

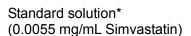
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## HPLC DATA SHEET

## シンバスタチン錠 (日本薬局方収載原案記載条件)

Simvastatin tablets (The draft for the Japanese Pharmacopoeia)

U120608B



H<sub>3</sub>C CH<sub>3</sub> CH<sub>3</sub>

Simvastatin

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25 -		
20 -		
15 -		Theor
10		
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0 -	1 2 3 4	5 6 7 mir

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	System suitability requirement	Result
Theoretical plate number (Simvastatin)	≧3000	6000
Talling factor (Simvastatin)	≦2.0	0.99
Relative standard deviation of the peak area (Simvastatin)	<b>≦</b> 1.0%	0.05%

Column : YMC-Triart C18 (5 μm, 12 nm)

150 X 4.0 mml.D.

Eluent : methanol/0.02 M  $KH_2PO_4$  (4/1)

Flow rate : 1.3 mL/min (adjust the flow rate so that the retention time of simvastatin is about 4 min)

Temperature : 50°C

Detection : UV at 238 nm

Injection : 20 μL

(The draft for the Japanese Pharmacopoeia; Dissolution)

<sup>\*</sup> Standard solution was prepared from Simvastatin supplied as a reagent for laboratory use.