



your key to quality™

Jakarta, 11 Februari 2009

Nomor : 07/ CoA-K/DIR/II/2009
Lampiran : 3 (tiga) helai
Perihal : CoA Blue Cap

Kepada:

Yth. Bapak Tani Sunarjo
Direktur Utama PT Tobbest Busindo
Jalan Nuri No.1- Kompleks Bintaro Permai
Kebayoran Lama
Jakarta 12320

Dengan hormat,

Sehubungan dengan surat Bapak nomor 004/Dir.TBB/I/09 tanggal 6 Januari 2009 perihal Permohonan Pengujian secara Kualitatif untuk Produk Kulit yang digunakan secara topikal, bersama ini kami sampaikan :

1. Certificate of analysis no. 001/CoA/I/09 untuk produk Blue Cap Cream
2. Certificate of analysis no. 002/CoA/I/09 untuk produk Blue Cap Spray
3. Certificate of analysis no. 003/CoA/I/09 untuk produk Blue Cap Shampoo

Perlu kami beritahukan bahwa pemilihan jenis corticosteroid yang diidentifikasi dalam cream dan spray mengacu pada monograf cream dan spray USP 30 – 2007 yang mengandung corticosteroid, sedangkan untuk shampoo jenis corticosteroid yang diidentifikasi kami analogikan dengan cream. Identifikasi dilakukan dengan FTIR menggunakan pembandingan spektrum IR dari Library Spektrum FTIR – Nicolet 380, karena tidak ada hasil yang positif maka tidak dilakukan konfirmasi dengan UPLC – MS/MS.

Demikian kami sampaikan, terimakasih atas kepercayaan Bapak kepada perusahaan kami.

Hormat kami

PT CIPTA SINTESA MUSTIKA

BELab
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Mawarwati Djamaludin, Diplm.Pharm.
Direktur/CEO

Certificate of Analysis

Nr. 001/CoA II/09

Date of Issue : Feb-04-2009

Name of Product: Blue Cap Cream

Manufactured by Catalysis Spain

Imported by : PT Tobbest Busindo

Batch number: A-20

Expired date: May 2010

Requested by PT Tobbest Busindo for identification of steroid

Ingredients	
- Aqua	- Glyceryl stearate
- Isopropyl Palmitate	- Stearyl alcohol
- Octyl Octanoate	- Methyl gluceth 20
- Polyglyceril-3-methyl-glucose distearate	- Zink pyrithion 0,2%
- Sucrose Cocoate	- Propyl paraben
- Glycerine	- BHT
- Cyclomethicone	- Alcohol
	- Perfume

We, the undersigned, hereby certify that assay results determined by validated method of analysis of the above mentioned product were as follows:

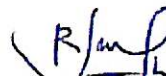
Description :
White cream, aromatic

Ingredients	Identification*)	Note
- Alclometasone	n.d	USP 30,**) p. 1311
- Betamethasone	n.d	USP 30,**) p. 1521
- Dexamethasone Na-PO ₄	n.d	USP 30,**) p. 1891
- Desoxymethasone	n.d	USP 30,**) p. 1878
- Fluocinolon acetonide	n.d	USP 30,**) p. 2151
- Flumethasone pivalate	n.d	USP 30,**) p. 2147
- Fluometholon	n.d	USP 30,**) p. 2162
- Hydrocortison	n.d	USP 30,**) p. 2292
- Methyl prednisolon acetate	n.d	USP 30,**) p. 2637
- Prednisolon	n.d	USP 30,**) p. 3004
- Triamcinolone acetonide	n.d	USP 30,**) p. 3393

*)using FTIR with isolation method according to USP 30**); n.d = not detected



Mawarwati Djusufudin, Diplm. Pharm.
Director/CEO

Dra. Rosmulyati Ilyas, Apt.
Technical Manager

Certificate of Analysis**Nr.002/CoA/II/09****Date of Issue : Feb-04-2009***Name of Product: Blue Cap Spray**Manufactured by : Catalysis Spain**Imported by : PT Tobbest Busindo**Batch number: A-2**Expired date: 05-12**Requested by PT Tobbest Busindo for identification of steroid*

Ingredients	
- Isopropyl myristate	- Sodium lauryl sulfate
- Alcohol	- Propellants (iso-butane, propane, butane)
- Zinc pyrithione 0,2%	
- Polysorbate 80	

*We, the undersigned, hereby c e r t i f y that
assay results determined by validated method of analysis of the above mentioned product
were as follows:*

Description :*Transparent liquid, aromatic*

Ingredients	Identification*)	Note
- Dexamethasone Na-PO ₄	n.d***	USP 30, **) p. 1891
- Triamcinolone acetonide	n.d	USP 30, **) p. 3393

)using FTIR with isolation method according to USP 30 : ***)n.d = not detected*



*Mawarwati Djanatuludin, Diplm. Pharm.
Director/CEO*

*Dra. Rosmulyati Ilyas, Apt.
Technical Manager*

Certificate of Analysis

Nr.003/CoA II/09

Date of Issue : Feb-04-2009

Name of Product: Blue Cap Shampoo

Manufactured by : Catalysi s- Spain

Imported by :PT Tobbest Busindo

Registration number : POM CL 0601602202

Batch number: A-8

Expired date: 07-12

Requested by PT Tobbest Busindo for identification of steroid


Ingredients:	
- Sodium laureth sulfate	- Zinc pirithione
- Aqua	- Alcohol
- Cocamidopropyl betaine	- Sodium chloride
- Propylene glycol-Peg55	- Dimethicone copolyol
- Propylene glycol oleat	- Menthol
- Glycol stearate-cocamide mea	- Perfume
- Mea-SLS	- Disodium EDTA

We, the undersigned, hereby **certify** that
 assay results determined by validated method of analysis of the above mentioned product
 were as follows:

Description : tranparant viscous fluid, aromatics.

Ingredients	Identification*)	Note
- Betamethasone	n.d***)	USP 30,**) p. 1521
- Dexamethasone Na-PO ₄	n.d	USP 30, **) p. 1891
- Desoxymethasone	n.d	USP 30, **) p. 1878
- Fluocinolon acetonide	n.d	USP 30, **) p. 2151
- Flumethasone pivalate	n.d	USP 30, **) p. 2147
- Fluometholon	n.d	USP 30, **) p. 2162
- Hydrocortison	n.d	USP 30, **) p. 2292
- Methyl prednisolon acetate	n.d	USP 30, **) p. 2637
- Prednisolon	n.d	USP 30, **) p. 3004
- Triamcinolone acetonide	n.d	USP 30, **) p. 3393

*)using FTIR with isolation method according to USP 30**); n.d***) =not detected


 Mawarwati Djamaudin, Diplm. Pharm.
 Director/CEO




 Dra. Rosmulyati Ilyas, Apt.
 Technical Manager