CLAIMS

Claim 1. A multivalent meningococcal polysaccharide-protein conjugate vaccine formulation, wherein said formulation is a liquid, lyophilized or liquid-lyophilized combination pentavalent formulation of Neisseria meningitidis serogroup A, C, Y, W and X capsular polysaccharides (MenA, MenC, MenY, MenW and MenX), each said capsular polysaccharide being conjugated separately to tetanus toxoid (TT) carrier protein to obtain MenA-TT, MenC-TT, MenY-TT, MenW-TT and MenX-TT conjugates, with one or more buffer and with or without an adjuvant along with pharmaceutically acceptable excipients, and wherein said MenA-TT, MenCTT, MenY-TT and MenW-TT conjugates are obtained by employing cyanylation chemistry and said MenX-TT conjugate is obtained by employing carbamate chemistry, wherein each of the serogroup capsular polysaccharide is degraded to a size suitable for conjugation with the TT carrier protein.

Claim 2. The vaccine formulation as claimed in claim 1, wherein each of the serogroup capsular polysaccharide is degraded to the size range of 0.38 $\pm$ 0.1 Kd when tested for molecular size distribution using high performance liquid chromatography column.

Claim 3. The vaccine formulation as claimed in claim 1, wherein said liquid formulation comprises of:

Ingredients	**Quantity/Concentration**
MenA-TT, MenC-TT, MenY-TT, MenW-TT and MenX-TT	4-20 μg of the capsular polysaccharide/ serogroup/ ml
Buffer	5-30 mM phosphate buffered saline
Excipients	0-150 mM NaCI and 5-30 mM histidine
Adjuvant	Aluminum phosphate as 500-2000 μg Al+++/ml
Water MQW	qs.

Claim 4. The vaccine formulation as claimed in claim 1, wherein said liquid formulation comprises of:

Ingredients	**Quantity/Concentration**
MenA-TT, MenC-TT, MenY-TT, MenW-TT and MenX-TT	10-25 μg of the capsular polysaccharide/ serogroup/ ml
Buffer	10-25 mM phosphate buffered saline, pH 7.0$\pm$0.2
Excipient	0-150 mM NaCI
Adjuvant	Aluminum phosphate as 750-1500 μg Al+++/m1

Water MQW	qs.

Claim 5. The vaccine formulation as claimed in claim 1, wherein said liquid formulation comprises of:

Ingredients	**Quantity/Concentration**
MenA-TT, MenC-TT, MenY-TT, MenW-TT and MenX-TT	10-20 µg of the capsular polysaccharide/ serogroup/ ml
Buffer	10 mM phosphate buffered saline, pH 7.0±0.2
Excipient	0-150 mM NaCl
Adjuvant	Aluminum phosphate as 1000 µg Al+++/ml
Water MQW	qs.

Claim 6. The vaccine formulation as claimed in claim 1, wherein said liquid formulation comprises of:

Ingredients	**Quantity/Concentration**
MenA-TT, MenC-TT, MenY-TT, MenW-TT and MenX-TT	10µg of the capsular polysaccharide/ serogroup/ ml
Buffer	10 mM phosphate buffered saline, pH 7.0±0.2
Excipient	0-150 mM NaCl
Water MQW	qs.

Claim 7. The vaccine formulation as claimed in claim 1, wherein each of the conjugates comprises a linker between the capsular polysaccharide and the TT carrier protein.

Claim 8. The vaccine formulation as claimed in claim 7, wherein said linker is adipic acid dihydrazide or hydrazine.

Claim 9. The vaccine formulation as claimed in claim 7, wherein said MenX-TT conjugate comprises hydrazine linker and said MenA-TT, said MenC-TT, said MenY-TT and said MenW-TT conjugates comprise adipic acid dihydrazide linker.

Claim 10. The vaccine formulation as claimed in claim 1, wherein each of the conjugates has the carrier protein to the capsular polysaccharide ratio between 0.3 to 1.0.

Claim 11. The vaccine formulation as claimed in claim 1, wherein said excipients are selected from adjuvant, buffer, preservative, stabilizer, surfactant, either alone or in

combination.

Claim 12. The vaccine formulation as claimed in claim 1, wherein said excipients are selected from sucrose, maltose, arginine, lactose, sorbitol, histidine, glycine, either alone or in variable combinations.

Claim 13. The vaccine formulation as claimed in claim 1, wherein said formulation is a mono-dose regimen or a multi-dose regimen with or without a preservative.

Claim 14. The vaccine formulation as claimed in claim 1, wherein optimum human dose of the vaccine formulation ranges between 2-10 micrograms of the capsular polysaccharide of each of the serogroups A, C, Y, W and X per dose.

Claim 15. The vaccine formulation as claimed in claim 1, wherein osmolality of the formulation is 240-330 mOsmol per Kg.

Claim 16. The vaccine formulation as claimed in claim 1, wherein pH of the formulation is 6.5 to 7.5.

Claim 17. The vaccine formulation as claimed in claim 1, wherein lyophilized portion of the lyophilized or the liquid-lyophilized formulation has a moisture content of not more than 3%.

Claim 18. The vaccine formulation as claimed in claim 1, wherein said vaccine formulation is stable at high temperature of 37$\pm$2°C for at least 21 days and at 25$\pm$2°C for at least 3 months showing less than 40% free capsular polysaccharide.

Claim 19. The vaccine formulation as claimed in claim 1, wherein said vaccine formulation is equally immunogenic even after exposure at 37$\pm$2° C for days as compared to the vaccine formulation stored at 5$\pm$3° C.

Claim 20. The vaccine formulation as claimed in claim 1, wherein said vaccine formulation is a liquid pentavalent meningococcal conjugate vaccine formulation as a monodose regimen or a multi-dose regimen with or without a preservative.

Claim 21. The vaccine formulation as claimed in claim 1, wherein said vaccine formulation is capable of being used in production of a liquid, lyophilized or liquid-lyophilized pentavalent MenA-TT, MenC-TT, MenY-TT, MenW-TT and MenX-TT combination vaccine.