

CERTIFICATE OF ANALYSIS

A- CNOTREN (ISOTRETINOIN) 10mg SOFT GELATIN CAPSULES

Man. Date: 02-05-2017

Expiry Date: 05-2019

Pack Lot: 1703506

Man .No: 7362

Batch Size: 300.000Caps

Active Ingredient Lot: IST-20170101

Active Ingredient Supplier: HUAPONT

Man Site: G.A. PHARMACEUTICALS S.A.

Pkg Site: Pharmathen International S.A

Deviation Report: ☒ NO

☐ YES (the deviation report is attached)

Controls	Specifications	Results
Appearance	10mg: Red-orange, size 3, oval, soft gelatin capsules	Conforms
Identification	a) HPLC-UV/Wst b) TLC	a) Positive b) Positive
Uniformity of dosage units	Complies with the test of content uniformity	AV: 1.0
Assay	95.0 - 105.0% of the stated amount	97.8%
Related substances	Tretinoin - NMT 2.0% 13-cis-5,6-Epoxy-5,6-dihydroretinoic acid - NMT 0.3% Individual unknown - NMT 0.2% Total impurities (except tretinoin) - NMT 0.5%	BQL(LOQ=0.1%) ND ND ND
Disintegration	Max. 20 mins in water at 37°C ± 1°C	06'.38"- 07'.15"
Dissolution	NLT 85% after 30 mins, in 0.1M NaOH	96.0%
Particle size	95% < 100µm	97.6%
Identification of Titanium dioxide	Positive	Positive
Identification of Iron Oxide	Positive	Positive
Microbial contamination	Total count < 1000/g Fungi < 100/g Coliforms < 0/g	TAMC: <10cfu/g TYMC: <10cfu/g E.Coli: absence
Blister tightness	Air and water tight after 30 seconds in 1% methylene blue solution, 160 mmHg pressure	Tight
Packaging	Cardboard box contains the appropriate number of blisters of opaque white PVC/PE/PVDC - Aluminium with the appropriate number of capsules and an instruction leaflet and is printed with Lot, Man, Exp.	Conforms

**RESPONSIBLE FOR
QUALITY CONTROL**

DATE OF ANALYSIS: 13-06-2017

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13/6/17

Comment 1: The above specifications became valid gradually during the period June 2003- March 2004. All future batches of finished product will be tested according to these specifications.

Comment 2: Identification of Titanium dioxide and Iron Oxide are performed every ten batches or annually, whenever sooner.