

मिसिल स.- 8(58)/2018/डी.पी/एनपीपीए-डीवी-II

F. No. 8(58)/2018/DP/NPPA-Div. II

कार्यवाहीस. : 190/58/2018/F

Proceeding No : 190/58/2018/F

Minutes of the 190th (overall) and 58th meeting of the Authority under DPCO, 2013 held on 28.06.2018 at 11:00 A.M

I. The 190th (overall) meeting of the Authority, which is the 58th meeting under the DPCO, 2013, was held on 28th June, 2018 at 11:00 AM under the Chairmanship of Dr. Rakesh Kumar Vats, Chairman, NPPA. The following members of the NPPA were present:

- (i) Ms. Ritu Dhillon, Member Secretary
- (ii) Dr. S. Eswara Reddy, DCG(I)
- (iii) A.K.Pradhan, Deputy Drug Controller, Deptt. of Health & Family Welfare

1.1 The following officers of NPPA also attended the meeting and assisted the Authority in its deliberations:

- i. Shri Amarpal Singh Sawhney, Director (Pricing)
- ii. Shri Baljit Singh, Asstt. Director (Pricing)
- iii. Shri Prasenjit Das, Asstt. Director (Pricing)

1.2 Dr. D. Usha Rao, Assistant Controller of Patent & Design, Patent Office, Delhi joined as a special invitee.

1.3 Chairman, NPPA welcomed all present in the meeting.

II. Agenda items

1. Agenda item no. 1 - Confirmation of Minutes of the 57th Meeting held on 08.06.2018.

1.1 The Authority confirmed the minutes of the 189th (overall) and the 57th Meeting under DPCO 2013 held on 08.06.2018.

2. Agenda item no. 2 – Action Taken Report

2.1 Noted.

3. Agenda item no. 3 - Status of New Drug application

3.1 The Authority noted the number of new drug applications, in process, with the Authority. It directed that DCGI may be requested to expedite the cases referred to it by NPPA.

4. Agenda item no. 4 – New Drug application

4.1. The Authority discussed the following cases of retail price fixation of new drugs in Agenda no. 4 falling under the purview of para 2(u) of DPCO, 2013 and approved the retail prices of 50(fifty) drugs under para 5 of the DPCO 2013. The following retail prices were approved:

Sl. No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
1.	Rosuvastatin + Clopidogrel Capsule (Crevast CV 20)	Each Hard gelatine capsule contains: Rosuvastatin Calcium IP eq. to Rosuvastatin 20mg, Clopidogrel Bisulphate IP eq. to Clopidogrel 75mg.	1 Capsule	M/s Synokem Pharmaceuticals Ltd/ M/s Eris Lifesciences Ltd.	16.73
2.	Fluconazole Dispersible Tablet (ULTICAN – 50 DT)	Each uncoated tablet contains: Fluconazole IP 50mg	1 Tablet	M/s Acme Formulations Pvt. Ltd. / M/s Sun Pharmaceutical Industries Ltd.	6.24
3.	Amoxicillin + Clavulante Dry Syrup (Clanoxy Forte)	Each 5ml of reconstituted Suspension: Amoxicillin Trihydrate IP eq. to Amoxicillin 400mg, Potassium Clavulante Diluted IP eq. to Clavulnic Acid 57mg	1 ML Pack	M/s Galpha Laboratories Limited	3.219

4.	Telmisartan + Metoprolol Tablet (Metolar TL 50)	Each film coated bilayered tablet contains: Telmisartan IP 40mg, Metoprolol Succinate IP 47.50mg eq. to Metoprolol Tartrate 50mg (ER)	1 Tablet	M/s Revenbhel Biotech Ltd.	11.05
5.	Telmisartan + Metoprolol Tablet (Metolar TL 25)	Each film coated bilayered tablet contains: Telmisartan IP 40mg, Metoprolol Succinate IP 23.50mg eq. to Metoprolol Tartrate 25mg (ER)	1 Tablet	M/s Revenbhel Biotech Ltd.	9.22
6.	Hydroxychloroquine Sulphate Tablets (OXCQ 300mg)	Each film coated tablet contains: Hydroxychloroquine Sulphate 300mg	1 Tablet	M/s Wallace Pharmaceuticals Pvt. Ltd.	9.58
7.	Glimepiride + Metformin Tablet	Each film coated bilayered tablet contains: Glimepiride 3mg, Metformin SR 500mg	1 Tablet	M/s Swiss Garnier Genexiaa Sciences / M/s Glenmark Pharmaceuticals Ltd.	6.89
8.	Glimepiride + Metformin + Voglibose Tablet	Each film coated bilayered tablet contains: Glimepiride 2mg, Metformin SR 500mg Voglibose 0.3mg Tablets	1 Tablet	M/s Swiss Garnier Genexiaa Sciences / M/s Glenmark Pharmaceuticals Ltd.	11.01
9.	Glimepiride + Metformin + Voglibose Tablet	Each film coated bilayered tablet contains: Glimepiride 2mg, Metformin SR 1000mg Voglibose 0.2mg Tablets	1 Tablet	M/s Swiss Garnier Genexiaa Sciences / M/s Glenmark Pharmaceuticals Ltd.	11.61
10.	Glimepiride + Metformin + Voglibose Tablet	Each film coated bilayered tablet contains: Glimepiride 1mg, Metformin SR 500mg Voglibose 0.3mg Tablets	1 Tablet	M/s Swiss Garnier Genexiaa Sciences / M/s Glenmark Pharmaceuticals Ltd.	9.40
11.	Telmisartan + Clinidipine + Chlorthalidone Tablet	Each film coated bilayered tablet contains: Telmisartan IP 40mg, Clinidipine 10mg & Chlorthalidone IP 6.25mg	1 Tablet	M/s Swiss Garnier Genexiaa Sciences / M/s Glenmark Pharmaceuticals Ltd.	10.37
12.	Clonazepam + Propranolol Tablet	Each uncoated tablet contains: Clonazepam IP 0.50mg, Propranolol Hydrochloride IP 20mg	1 Tablet	M/s Akums Drugs & Pharmaceuticals Limited / M/s Emcure Pharmaceuticals Limited	4.12
13.	Telmisartan + Chlorthalidone Tablet (Telpha-CH)	Each uncoated bilayered tablet contains: Telmisartan IP 40mg, Chlorthalidone IP 12.5mg	1 Tablet	M/s Pharmafabrikon	5.89
14.	Doxorubicin Hydrochloride Liposome Injection 2mg/ml (20mg/vial) 10ml (Pegylated Liposomal)	Each ml contains: Doxorubicin Hydrochloride 2mg (Pegylated Liposomal) Water for Injection	10 ML Vial	M/s Natco Pharma Limited / M/s Aureate Health Pvt. Ltd.	6459.20

	Concentrate for Infusion				
15.	Cilnidipine + Telmisartan Tablet (Cilniblu T)	Each film coated tablet contains: Cilnidipine IP 10mg, Telmisartan IP 40mg	1 Tablet	M/s Akums Drugs & Pharmaceuticals Ltd. / M/s Blue Cross Laboratories Pvt. Ltd.	4.00
16.	Sofosbuvir + Velpatsvir Tablet	Each film coated tablet contains: Sofosbuvir 400mg, Velpatsvir 100mg	28's Tablets	M/s Natco Pharma Ltd. / M/s Aprazer Health Care Pvt. Ltd.	15481.86
17.	Sofosbuvir + Ledipasvir Tablet	Each film coated tablet contains: Sofosbuvir 400mg, Ledipasvir 90mg	1 Tablet	M/s Natco Pharma Ltd. / M/s Aprazer Health Care Pvt. Ltd.	589.92
18.	Etoricoxib + Paracetamol Tablet	Each film coated tablet contains: Etoricoxib 60mg, Paracetamol 325mg	1 Tablet	M/s Cadila Pharmaceuticals Limited	5.46
19.	Adapalene + Benzoyl Gel	Contains: Adapalene BP 0.1% w/w Benzoyl Peroxide IP eq. to Anhydrous Benzoyl Peroxide 2.5%w/w	1 GM	M/s Apex Laboratories Private Limited	18.42
20	Teneligliptin + Metformin Tablet (Walaphage T 1000)	Each uncoated bilayer tablet contains: Teneligliptin Hydrobromide Hydrate eq. to Teneligliptin 20mg Metformin HCl 1000mg (SR)	1 Tablet	M/s Synokem Pharmaceuticals Ltd. / M/s Wallace Pharmaceuticals Pvt. Ltd.	10.09
21.	Teneligliptin + Metformin Tablet (Walaphage T 500)	Each uncoated bilayer tablet contains: Teneligliptin Hydrobromide Hydrate eq. to Teneligliptin 20mg Metformin HCl 500mg (SR)	1 Tablet	M/s Synokem Pharmaceuticals Ltd. / M/s Wallace Pharmaceuticals Pvt. Ltd.	9.79
22.	Brimonidine + Timolol Eye Drops (New Albrim LST)	Contains: Brimonidine Tartrate IP 0.2%w/v, Timolol Maleate IP eq. to Timolol 0.5% w/v Sterile aqueous vehicle q.s.	1 ML	M/s Akums Drugs & Pharmaceuticals Ltd. / M/s Alembic Pharmaceuticals Limited	18.75
23.	Glimipiride + Metformin Tablet (GLYCOMET GP 3)	Each modified bi-layered tablet contains: Glimipiride IP 3mg, Metformin Hydrochloride IP 500mg (ER)	1 Tablet	M/s Anphar Organics. / M/s USV Private Limited	6.89
24.	Paclitaxel (Protein bound Particles) for Injectable Suspension	Each vial contains: Paclitaxel IP 100mg/vial Lyophilized	Each Pack	M/s Beta Drugs Ltd / M/s RPG Life Sciences Limited	11590.00
25.	Glimipiride + Metformin Tablet (Glimison - M 0.5)	Each Uncoated bilayered Tablet contains: Glimipiride IP 0.5mg & Metformin HCL IP 500mg (in prolonged release form)	1 Tablet	M/s Unison Pharmaceuticals Limited	1.79
26.	Teneligliptin + Metformin Tablet (Teneblu M Forte)	Each uncoated bilayer tablet contains: Teneligliptin Hydrobromide	1 Tablet	M/s Synokem Pharmaceuticals Ltd. / M/s Blue Cross	9.50

		Hydrate eq. to Teneiglipitin 20mg Metformin HCl 1000mg (SR)		Laboratories Pvt. Ltd.	
27.	Teneiglipitin + Metformin Tablet (Teneblu M)	Each uncoated bilayer tablet contains: Teneiglipitin Hydrobromide Hydrate eq. to Teneiglipitin 20mg Metformin HCl 500mg (SR)	1 Tablet	M/s Synokem Pharmaceuticals Ltd. / M/s Blue Cross Laboratories Pvt. Ltd.	7.50
28.	Olmesartan + Amlodipine + Hydrochlorothiazide Tablet (Amlokind – 5)	Each film coated tablet contains: Olmesartan Medoxomil IP 40mg, Amlodipine Besilate IP eq. to Amlodipine 5mg & Hydrochlorothiazide IP 12.5	1 Tablet	M/s Pure & Cure Healthcare Pvt. Ltd. / M/s Mankind Pharma Limited	12.95
29.	Travoprost + Timolol Maleate + Benzalkonium Eye Drops	Contains: Travoprost IP 0.004%w/v, Timolol Maleate IP eq. to Timolol 0.5% w/v, Benzalkonium Chloride Solution IP 0.01% v/v	1 ML	M/s Pure & Cure Healthcare Pvt. Ltd. / M/s LifeStar Pharma Private Limited	130.76
30.	Brimonidine + Timolol Maleate + Benzalkonium Eye Drops	Contains: Brimonidine Tartrate IP 0.2%w/v, Timolol Maleate IP eq. to Timolol 0.5% w/v, Benzalkonium Chloride Solution IP 0.02% v/v	1 ML	M/s Pure & Cure Healthcare Pvt. Ltd. / M/s LifeStar Pharma Private Limited	21.68
31.	Teneiglipitin + Metformin Tablet (Glipijub M Forte)	Each uncoated bilayered tablet contains: Teneiglipitin Hydrobromide Hydrate eq. to Teneiglipitin 20mg Metformin HCl 1000mg (ER)	1 Tablet	M/s Glenmark Pharmaceuticals Ltd. / M/s Jubilant Lifesciences Limited	10.06
32.	Teneiglipitin + Metformin Tablet (Glipijub M)	Each uncoated bilayered tablet contains: Teneiglipitin Hydrobromide Hydrate eq. to Teneiglipitin 20mg Metformin HCl 500mg (ER)	1 Tablet	M/s Glenmark Pharmaceuticals Ltd. / M/s Jubilant Lifesciences Limited	9.79
33.	Teneiglipitin + Metformin Tablet	Each uncoated bilayered tablet contains: Teneiglipitin Hydrobromide Hydrate eq. to Teneiglipitin 20mg Metformin HCl 1000mg (ER)	1 Tablet	M/s Unison Pharmaceuticals Pvt. Ltd.	6.25
34.	Teneiglipitin + Metformin Tablet	Each uncoated bilayered tablet contains: Teneiglipitin Hydrobromide Hydrate eq. to Teneiglipitin 20mg Metformin HCl 500mg (ER)	1 Tablet	M/s Unison Pharmaceuticals Pvt. Ltd.	5.358
35.	Travoprost + Timolol Eye Drops (Travisight –T)	Each ml contains: Travoprost IP 40mcg, Timolol Maleate IP eq. to Timolol 5mg	1 ML	M/s Akums Drugs & Pharmaceuticals Ltd. / M/s Alembic Pharmaceuticals Ltd.	86.30

36.	Cilnidipine + Telmisartan + Chlorthalidone Tablet	Each filmcoated tablet contains: Cilnidipine 10mg, Telmisartan IP 40mg, Chlorthalidone 6.25mg	1 Tablet	M/s Safetab Life Science / M/s Lupin Limited	10.37
37.	Telmisartan + Hydrochlorthiazide Tablet (Telpha-H)	Each uncoated bilayered tablet contains: Telmisartan IP 40mg, Hydrochlorthiazide IP 12.5mg	1 Tablet	M/s Pharmafabrikon	7.14
38.	Ferrous Ascorbate + Folic Acid Tablet	Each film coated tablet contains: Ferrous Ascorbate eq. to Elemental Iron 100mg, Folic Acid IP 1.5mg,	1 Tablet	M/s Tirupati Medicare Ltd / M/s Zydus Cadila Healthcare Limited	8.89
39.	Doxorubicin Hydrochloride Injection	Each ml contains: Doxorubicin Hydrochloride IP 2mg (As pegylated liposomal) Water for Injection	25 ML	M/s Natco Pharma Ltd. / M/s Zydus Cadila Healthcare Limited	13473.68
40.	Rosuvastation + Clopidogrel Capsule	Each hard gelatine capsule contains: Rosuvastation Calcium IP 20mg (As pellets), Clopidogrel Bisulphate IP 75mg (as pellets)	1 Capsule	M/s Synokem Pharmaceuticals Limited / M/s INTAS Pharmaceuticals Limited	16.26
41.	Cilnidipine + Telmisartan Tablet (NEXOVAS T)	Each film coated tablet contains: Cilnidipine 10mg & Telmisartan IP 40mg	1 Tablets	M/s Macleods Pharmaceuticals Limited	7.67
42.	Cilnidipine + Telmisartan Tablet (ZITELMI -CL)	Each film coated tablet contains: Cilnidipine 10mg & Telmisartan IP 40mg	1 Tablets	M/s Akums Drugs & Pharmaceuticals Limited / M/s FDC Limited	7.14
43.	Diclofenac + Linseed Oil + Methyl Salicylate + Menthol + Benzyl Alcohol GEL (Dan)	contains: Diclofenac Diethylamine 1.16% w/w + Linseed Oil 3% w/w + Methyl Salicylate 10% w/w Menthol 5% w/w Benzyl Alcohol 1% w/w GEL base q. s.	1 GM	M/s Tuton Pharmaceuticals / M/s Unison Pharmaceuticals Pvt. Ltd.	1.40
44.	Telmisartan + Amlodipine Tablet (Telmiride - AM)	Each film coated tablets contains: Telmisartan IP 40mg + Amlodipine 5mg	1 Tablet	M/s Unison Pharmaceuticals Pvt. Ltd.	2.99
45.	Cilnidipine + Telmisartan Tablet (Telmiride - LN)	Each film coated tablet contains: Cilnidipine 10mg & Telmisartan IP 40mg	1 Tablet	M/s Windlas Biotech Pvt. Ltd. / M/s Unison Pharmaceuticals Pvt. Ltd.	3.57
46.	Voglibose + Metformin Tablet (Voglyson - M 0.2)	Each uncoated bilayered tablet Contains: Voglibose 0.2mg & Metformin Hydrochloride 500mg	1 Tablet	M/s Unison Pharmaceuticals Pvt. Ltd.	3.20
47.	Voglibose + Glimepiride + Metformin Tablet (BETAGLIM 2 MV	Each tablets contains: Voglibose IP 0.3mg, Glimepiride IP 2mg & Metformin (SR) 500mg	1 Tablet	M/s Windlas Biotech Pvt. Ltd. / M/s Panacea Biotech Ltd.	9.37

	0.3)				
48.	Voglibose + Glimepiride + Metformin Tablet (BETAGLIM 1 MV 0.3)	Each tablets contains: Voglibose IP 0.3mg, Glimepiride IP 1mg & Metformin (SR) 500mg	1 Tablet	M/s Windlas Biotech Pvt. Ltd. / M/s Panacea Biotech Ltd.	8.03
49.	Voglibose + Glimepiride + Metformin Tablet (BETAGLIM 2 MV)	Each tablets contains: Voglibose IP 0.2mg, Glimepiride IP 2mg & Metformin (SR) 500mg	1 Tablet	M/s Windlas Biotech Pvt. Ltd. / M/s Panacea Biotech Ltd.	8.48
50.	Voglibose + Glimepiride + Metformin Tablet (BETAGLIM 1 MV)	Each tablets contains: Voglibose IP 0.2mg, Glimepiride IP 1mg & Metformin (SR) 500mg	1 Tablet	M/s Windlas Biotech Pvt. Ltd. / M/s Panacea Biotech Ltd.	7.14

5. Agenda item no. 5 - Implementation of review orders

5.1 Agenda item no. 5(i) Review order in respect of M/s Dr. Reddy's Laboratories Ltd for retail price fixation of Atocor CV 10 mg capsule (Atorvastatin 10 mg + Clopidogrel 75 mg)

5.1.1 The authority deliberated upon and considered the review order issued by DoP for working out the retail price of the drug as per para 5(i) of DPCO, 2013 and decided to revise the retail price of Atocor CV 10 mg capsule (Atorvastatin 10 mg + Clopidogrel 75 mg) to Rs. 10.92 per capsule from the existing ceiling price of Rs. 8.394 per capsule.

5.2 Agenda item no. 5(ii) Review order in respect of M/s Dr. Reddy's Laboratories Ltd for retail price fixation of Atocor CV 20 mg capsule (Atorvastatin 20 mg + Clopidogrel 75 mg)

5.2.1 The authority deliberated upon and considered the review order issued by DoP for working out the retail price as per para 5(i) of DPCO, 2013 and decided to revise the retail price of Atocor CV 20 mg capsule (Atorvastatin 20 mg + Clopidogrel 75 mg) to Rs. 15.625 per capsule from the existing ceiling price of Rs. 10.596 per capsule.

5.3 Agenda item no. 5(iii) Review order in respect of M/s Sun Pharma laboratories Ltd for retail price fixation of Tigatel CH 80 tablet (Telmisartan 80 mg + Chlorthalidone 12.5 mg)

5.3.1 The authority deliberated upon and considered the review order issued by DoP for working out the retail price as per para 5(i) of DPCO, 2013 and decided to revise the retail

price of Tigatel CH 80 tablet (Telmisartan 80 mg + Chlorthalidone 12.5 mg) to Rs. 13.06 per tablet from the existing ceiling price of Rs. 6.713 per tablet.

5.4 Agenda item no. 5(iv) Review order in respect of M/s Sun Pharmaceutical Industries Ltd for retail price fixation of Ranixime plus tablet (Cefixime 200 mg + Ofloxacin 200 mg tablet)

5.4.1 The authority deliberated upon and considered the review order issued by DoP for working out the retail price as per para 5(i) of DPCO, 2013 and decided to revise the retail price of Ranixime plus tablet (Cefixime 200 mg + Ofloxacin 200 mg tablet) to Rs. 10.59 per tablet from the existing ceiling price of Rs. 9.46 per tablet.

5.5 Agenda item no. 5(v) Review order in respect of M/s Eris Lifesciences Ltd for retail price fixation of Rosuvastatin 20mg + Clopidogrel 75 mg hard gelatin capsule

5.4.1 The authority deliberated upon and considered the review order issued by DoP for working out the retail price as per para 5(i) of DPCO, 2013 and decided to revise the retail price of Rosuvastatin 20mg + Clopidogrel 75 mg hard gelatin capsule to Rs. 16.60 per capsule from the existing ceiling price of Rs. 7.80 per capsule.

5.6 Agenda item no. 5(vi) Review order in respect of M/s Zydus Healthcare Ltd for retail price fixation of Rosuvastatin 20mg + Clopidogrel 75 mg hard gelatin capsule

5.6.1 The authority deliberated upon and considered the review order issued by DoP for working out the retail price as per para 5(i) of DPCO, 2013 and decided to revise the retail price of the drug to Rs. 16.06 per capsule from the existing ceiling price of Rs. 7.80 per capsule.

5.7 Agenda item no. 5(vii) Price revision on account of DoP directions on the review application of M/s Samrath Lifesciences Pvt Ltd in respect of Furesmide Oral solution and Digoxin Oral Liquid 0.05mg/ml

5.7.1 The authority was apprised that the company was granted a personal hearing on 18.06.2018 as per the directions of DoP, wherein it provided data which was also cross verified from Pharmatrac. Based on this data, the ceiling prices of the formulations 'Furesmide Oral solution 10mg/ml' and 'Digoxin Oral Liquid 0.05mg/ml' were reworked as

per para 6 of DPCO, 2013. The authority decided to revise the ceiling price of 'Furesmide Oral solution 10mg/ml' and 'Digoxin Oral Liquid 0.05mg/ml' to Rs. 2.60 per ml and Rs. 1.19 per ml respectively.

5.8 Agenda item no. 5(viii) Review order in respect of M/s Sun Pharmaceutical Industries Ltd for Sodium Valproate 200 mg tablet

5.8.1 The Authority deliberated upon the recommendations made by the multidisciplinary Committee of Experts on 13.06.2018 on the review order. The Authority rejected the contention of the review applicant and decided to close the review order in respect of M/s Sun Pharmaceutical Industries Ltd for Sodium Valproate 200 mg tablet without any change in the ceiling price.

6 Agenda item no. 6 Application for price exemption under para 32 of the DPCO 2013.

6.1 The following applications under relevant sub-paragraphs of para 32 alongwith document submitted by the companies were duly examined and discussed by the Authority:

Sl No	Product
	M/s Sun Pharmaceuticals Industries Ltd in respect of their product
1	'Ready to use infusion bags Gemcitabine Hydrochloride injection 10mg/ml (Ready to use infusion bags 1200mg/120ml, 1400mg/140ml and 1600mg/160ml)'.
2	Silver Sulfadizine (Nanonized) 0.5% w/w and Clorhexidine gluconate 0.2% w/w topical cream
3	Diclofenac Topical Solution
	M/s Meril Lifesciences Pvt Ltd in respect of their product
4	Sirolimus eluting BioResorbable vascular scaffold system(MeRes100).

6.2 A representative of 'The Patent office' joined as a special invitee. For cases at Sl no 1, 3, and 4, the authority noted that companies have produced documents showing that patents have been granted under Indian Patents Act, 1970 for producing the new drugs in the country by a new process developed through indigenous research and development and companies have also produced documents showing approval of such new drugs from DCGI. However, the authority observed that the matter requires further interpretation

with regard to applicability under para 32 of DPCO, 2013. The representative of the the Patent Office sought time for cross verifying the submissions made by the company for grant of patent under Indian Patents Act, 1970. Therefore, the Authority decided to deliberate upon the matter, further, in the next meeting.

6.3 The Authority also observed that in case of Sl. No. 3, the patent had been granted to Mr. Ketan R. Patel, CMD, Troikka, whereas, the exemption application had been moved by M/s Sun Pharmaceuticals Ltd. Therefore, the Authority decided that M/s Sun Pharmaceuticals Industries Ltd. would be required to produce an NOC/tripartite agreement between Mr. Ketan R. Patel, CMD, TROIKKA, M/s TROIKKA Pharmaceuticals Ltd and M/s Sun Pharmaceuticals Industries Ltd.

6.4 It was noted that in case of Sl. No. 2, patent has not yet been granted under Indian Patents Act, 1970. The claim of the company that it had developed a new delivery system through indigenous research, could also not be established. Therefore, the claim of the company for exemption under para 32 was rejected by the Authority.

7. Agenda item no. 7 Minutes of 3rd Meeting of Multidisciplinary committee of experts held on dated 13.06.2018

7.1 Noted.

The meeting ended with a vote of thanks to the Chair.

Sd/-
(Ritu Dhillon)
Member Secretary