



**STARCAP 1500®**  
CO-PROCESSED STARCH EXCIPIENT

Formulation  
Direct Blend & Encapsulation  
Gabapentin 300 mg Capsule

## Formulation Used to Produce Gabapentin (300mg) Capsules

### Formulation and Capsule Properties

Ingredients	Percent (w/w)	Capsule Properties (19.5mm dosing disc)	
Gabapentin [Kemprotec]	75.00%	Capsule Size	No. 0
StarCap 1500® [Colorcon]	24.75%	Capsule Fill Weight	400mg
Magnesium Stearate NF [Mallinckrodt]	0.25%	Dissolution (10 min)	95% of LC
Total:	100.00%	Content Uniformity	
		Average (n=10)	101.2% of LC
Hard Gelatin Capsule Shell No. 0, White/White	qs	RSD%	1.53%

### Process (Direct Blend and Encapsulation)

- Encapsulation was conducted on a tamp-filling machine, In-Cap (Dott. & Bonapace C.), set up for hard gelatin shells size #0, with a dosing disc of 19.5mm thickness, and encapsulation speed 2.
- The pin setting was set in ascending order of 3.5, 6.0, 6.0, and 7.0.

### Dissolution

- The dissolution method for Gabapentin capsules is not currently posted in the USP 29 Monographs.
- The dissolution test was performed following the recommendations from the FDA.

Drug Name	Dosage Form	USP Apparatus	Speed (RPMs)	Medium	Volume (mL)	Recommended Sampling Times (minutes)	Date Updated
Gabapentin	Capsule	II (Paddle)	50	0.06 N HCl	900	5, 10, 20 and 30	01/30/2004

Dissolution Profile	
Time	Average % Released (n=12)
0	0
5	80
10	95
15	97
20	98
30	100
40	100
50	101
60	101