Alpha Drugs

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ZENALB 20%, a low salt albumin from BIO PRODUCTS LABORATORY, UK (a part of the National Health Service of the UK Government)

BPL is quite unusual in having a low salt 20% albumin (@70mmol/L—80mmol/L) see attached breakdown of last 7 batches imported in India. Also attached is a comparison of the available imported brands in the Indian market along with their package inserts. As it can be seen all these products have physiological salt levels of between 120mmol/L – 160mmol/L, which is much higher than Zenalb's salt level.

BPL's original Human Albumin product (pre- 1990s) was also low salt at the request of UK clinicians, BPL carried this over with Zenalb 20 when they introduced the new ion exchange column chromatography step ('A7 process'). As the chromatography is run at low ionic strength it is relatively easy to add some salt back to the required level during formulation, though some of the sodium also comes from the sodium octanoate stabilizer.

As many of the patients receiving 20% albumin are critically ill and are likely to have multiple clinical complications including possibly poor renal function and/or electrolyte imbalance, a sodium over load can potentially result in edema in such patients.

If a doctor administers Zenalb 20, then there is still "scope" to manage the patient's electrolyte balance. So, if a patient has a high sodium level, the doctor won't add to the problem by giving Zenalb 20. Likewise, if the patient has a low sodium level, he/she can receive Zenalb 20 and then still receive a saline infusion (or similar) if the doctor wants to top up the sodium. In other words, Zenalb 20 allows a more "targeted approach" to manage the patient's plasma colloid osmotic pressure without having a knock-on effect with the sodium level.

Certificate of Analysis

This Certificate of Analysis for ZENALB 20 Batch No. ABCN9685 is supplied to Alpha Drugs, India

Bio Products Laboratory

Product Licence: 08801/0007
Manufacturing Date: 05 JUL 12
Expiry Date: JUN 15

Test	Compliance Reference	Limits	This Batch
Characteristics			
pH at 20°C	Ph.Eur.	6.7 - 7.3	6.9
Biological Safety Tests			
Endotoxin, EU/mL	BPL	<= 0.50	<0.5
Sterility	Ph.Eur.	Pass	Pass
Pyrogenicity	Ph.Eur.	Pass	Pass
Viral Marker Tests			
Hepatitis Bs Antigen	BPL	Negative	Negative
Anti-HIV (1 and 2)	BPL	Negative	Negative
Purity/Specific Function			
Total Protein, g/L	Ph.Eur.	190 - 210	199
Protein comp. Albumin, %	Ph.Eur.	>= 95	98.5
Protein comp. gammaglobulin, %	BPL	<= 0.1	0.0
HPLC (H10,60) (F) Peak A, % abs	Ph.Eur.	<= 10.0	3.3
HPLC (H10,60) (L) Peak A, % abs	Ph.Eur.	<= 10.0	3.1
Excipients			
Sodium, mmol/L	Ph.Eur.	50 - 120	73
Chloride, mmol/L	BPL	<= 40	18
Octanoate, mmol/L	BPL	20 - 40	30
Impurities			
Aluminium, µg/L	Ph.Eur.	<= 200	15
Ethanol, % v/v	BPL	<= 0.25	<0.01
Potassium, mmol/g protein	Ph.Eur.	<= 0.05	<0.001
Citrate, mmol/L	BPL	<= 0.1	<0.02
Haem, Abs at 403nm	Ph.Eur.	<= 0.15	0.039
PKA, IU/mL	Ph.Eur.	<= 35	Non Detectable
Human Protein Identity	Ph.Eur.	Positive	Positive
Optical Density at 405nm, AU	BPL	< 0.50	0.03

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Signed: _____ Dated: 26 OCT 2012
QA Department Manager