



SUNIL HEALTHCARE LIMITED

Regd. Office & Plant : 17/18, Old Industrial Area, Alwar - 301001, Rajasthan, India
 Phones : 0144-2373829 to 2373832 (4 lines) Fax : 0144-2373826
 E-mail : shl@dataone.in, Website : www.sunilhealthcare.com

CERTIFICATE OF ANALYSIS

Customer Name: M/s -			
NAME OF THE PRODUCT: Hard Gelatin Capsule Shells IP		COA NO.	: 0M/019/09
Product code : 0524		Spec. Ref	: STP/QCD/FP-03
Cap Colour	: BLACK	Invoice No.	: -
Cap Colour Code	: BK3	Body Colour	: YELLOW
Size	: 0	Body Color code	: YL190
Batch No.	: 9M19	Lock Type	: EASY FILL
MFG. Date	: FEBRUARY 2009	Qty in lac	: -
		EXP. Date	: JANUARY 2014
PRINTING DETAILS :			
Print Text	CAP : -	BODY	: -
Print Colour	CAP : -	BODY	: -
Print Art Work Ref	: -		
TEST	SPECIFICATION	UNIT	RESULT
IDENTIFICATION			
1. Description	Empty Hard Gelatin Capsules	-	Complies
2. Capsule colour	As per approved colour shade	-	Complies
3. Identification of gelatin	Positive for gelatin	-	Complies
4. Identification of Dyestuffs	Conforms to composition	-	Complies
5. Identification of Iron Oxides	Conforms to composition	-	Complies
6. Identification of Titanium dioxide	Conforms to composition	-	Complies
PERFORMANCE			
1. Disintegration Time	0.00 – 15.00	MIN	7.200
2. Loss on Drying	12.5 – 16.00	%	14.400
3. Average Weight	86.40 – 105.60	MG	97.950
PURITY			
1. Odour	No Foreign odour	-	Complies
SAFETY			
1. Sulphated ash	Maximum 7 %	-	Complies
2. Arsenic	Maximum 2 ppm	-	Complies
3. Heavy Metals	Maximum 50 ppm	-	Complies
4. Lubricant content	Maximum 0.5 %	-	Complies
5. Sulphur Dioxide	Maximum 200 ppm	-	Complies
MICROBIAL LIMITS			
1. Total Bacterial count (cfu/g)	0 – 500	CFU	180
2. Yeast and Molds (cfu/g)	0 – 100	CFU	10
3. E.coli	Absent in 10g	-	Absent
4. Salmonella	Absent in 10g	-	Absent
5. Pseudomonas aeruginosa	Absent in 10g	-	Absent
6.S.aureus	Absent in 10g	-	Absent

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Encapsulating Health

Head Office: 1st Floor, Sheetla House, 73/74, Nehru Place, New Delhi- 110 019, India
 Phone : 011- 26447086 Fax : 011-26221440 E-mail : sunilhealthcare@eth.net



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Print Art Work Ref	: -		
TEST	SPECIFICATION	UNIT	RESULT
<u>DIMENSIONS</u>			
1. Outside diameter -Cap	7.57 – 7.69	MM	Complies
2. Outside diameter –Body	7.26 – 7.38	MM	Complies
3. Length -Cap	10.68– 11.68	MM	10.82 – 11.46
4. Length –Body	18.22 – 19.22	MM	18.46 – 18.88
5. Double wall thickness –Cap	0.187 – 0.223	MM	Complies
6. Double wall thickness –Body	0.177 – 0.213	MM	Complies
Gelatin Control No. : RM/008/09			
Lot No of Gelatin : NGL-416			
Source of Gelatin : Animal bones			
Supplier of Gelatin : Narmada Gelatin			
Suitability certificate No : R1-CEP2001-166-REV 00			
Attribute Defects			
Visual	QI Minimum 96 %	> 96 %	
Print	QI Minimum 96 %	> 96 %	
DISPOSITION: Capsules are produced under very carefully controlled WHO-GMP conditions. Controls are performed continuously throughout the process and guarantee that capsules conform to highest quality standards.			
The above batch conforms to the prescribed release specification for Hard Gelatin Capsule Shells IP			
Machine setting requirement			
Capsule Size 0 Recommended Closed Joined Length in mm (Tolerance on avg of 10± 0.4 mm)			
Easy Fill Lock 21.4			
Approximate capacity in ml Volume 0.68			



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PRODUCT INFORMATION

COMPONENT	SPECIFICATION	FUNCTION	QUANTITY IN%
Purified Water	Ph. Eur. +IP	Moisture	14.400
Sodium Lauryl sulphate	USP+ Ph. Eur +IP	Surfactant	0.100
Povidone	USP + IP	Moisture retainer	0.100
Bronopol	BP	Preservative	0.100
COMPOSITION – CAP – BLACK(BK3)			
Ingredient /Reference	EEC. NO.	CI.No.	Function
Brilliant blue FCF-FD&C Blue 1	E133	42090	Colorant
Ponceau 4R	E124	16255	Colorant
Sunset Yellow FCF FD&C Yellow 6	E110	15985	Colorant
Gelatin	-	-	Structure
COMPOSITION – BODY YELLOW (YL190)			
Ingredient /Reference	EEC. NO.	CI.No.	Function
Quinoline Yellow WS-FD&C Yellow 10	E104	47005	Colorant
Sunset Yellow FCF FD&C Yellow 6	E110	15985	Colorant
Titanium dioxide	E171	77891	Opacifier
Gelatin	-	-	Structure
Pharmacopoeia Reference			
			Quantity in %
			95/45/EC: CFR 21
			0.7120
			95/45/EC: CFR 21
			0.7200
			95/45/EC: CFR 21
			0.2800
			EP + USP/NF + IP
			83.5880
<p>Limitations: Due to the raw materials, their sourcing and technology the colorant composition data indicated are target values and actual values may vary nature the consistency of lot colour.</p> <p>Machine Lubricant: Liquid paraffin Ph. Eur + IP</p> <p>Printing Ink: Edible ink prepared using pharmaceutical grade materials.</p> <p>All ingredients are of pharmaceutical grade. Gelatin used in the manufacture is derived from bones of ruminants that have never been in any country where BSE exists. The capsules therefore do not pose a BSE risk.</p> <p>Transportation Between 15 Deg C & 25 Deg C Between 40 % & 65 % RH</p> <p>Storage Between 15 Deg C & 25 Deg C Between 40 % & 65 % RH</p> <p>Usage Between 15 Deg C & 25 Deg C Between 40 % & 65 % RH</p> <p>Handling Precautions</p> <ol style="list-style-type: none"> Use Only S.S Scoops & Spatulas. Do not Store near a Source of heat. Avoid wide temperature fluctuation during Storage. Do not leave the capsules in a hopper. Keep Mouth of bag closed when not in use. <p>Shelf Life 5 Years from date of manufacturing.</p>			
Prepared By	:	Approved By	:
Name	:Sunil Sharma	Name	:R. Kukreja
Designation	:Asstt.Chemist-QC	Designation	:Executive -QC
Date	:-	Date	:-

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