

DOCUMENT	SKU	VERSION	ISSUED	STATUS
DI-P01	HP-00-NAT-NAT-B070	v1	DD Month YYYY	SAMPLE

HPMC hard capsule, size 00, natural

SKU	SHELL MATERIAL	SIZE
HP-00-NAT-NAT-B070	HPMC (hypromellose)	00
CAP / BODY COLOR	OPACIFIER	CAPSULES PER BOX
Natural / Natural	None	70,000 (box B070)

DIMENSIONS

PARAMETER	TARGET (MM)	TOLERANCE (MM)
Cap length	[]	± []
Body length	[]	± []
Closed (prelocked) length	[]	± []
Cap external diameter	[]	± []
Body external diameter	[]	± []
Volume capacity	[] ml	-

PHYSICAL AND CHEMICAL

PARAMETER	LIMIT	METHOD
Appearance	[Conforms]	[]
Identification (hypromellose)	[Positive]	[]
Tightness	[Conforms]	[]
Friability	[Conforms]	[]
Average empty weight	[] mg ± [] mg	[]
Loss on drying	≤ [] %	[]
Residue on ignition	≤ [] %	[]
Disintegration	≤ [] min	[]

MICROBIOLOGICAL

PARAMETER	LIMIT	METHOD
Total aerobic microbial count	≤ [] CFU/g	[]
Total yeasts and molds	≤ [] CFU/g	[]
Escherichia coli	[Absent] in [] g	[]
Salmonella	[Absent] in [] g	[]

COMPOSITION [Hypromellose, gelling agent, water]. Full composition in the Composition and colorant statement (DI-P11). Elemental impurities in the ICH Q3D statement (DI-P09).

PACKAGING Supplied in the manufacturer's full, sealed original box. The lot number on every carton traces to the manufacturer's batch (DI-P17).

STORAGE Example: 5 years in sealed original packaging at 15-25 °C and 40-60% RH (DI-P15).

SCOPE These limits apply to every lot supplied under this SKU, from any qualified manufacturing site.

SIGNATURE (EXAMPLE)DATE

Signature (example)RP/QA LEAD, CAPSULES.COM