Claims:

1. A vaccine composition comprising live attenuated recombinant dengue virus comprising Δ30 mutation and/or Δ31 mutation in the 3' untranslated region, and a stabilizer, wherein, the stability of the composition is enhanced by the stabilizer which is gelatin or hydrolyzed gelatin and/or collagen or hydrolyzed collagen present in an amount 15-22 mg/0.5 ml.

2. A vaccine composition according to claim 1 which is tetravalent in terms of live attenuated recombinant dengue virus, wherein the dengue strains are selected from dengue virus type 1, dengue virus type 2, dengue virus type 3, and dengue virus type 4.

3. A vaccine composition according to claim 2 wherein the dengue virus carries Δ30 mutation and/or Δ31 mutation in the 3' untranslated region.

4. A vaccine composition according to claim 2, wherein one or more strains of dengue are chimeric comprising dengue 1 backbone or dengue 2 backbone or dengue 3 backbone or dengue 4 backbone.

5. A vaccine composition according to claim 2 wherein the dengue strains have a phenotype which is temperature sensitive in Vero cells or the human liver cell line HuH-7.

6. A vaccine composition according to claim 1 further comprising human serum albumin.

7. A vaccine composition according to claim 1 further comprising bulking agents and/or buffering agents.

8. A vaccine composition according to claim 7, wherein the bulking agent is selected from a group comprising of lactose, sucrose, mannitol and trehalose.

9. A vaccine composition according to claim 7, wherein the buffering agents are selected from the group comprising of potassium dihydrogen phosphate, Di-potassium hydrogen phosphate and monosodium glutamate.

10. A vaccine composition according to claim 1, further comprising supplemental media.

11. A vaccine composition according to claim 1 wherein the final pH of the composition is about 6-7.

12. A vaccine composition according to claim 1, wherein the said composition is lyophilized.

13. A vaccine composition according to claim 2 wherein the dengue strains are propagated in VERO cells.

14. A vaccine composition according to claim 1 wherein the dengue virus is present at a dose of not less than 3.0 $\log_{10}$PFU per 0.5 ml.

15. A vaccine composition according to claim 12, wherein the lyophilized vaccine is reconstituted to obtain a stabilized vaccine.

16. A vaccine composition according to claim 1, wherein gelatin or hydrolyzed gelatin is present in an amount of 1-30 mgs/0.5 ml and/or collagen or hydrolyzed collagen is present in an amount of 1-30 mgs/0.5 ml.

17. A vaccine composition according to claim 6, wherein human serum albumin is present in an amount of 10-15 mg/0.5ml.

18. A vaccine composition according to claim 17, wherein human serum albumin is present in an amount of 12.5 mg/0.5 ml or 10 mg/0.5 ml.

19. A vaccine composition according to claim 16, wherein gelatin or hydrolyzed gelatin is present in an amount of 15-22 mg/0.5 ml.

20. A vaccine composition according to claim 19, wherein gelatin or hydrolyzed gelatin is present in an amount of 22 mg/0.5 ml or 15 mg/0.5 ml.

21. A vaccine composition according to claim 16 wherein collagen or hydrolyzed collagen is present in an amount of 15-22 mg/0.5 ml.

22. A vaccine composition according to claim 21 wherein collagen or hydrolyzed collagen is present in an amount of 22 mg/0.5 ml or 15 mg/0.5 ml.

23. A vaccine composition according to claim 4, wherein the said composition is a stable lyophilized tetravalent vaccine comprising Dengue virus serotype 1 (rDEN 1Δ30), Dengue virus serotype 2 (rDEN 2/4Δ30), Dengue virus serotype 3 (rDEN 3Δ30/31) and Dengue virus serotype 4 (rDEN 4Δ30), wherein the stability of the composition is enhanced by presence of gelatin or hydrolyzed gelatin and/or collagen or hydrolyzed collagen.

24. A vaccine composition according to claim 23, wherein the dengue virus is present at the dose of not less than 3.0 $\log_{10}$PFU per 0.5 ml.

25. A vaccine composition according to claim 23, wherein the composition is according to the formula as represented in following Tables:

Table 2

S.No.	Name of the component	Quantity (Per dose of 0.5 ml)
1.	Dengue virus serotype 1 (rDEN 1Δ30)*	NLT 3.0 $\log_{10}$ PFU[1]
2.	Dengue virus serotype 2 (rDEN 2/4Δ30)*	NLT 3.0 $\log_{10}$ PFU[1]
3.	Dengue virus serotype 3 (rDEN 3Δ30/31)*	NLT 3.0 $\log_{10}$ PFU[1]
4.	Dengue virus serotype 4 (rDEN 4Δ30)*	NLT 3.0 $\log_{10}$ PFU[1]
Excipients		Range
1.	Gelatin	10 to 30 mg
2.	Mannitol	5 to 25 mg
3.	Trehalose	4 to 16 mg
4.	Sucrose	25 to 60 mg
5.	Potassium dihydrogen phosphate (KH_2PO_4)	~ 260 µg
6.	Di-potassium hydrogen phosphate (K_2HPO_4)	~ 630 µg

S.No.	Name of the component	Quantity (Per dose of 0.5 ml)
7.	Monosodium glutamate	~ 460 µg
8.	Dulbecco's Modified Eagle's Medium	~ 500 µg
9.	Water for injection	Q.s. to 0.5 ml

Table: 3

SN	**Name of the component**	**Quantity (Per dose of 0.5 ml)**
1.	Dengue virus serotype 1 (rDEN 1Δ30)*	NLT 3.0 $\log_{10}$ PFU[1]
2.	Dengue virus serotype 2 (rDEN 2/4Δ30)*	NLT 3.0 $\log_{10}$ PFU[1]
3.	Dengue virus serotype 3 (rDEN 3Δ30/31)*	NLT 3.0 $\log_{10}$ PFU[1]
4.	Dengue virus serotype 4 (rDEN 4Δ30)*	NLT 3.0 $\log_{10}$ PFU[1]
Excipients		**Range**
1.	Hydrolyzed Gelatin	22 mg
2.	Mannitol	15 mg
3.	Trehalose	8 mg
4.	Sucrose	37.5 mg
5.	Potassium dihydrogen phosphate (KH_2PO_4)	~ 260 µg
6.	Di-potassium hydrogen phosphate (K_2HPO_4)	~ 630 µg
7.	Monosodium glutamate	~ 460 µg
8.	Dulbecco's Modified Eagle's Medium	~ 500 µg
9.	Sterile Water for Injection	Q.s. to 0.5 ml

Table: 7

SN	**Name of the component**	**Quantity (Per dose of 0.5 ml)**

SN	Name of the component	Quantity (Per dose of 0.5 ml)
1.	Dengue virus serotype 1 (rDEN 1Δ30)*	NLT 3.0 $\log_{10}$ PFU[1]
2.	Dengue virus serotype 2 (rDEN 2/4Δ30)*	NLT 4.0 $\log_{10}$ PFU[1]
3.	Dengue virus serotype 3 (rDEN 3Δ30/31)*	NLT 3.0 $\log_{10}$ PFU[1]
4.	Dengue virus serotype 4 (rDEN 4Δ30)*	NLT 3.0 $\log_{10}$ PFU[1]
Excipients		**Range**
1.	Gelatin	22 mg
2.	Mannitol	10 mg
3.	Trehalose	5 mg
4.	Sucrose	55 mg
5.	Potassium dihydrogen phosphate (KH_2PO_4)	~ 260 µg
6.	Di-potassium hydrogen phosphate (K_2HPO_4)	~ 630 µg
7.	Monosodium glutamate	~ 460 µg
8.	Dulbecco's Modified Eagle's Medium	~ 750 µg
9.	Sterile Water for Injection	Q.s. to 0.5 ml

Table: 8

SN	Name of the component	Quantity (Per dose of 0.5 ml)
1.	Dengue virus serotype 1 (rDEN 1Δ30)*	NLT 3.0 $\log_{10}$ PFU[1]
2.	Dengue virus serotype 2 (rDEN 2/4Δ30)*	NLT 4.0 $\log_{10}$ PFU[1]
3.	Dengue virus serotype 3 (rDEN 3Δ30/31)*	NLT 3.0 $\log_{10}$ PFU[1]
4.	Dengue virus serotype 4 (rDEN 4Δ30)*	NLT 3.0 $\log_{10}$ PFU[1]
Excipients		**Range**
1.	Gelatin	15 mg
2.	Mannitol	12 mg

SN	Name of the component	Quantity (Per dose of 0.5 ml)
3.	Trehalose	10 mg
4.	Sucrose	55 mg
5.	Potassium dihydrogen phosphate (KH_2PO_4)	~ 270 µg
6.	Di-potassium hydrogen phosphate (K_2HPO_4)	~ 630 µg
7.	Monosodium glutamate	~ 480 µg
8.	Leibovitz L-15 Medium	~ 850 µg
9.	Sterile Water for Injection	Q.s. to 0.5 ml

Table: 9

SN	Name of the component	Quantity (Per dose of 0.5 ml)
1.	Dengue virus serotype 1 (rDEN 1Δ30)*	NLT 3.0 $\log_{10}$ PFU[1]
2.	Dengue virus serotype 2 (rDEN 2/4Δ30)*	NLT 3.0 $\log_{10}$ PFU[1]
3.	Dengue virus serotype 3 (rDEN 3Δ30/31)*	NLT 3.0 $\log_{10}$ PFU[1]
4.	Dengue virus serotype 4 (rDEN 4Δ30)*	NLT 3.0 $\log_{10}$ PFU[1]
Excipients		**Range**
1.	Hydrolyzed Gelatin	22 mg
2.	Mannitol	12 mg
3.	Trehalose	10 mg
4.	Sucrose	35 mg
5.	Potassium dihydrogen phosphate (KH_2PO_4)	~ 270 µg
6.	Di-potassium hydrogen phosphate (K_2HPO_4)	~ 630 µg
7.	Monosodium glutamate	~ 480 µg

SN	Name of the component	Quantity (Per dose of 0.5 ml)
8.	Leibovitz L-15 Medium	~ 850 µg
9.	Sterile Water for Injection	Q.s. to 0.5 ml

Table: 10

SN	Name of the component	Quantity (Per dose of 0.5 ml)
1.	Dengue virus serotype 1 (rDEN 1Δ30)*	NLT 3.0 $\log_{10}$ PFU[1]
2.	Dengue virus serotype 2 (rDEN 2/4Δ30)*	NLT 3.0 $\log_{10}$ PFU[1]
3.	Dengue virus serotype 3 (rDEN 3Δ30/31)*	NLT 3.0 $\log_{10}$ PFU[1]
4.	Dengue virus serotype 4 (rDEN 4Δ30)*	NLT 3.0 $\log_{10}$ PFU[1]
Excipients		**Range**
1.	Gelatin	15 mg
2.	Mannitol	12 mg
3.	Trehalose	10 mg
4.	Sucrose	55 mg
5.	Potassium dihydrogen phosphate (KH_2PO_4)	~ 270 µg
6.	Di-potassium hydrogen phosphate (K_2HPO_4)	~ 630 µg
7.	Monosodium glutamate	~ 480 µg
8.	Leibovitz L-15 Medium	~ 850 µg
9.	Sterile Water for Injection	Q.s. to 0.5 ml

Table: 11

SN	Name of the component	Quantity (Per dose of 0.5 ml)
1.	Dengue virus serotype 1 (rDEN 1Δ30)*	NLT 3.0 $\log_{10}$ PFU[1]

SN	Name of the component	Quantity (Per dose of 0.5 ml)
2.	Dengue virus serotype 2 (rDEN 2/4Δ30)*	NLT 4.0 $\log_{10}$ PFU[1]
3.	Dengue virus serotype 3 (rDEN 3Δ30/31)*	NLT 3.0 $\log_{10}$ PFU[1]
4.	Dengue virus serotype 4 (rDEN 4Δ30)*	NLT 3.0 $\log_{10}$ PFU[1]
Excipients		**Range**
1.	Hydrolyzed Gelatin	22 mg
2.	Mannitol	20 mg
3.	Trehalose	10 mg
4.	Sucrose	37.5 mg
5.	Potassium dihydrogen phosphate (KH_2PO_4)	~ 270 µg
6.	Di-potassium hydrogen phosphate (K_2HPO_4)	~ 630 µg
7.	Monosodium glutamate	~ 480 µg
8.	Leibovitz L-15 Medium	~ 850 µg
9.	Dulbecco's Modified Eagle's Medium	~ 500 µg
10.	Sterile Water for Injection	Q.s. to 0.5 ml

Table: 19

SN	Name of the component	Quantity (Per dose of 0.5 ml)
1.	Dengue virus serotype 1 (rDEN 1Δ30)*	NLT 3.0 $\log_{10}$ PFU[1]
2.	Dengue virus serotype 2 (rDEN 2/4Δ30)*	NLT 3.0 $\log_{10}$ PFU[1]
3.	Dengue virus serotype 3 (rDEN 3Δ30/31)*	NLT 3.0 $\log_{10}$ PFU[1]
4.	Dengue virus serotype 4 (rDEN 4Δ30)*	NLT 3.0 $\log_{10}$ PFU[1]

SN	Name of the component	Quantity (Per dose of 0.5 ml)
Excipients		**Range**
1.	Hydrolyzed Collagen	22 mg
2.	Mannitol	15 mg
3.	Trehalose	8 mg
4.	Sucrose	37.5 mg
5.	Potassium dihydrogen phosphate (KH_2PO_4)	~ 260 µg
6.	Di-potassium hydrogen phosphate (K_2HPO_4)	~ 630 µg
7.	Monosodium glutamate	~ 460 µg
8.	Dulbecco's Modified Eagle's Medium	~ 500 µg
9.	Sterile Water for Injection	Q.s. to 0.5 ml

Table: 22

SN	Name of the component	Quantity (Per dose of 0.5 ml)
1	Dengue virus serotype 1 (rDEN 1Δ30)*	NLT 3.0 $\log_{10}$ PFU[1]
2	Dengue virus serotype 2 (rDEN 2/4Δ30)*	NLT 4.0 $\log_{10}$ PFU[1]
3	Dengue virus serotype 3 (rDEN 3Δ30/31)*	NLT 3.0 $\log_{10}$ PFU[1]
4	Dengue virus serotype 4 (rDEN 4Δ30)*	NLT 3.0 $\log_{10}$ PFU[1]
Excipients		**Range**
5	Collagen	22 mg
6	Mannitol	10 mg
7	Trehalose	5 mg
8	Sucrose	55 mg
9	Potassium dihydrogen phosphate (KH_2PO_4)	~ 260 µg
10.	Di-potassium hydrogen phosphate	~ 630 µg

SN	Name of the component	Quantity (Per dose of 0.5 ml)
	(K_2HPO_4)	
11.	Monosodium glutamate	~ 460 µg
12.	Dulbecco's Modified Eagle's Medium	~ 750 µg
13.	Sterile Water for Injection	Q.s. to 0.5 ml

Table: 23

SN	Name of the component	Quantity (Per dose of 0.5 ml)
1	Dengue virus serotype 1 (rDEN 1Δ30)*	NLT 3.0 $\log_{10}$ PFU[1]
2	Dengue virus serotype 2 (rDEN 2/4Δ30)*	NLT 4.0 $\log_{10}$ PFU[1]
3	Dengue virus serotype 3 (rDEN 3Δ30/31)*	NLT 3.0 $\log_{10}$ PFU[1]
4	Dengue virus serotype 4 (rDEN 4Δ30)*	NLT 3.0 $\log_{10}$ PFU[1]
Excipients		**Range**
5	Hydrolyzed Collagen	15 mg
6	Mannitol	12 mg
7	Trehalose	10 mg
8	Sucrose	55 mg
9	Potassium dihydrogen phosphate (KH_2PO_4)	~ 270 µg
14.	Di-potassium hydrogen phosphate (K_2HPO_4)	~ 630 µg
15.	Monosodium glutamate	~ 480 µg
16.	Leibovitz L-15 Medium	~ 850 µg
17.	Sterile Water for Injection	Q.s. to 0.5 ml

26. A vaccine composition according to claim 23 for use in preventing disease caused by dengue virus.

27. A vaccine kit comprising a first container containing a stabilized vaccine composition according to claim 23 and a second container containing an aqueous solution for the reconstitution of the vaccine.