutical dosage forms fell between 95.50-100.04%, and their data are given in Table 3.

Precision

The precision of the developed chromatographic method was evaluated by calculating RSD% values for intra-day and inter-day precision, as well as the repeatability of the sample application and measurement of DAP and VIL. These values were found to be 2.0% or less, indicating that the developed method has achieved an acceptable level of precision. The data supporting the precision of the developed method are given in Tables 4 and 5.

Detection limit and quantification limit

The LOD and LOQ were calculated for the analytes DAP and VIL based on the standard deviation of the response and the slope method, as per ICH Q2(R1). The detection limit was found to be 0.02 µg/band for DAP and 0.19 µg/band for VIL, while the quantification limit was found to be 0.07 µg/band for DAP and 0.58 µg/band for VIL, respectively.

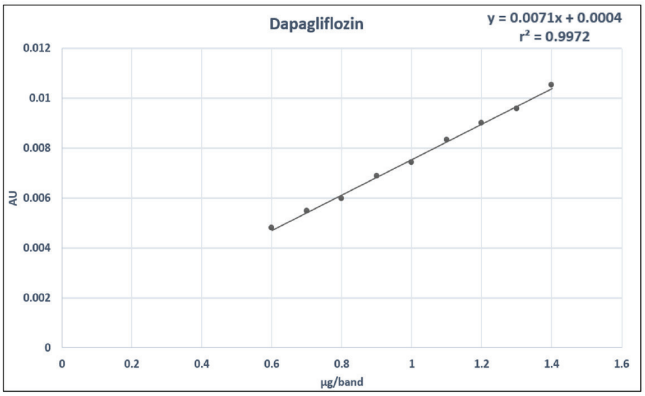

Figure 4. Calibration curve of dapagliflozin (0.6-1.4µg/band)
AU: Absorbance unit

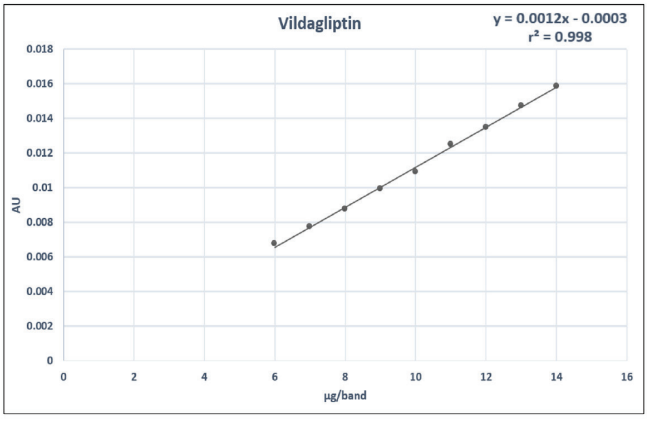

Figure 5. Calibration curve of vildagliptin (6-14µg/band)
AU: Absorbance unit

Specificity

The densitometric spectrum of the standard and the formulation was compared for both DAP and VIL at their corresponding R_f values, specifically at the peak start, apex, and end of the band. The absence of significant differences in the spectra of the standard and sample indicates that the developed method is specific.

Assay of the market available fixed-dose combination

The developed chromatographic method was used on the FDC of DAP and VIL to simultaneously estimate both analytes. The assay results obtained for the formulation are given in Table 6.

DISCUSSION

The HPTLC method is known for its ability to analyze several samples concurrently, which enables the analysis of more samples within a short time. Moreover, it is a cost-effective option.[17] In this study, an HPTLC method was developed and validated for the simultaneous estimation of DAP and VIL in an FDC.

Initial method development began with the use of a CAMAG TLC plate viewer, which operates at fixed wavelengths of 254 nm and 366 nm.[18] While DAP showed adequate ultraviolet (UV) absorption at these wavelengths, VIL did not exhibit a significant response, making it difficult to detect using this setup. This limitation required a shift in strategy. To overcome this, we proceeded with the CAMAG TLC Scanner IV, which allows scanning across a range of wavelengths. This enabled a more thorough spectral evaluation of both compounds. Through this approach, 210 nm was identified as a suitable detection wavelength, as both DAP and VIL showed adequate absorbance at this point. This wavelength provided clear, distinct bands for both analytes, making it ideal for simultaneous analysis.

Table 3. Recovery studies data for DAP and VIL (n=3)

Level	DAP		VIL	
	Recovery%	RSD*%	Recovery%	RSD*%
50%	97.92	1.08	98.17	0.81
100%	100.04	1.25	99.69	0.44
150%	95.50	0.92	96.86	1.71

DAP: Dapagliflozin, RSD: Relative standard deviation, VIL: Vildagliptin

Table 4. Intra-day and inter-day precision (n=3)

Precision studies	Analyte	µg/band	RSD%	Analyte	µg/band	RSD%
Intra-day precision	DAP	0.6	1.55	VIL	6	0.83
		0.8	1.07		8	1.46
		1.0	0.85		10	0.89
Inter-day precision	DAP	0.6	1.02	VIL	6	0.21
		0.8	0.96		8	0.93
		1.0	1.26		10	1.17

DAP: Dapagliflozin, RSD: Relative standard deviation, VIL: Vildagliptin

Table 5. Repeatability of the sample application and sample measurement

A) Repeatability of the sample application					
Concentration (µg/band)		**Peak area**		**RSD%**	
DAP	**VIL**	**DAP**	**VIL**	**DAP**	**VIL**
0.8	8	0.00592	0.00882	1.15	0.93
		0.00576	0.00872		
		0.00583	0.00868		
		0.00592	0.00882		
		0.00588	0.00891		
		0.00579	0.00877		
B) Repeatability of sample measurement					
Concentration (µg/band)		**Peak area**		**RSD%**	
DAP	VIL	DAP	VIL	DAP	VIL
0.8	8	0.00597	0.00876	0.89	0.63
		0.00590	0.00868		
		0.00592	0.00864		
		0.00584	0.00879		
		0.00598	0.00873		
		0.00589	0.00870		

DAP: Dapagliflozin, RSD: Relative standard deviation, VIL: Vildagliptin

Table 6. Result of formulation analysis (n=3)

Drug	Amount of drug (mg/tablet)		Label claim%	RSD%*
	Labelled	Estimated		
DAP	10	10.05	104.89	0.65
VIL	100	102.80	102.8	0.42

DAP: Dapagliflozin, RSD: Relative standard deviation, VIL: Vildagliptin

The issue encountered with VIL at fixed wavelengths underscores the importance of wavelength selection, especially in methods involving multiple compounds with different UV profiles. The flexibility offered by densitometric scanning allowed for effective method optimization, leading to a reliable and practical technique for routine quality control. This method demonstrates how careful wavelength selection and the right instrumentation can address detection challenges during method development. The outcome is a simple, reproducible, and sensitive procedure suitable for simultaneous estimation of DAP and VIL in combined pharmaceutical formulations.

CONCLUSION

An HPTLC method has been developed for the estimation of fixed-dose formulation of DAP and VIL. According to ICH Q2(R1) guidelines, the developed method was validated. The suggested approach was found to be accurate, precise, and specific in determining DAP and VIL in tablet formulation. As a result, the developed chromatographic method can be used for routine quality control analysis of DAP and VIL in an FDC to quantify both analytes simultaneously.

Ethics

Ethics Committee Approval: This research work does not require ethical committee approval.

Informed Consent: Not required.

Footnotes

Authorship Contributions

Concept: Y.V.K., S.A., Design: Y.V.K., S.A., Data Collection or Processing: Y.V.K., V.K., Analysis or Interpretation: Y.V.K., S.A., V.K., Literature Search: Y.V.K., Writing: Y.V.K., V.K.,

Conflict of Interest: The authors declare no conflicts of interest.

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