	भारतीय मानक ब्यूरो BUREAU OF INDIAN STANDARDS	
	(PETROLEUM, COAL & RELATED PRODUCTS DEPTT.)	
MINUTES		
Organic Chemicals, Alcohols & Allied Products Sectional Committee, PCD 09		**38th Meeting**
DATE & TIME	13 September 2024, 10:00 am	
VENUE	Physical Mode	
	Details	
	Venue	Western Regional Laboratory, Manakalaya, Bureau of Indian Standards E-9, M.I.D.C., Behind Marol Telephone Exchange, Andheri (East), Mumbai - 400 093
	City	Mumbai, India
CHAIRPERSON	**Dr C.V Rode, In Personal Capacity**	
MEMBER SECRETARY	Ms Aditi Choudhary, Scientist 'C' (PCD), BIS E-mail: pcd9@bis.gov.in; pcd@bis.gov.in	

Item 0 OPENING OF THE MEETING

0.1 Welcome by Bureau of Indian Standards

On behalf of BIS, Ms Aditi Choudhary, Scientist C, welcomed the Chairman, PCD 9 and all the members to 38th meeting of Organic Chemicals, Alcohols and Allied Products Sectional Committee, PCD 9. She thanked all the members for making it convenient to attend physically meeting. She informed the Committee that the agenda items of the meeting comprise of mostly comments on standards on which QCOs have been issued and thus urgent. She requested all the members to actively participate in the meeting and consider the national interest while discussing various Agenda items. She also requested them to confine their discussions to relevant subjects to complete the agenda within the timeframe. Further, she also briefed the Committee members about the reforms taken by BIS in this financial year.

0.2 Opening remarks by the Chairperson

The meeting started with Dr C.V. Rode, Chairman, PCD 9 addressing all the members of Organic Chemicals, Alcohols and allied Products Sectional Committee, PCD 9 to its 38th meeting. He appreciated the efforts made by the experts in standardization activity and also making it

convenient to attend the meeting physically amid their busy schedule. He requested the members for their active participation for discussing the comments as received and revision of existing Indian Standards for the benefit of consumers. He concluded his remarks by urging the members to do justice to the meeting by making it an interactive session and wished it a success.

Item 1 CONFIRMATION OF THE MINUTES OF THE 37th MEETING OF PCD 09

1.1 The Committee NOTED item 1 of the agenda and CONFIRMED the minutes of 37th meeting of PCD 9, as no comments were received on the minutes circulated.

Item 2 THE PRESENT TITLE, SCOPE AND COMPOSITION OF PCD 09

2.1 The Committee NOTED item 2.1 of the agenda about the title, scope and composition of the Committee. While reviewing the composition, the Committee NOTED that representative of Laxmi Organic Industries, Mumbai have not attend the last meeting and also this meeting. Further, they don't actively participate in the activities of PCD 9. In view of this the Committee DECIDED to WITHDRAW Laxmi Organic Industries and give other industries the chance to be part of Committee, who are willing to contribute.

In addition to the active participation, the Committee NOTED that the participation from industry is very high, while there is a need to co-opt organizations including laboratories and academia to balance out the existing composition. After detailed deliberations, REQUESTED BIS Sectt. to seek willingness from the following laboratories and academia to be the part of Committee:

a) Geo-chem

b) SGS

c) IIT Bombay

d) ICT, Mumbai

[Action to be taken: BIS Sectt.]

2.2 Request received for Co-option in Sectional Committee

2.2.1 *Representation received from Shri Aman in personal capacity*

The Committee NOTED item 2.2.1 of the agenda about the request received from Shri Aman in personal capacity. After deliberation, the Committee DECIDED *not to co-opt* Shri Aman, as he has his expertise in microbiology, whereas the experts relevant to PCD 9 primarily have a background in chemistry or chemical engineering.

2.2.2 *Representation received from Shri S Murugapoopathi in personal capacity*

The Committee NOTED item 2.2.2 of the agenda about the request received from Shri S Murugapoopathi in personal capacity. After deliberation, the Committee DECIDED *not to co-opt* Shri S Murugapoopathi, as his research background in biodiesel and solar energy is more relevant to the PCD 3 sectional committee than to PCD 9.

2.2.3 *Representation received from PSNA College of Engineering and Technology*

The Committee NOTED item 2.2.3 of the agenda about the request received from Shri Kannan G representing PSNA College of Engineering and Technology. After deliberation, the Committee DECIDED *not to co-opt* Shri Kannan G, as his research background in biodiesel and thermal energy is more relevant to the PCD 3 sectional committee than to PCD 9.

2.2.4 *Representation received from Malaviya National Institute of Technology Jaipur*

The Committee NOTED item 2.2.4 of the agenda about the request received from Shri Rohidas Bhoi representing Malaviya National Institute of Technology Jaipur. After detailed deliberation, the Committee DECIDED to keep the *co-option request on hold* and simultaneously seek willingness from other academia like ICT, Mumbai and IIT, Bombay. On receiving their willingness, the co-option of MNIT may be deliberated in detail.

2.2.5 *Representation received from I.G. Petrochemical Ltd*

The Committee NOTED item 2.2.5 of the agenda that was tabled during the meeting about the request received from Shri Panchi Pungnoor representing I.G. Petrochemical. The Committee NOTED his expertise on products like Phthalic Anhydride, Maleic Anhydride, Benzoic Acid and Di Ethyl Phthalate plasticizer, which lies under the scope of PCD 9. After detailed deliberation, the Committee DECIDED to *Co-opt* I.G. Petrochemical Limited with Shri Panchi Pungnoor as representing expert.

2.3 Reconstitution of Subcommittee's/Panel/Working group

The Committee NOTED item 2.3 of the agenda about the restructuring of technical committees. After detailed deliberation, the Committee DECIDED to dissolve the existing two subcommittees PCD 9:1 and PCD 9:2 as they have been dormant since long time, as most of the work has been handled by Panel or Working groups or Sectional Committee, given the controversial nature of topics under PCD 9, which require immediate attention. Further, currently due to urgency, the recommendations from the Panel or Working Group are submitted directly to the Sectional Committee for approval. Additionally, the Committee observed that the scope of the two subcommittees is not clearly defined. The standards under the Alcohols and Allied Products Subcommittee (PCD 9:2) also fall under the Organic Chemicals Subcommittee (PCD 9:1), making it more practical to dissolve the subcommittees.

The Committee further DECIDED to replace the subcommittees with Panels, which have the flexibility to continue its operations indefinitely while existing Panels will be renamed as working group. In contrast, a Working Group will be formed to address specific tasks or projects with

a defined scope and timeframe. These Working Groups will be temporary, focusing on particular objectives that need specialized attention. Once their assigned task is completed, the Working Group will be dissolved.

After detailed deliberations, the Committee REQUESTED BIS Sectt. to prepare the complete list of existing working group and Panel under PCD 9 and put up to Committee in next meeting. The same may then be reviewed by Committee if required.

[Action to be taken: BIS Sectt.]

Item 3 ISSUES ARISING OUT OF PREVIOUS MEETINGS

3.1 New Subjects received from DCPC

The Committee NOTED item 3.1 of the agenda and after deliberation, DECIDED as follows:

Sl No.	NWIP Title	Present Status	Decision of the Committee
1.	PBO-BUTO-AM OR 1-[(4R,5R)-5-[(4-METHOXYPHENYL) THIO] [HS Code 29339900]	Mail was sent to DCPC on dated 18 April 2024, no clarification has been received. Based on the last meeting decision the subject may be dropped.	The Committee NOTED that no clarification have been received from DCPC and thus based on the last meeting DECIDED to drop the subject. Further, formulation of standard may be taken up in future on receival of correct name of the product.

3.2 COMMENTS ON PUBLISHED STANDARDS

3.2.1 IS 5573 : 1984 Specification for ethylene oxide (First Revision)

The Committee NOTED item 3.2.1 of the agenda and the recommendation of the Panel. The Committee NOTED the information that there are currently no established international standards on requirement ethylene oxide. In addition, the Committee REVIEWED the Panel's comparison made between the requirements of foreign manufacturers Lyondell Basell; Balchem and Chemgas along with existing requirements and newly proposed requirements.

After detailed deliberation, the Committee ENDORSED Panel's decision to modify the requirements of ethylene oxide to ensure the consumer safety given the highly hazardous nature of ethylene oxide and also to prevent substandard quality of ethylene oxide being manufactured or imported in the country. The following are the modified requiremnets:

Sl No.	Characteristic	Modified requirements

(1)	(2)	(9)
i)	Colour, Pt-Co scale, *Max*	Decided to make the parameter optional
ii)	Aldehydes (as acetaldehyde content), percent by mass, *Max*	Decided to modify the limit to 50 ppm
iii)	Moisture content, percent by mass, *Max*	Decided to modify the limit to 300 ppm
vi)	Acidity (as CH_3COOH), percent by mass, *Max*	Decided to keep the limit to 20 ppm
vi)	Non-volatile matter*, percent by mass, *Max*	Decided to modify the limit to 50 ppm
vii)	Ethylene oxide content (by difference), percent by mass, *Min*	Decided to modify the limit to 99.95 %
*The non- volatile matter content may increase during storage with time, but the limit specified shall be adhered to at the time of supply by the manufacturer.		

The Committee further requested BIS Sectt. to prepare the draft by incorporating the proposed changes and circulate to panel members for review for 15 days. If no comments are received, the draft is to be issued into wide circulation for a period of 2 months. Additionally, the Committee REQUESTED BIS Sectt. to send the draft to PESCO also, when circulated for wide circulation.

[Action to be taken: BIS Sectt.]

3.2.2 IS 695 : 2020 Acetic Acid — Specification (Fourth Revision)

The Committee NOTED item 3.2.2 of the agenda and after deliberations DECIDED as follows:

Sl. No. **(1)**	**Clause/Sub-clause/ para/table/fig. No. commented** **(2)**	**Proposed change** **(3)**	**Decision of the Committee in last meeting** **(4)**	**Present Status** **(5)**	**Decision of the Committee** **(6)**
1	Clause 7.1, Table 1; A-7.0	**A-7.1 (Referee Method)** Alternatively, it can be analyzed by	The Committee REQUESTED BIS Sectt. to seek complete method from proposer and on receiving the inputs, forward it to Shri C.S.	Based on the decision of the Committee, proposer has been requested for the method. Alternatively, GNFC ltd informed BIS	During deliberations, the Committee acknowledged that the prepared solution while testing, being a suspension solution, would not yield appropriate results when

		instrumental test method such as UV-Vis spectrophotometer.	Patel, GNFC for seeking inputs regarding compatibility of spectrophotometer method, as proposed, for determination of 'Sulphate (as SO4) content in acetic acid.	Sectt. that hey are using existing method only for determination of while 'Sulphate (as SO4) content in acetic acid.	tested using a UV-Vis spectrophotometer. Therefore, NOT AGREED to incorporate UV-Vis spectrophotometer as an alternate method.
2	Clause 7.1, Table 1; A-6.1 & 6.2	**A-6.3 (Referee Method)** Alternatively it can be analyzed by any established/validated instrumental test methods such as ICP-OES, ICP-MS, etc.	• During deliberation, BIS Sectt. informed the Committee that there exists IS 1448 (Part 172) ICP-OES Method for Determination of Trace Elements in Petroleum Products. • In view of this, the Committee, REQUESTED BIS Sectt. to forward the same to Shri C.S. Patel, GNFC for seeking inputs regarding compatibility of IS 1448 (Part 172), for determination of iron content in acetic acid.	It is informed that the determination of iron and heavy metals using ICP-OES has been incorporated as per Amendment 3.	The Committee NOTED the information that the determination of iron and heavy metals using ICP-OES has been incorporated as per Amendment 3. Thus, NOT AGREED on the comment as already covered though amendment.

3.2.3 IS 717 Carbon disulphide, technical — Specification

The Committee NOTED item 3.2.3 of the agenda and after deliberations DECIDED as follows:

Sl. No. **(1)**	**Clause/Sub-clause/ para/table/fig. No. commented** **(2)**	**Proposed change** **(3)**	**Decision of the Committee in last meeting** **(4)**	**Present Status** **(5)**	**Decision of the Committee** **(6)**
1.	1. Scope	Additional statement this standard exclude the ACS and lab	During the deliberations, the Committee felt a need that a deliberation is required, if the	Inputs awaited from Panel.	During deliberations the Committee NOTED that ACS grade is the purest form and is

		grade carbon disulphide from the listed requirements, the methods of sampling and test.	ACS and lab grades are to be incorporated in the standard or not. For deliberation on the incorporation of ACS or lab grade, the Committee constituted the following Panel: Composition of the Panel: i) Indobijin Chemical Pvt. Ltd (Convener); ii) United Phosphorus Limited, Mumbai; iii) Merk Group iv) User Industry v) DCPC		imported in India in very less quantity. The Committee was also of the view that ACS grade may also be covered by existing grade and thus incorporating another grade as ACS may be of low significance. In the view of this, the Committee REQUESTED BIS Sectt. to request MERCK for submitting data for ACS grade, how it is different from the present grade. In addition to the comparison, also requested MERCK to submit data of amount of Carbon disulphide manufactured by them domestically and imported by them specifying its final application. On receiving the data, the same may be forwarded to working group (*formerly called Panel*) for further deliberations.
2.	1	Additional statement this standard exclude the ACS and lab grade carbon disulphide from the listed requirements, the methods of sampling and test.			

[Action to be taken: MERCK and Working group (*formerly called Panel*)]

3.2.4 IS 5295 : 2023 — Ethylene Glycol - Specification (Third Revision)

The Committee NOTED item 3.2.4 of the agenda and after deliberations DECIDED as follows:

Sl. No. (1)	Clause/Sub-clause/ para/table/fig. No.	Proposed change	Decision of the Committee in previous meeting	Present Status (5)	Decision of the Committee (6)

	commented (2)	(3)	(4)		
i.	4.2/Table 1/ SI No.ii	ASTM D4052-2022 would be the similar and appropriate test method (oscillating U-tube) for Relative density at 20 °C/20 °C. or Can give in foot note as IS 1447 (Part 167): 2018 test method Scope shall be used as 0.600 to 1.116 instead of 0.600 to 1.100 for glycol product.	BIS Sectt. informed the Committee that the standard referred is IS 1448 (Part 167) and not IS 1447 (Part 167). Further, REQUESTED BIS Sectt. to contact BIS licensee for seeking inputs on the applicability of IS 1448 (Part 167) for determination of Relative density at 20 °C/20 °C. Based on the inputs received from licensees the comments will again be discussed in next meeting.	Inputs awaited from BIS licensees for the applicability of IS 1448 (Part 167) for determination of Relative density at 20 °C/20 °C. Inputs as received from Shri Pramod Mall, Reliance and Shri Dr Y.S. Jhala, IOCL : IS 1448 Part 167 is an adoption of ISO 12185 which is mainly prepared for Petroleum Products. However Digital density meters available in market having compliance of ISO 12185 can work very well in this range. Equivalent method for this test in ASTM is D4052 and D5931, D5931 is specially drafted for Glycol and Glycol Water mixtures that is also based on same equipment (Documents attached) Based on above following is path	After detailed deliberation, the Committee concluded that IS 1448 Part 167 is an adoption of ISO 12185, which is primarily intended for petroleum products. This has caused confusion among users, as the test method's applicability range (0.600 to 1.100) does not align with the existing values specified in IS 5295 (1.114-1.116), despite the underlying principle being the same. To address this issue, the Committee decided to incorporate an indigenous method based on ASTM D 5931 and delete reference of IS 1448 Part 167. Further, REQUESTED BIS Sectt. to prepare the draft amendment based on the above change and circulate to Committee for 15 days. If no comments are received, issue into wide circulation for a period of 2 months.

				Forword We can mention in IS5295 below text “ IS 1448:167 is having range up to 1100, however digital density meter are having capability for testing in this range. Lab to verify the equipment before use” We can create Annexure based on D5931 as referee method”	
Sl. No. **(1)**	**Clause/Sub-clause/ para/table/fig. No. commented** **(2)**	**Commentator / Organization/ Abbreviation** **(3)**	**Justification** **(4)**	**Proposed change** **(5)**	**Decision of the Committee** **(6)**
ii.	4.2: Table 1 (4.2 B - 1.3.5 and B-7.2.5)	Shashank Mahana shashank.mahana@external.merckgroup.com 9090746554 Additional Contact: Santosh Wagh	Making freezing point test "optional" quality parameter for General Grade - Ethylene Glycol which is intended as a reagent (in IS 5295:2023). Justification: Ethylene glycol serves as a vital antifreeze coolant in the aviation sector. Its freezing point is an important physical characteristic when considering its application as an anti-coolant in	Table 1 : Requirement for ethylene glycol (clause 4.2 B -1.3.5 and B-7.2.5) General Grade vii *Freezing point of equal volume of material & water max -30°C	During deliberations, manufacturers and users of MEG informed the Committee that it is an important parameter to be tested for both general grade and fiber grade and making it optional parameter may lead to mishandling of MEG.

		santosh.wagh@merckgroup.com 8291093309 Saroj Varavadekar saroj.varavadekar@merckgroup.com 9513560063	aviation industry. However, this property does not notably affect the performance or efficacy of ethylene glycol when utilized as a reagent in fields like pharmaceuticals, chemicals, research and development and academia. IS 5759: 2006 ANTIFREEZE COOLANT ? SPECIFICATION covers antifreeze radiator coolant which is a specialty chemical used for prevention of freezing of cooling liquid and prevention of corrosion of cooling system of liquid cooled combustion engine. General requirement in clause 2.1 of IS 5759: 2006 specifically mentions the usage of mainly ethylene glycol and other glycols such as propylene glycol as an ANTIFREEZE COOLANT in different concentrations. In such scenario, we are requesting you to make freezing point test "optional" for Ethylene Glycol - General Grade intended as a reagent.	Note: Freezing point parameter is applicable only for ethylene glycol which is intended as an antifreeze coolant in aviation industries. This parameter is optional if general grade ethylene glycol is intended as a reagent.	After detailed deliberation, the Committee DECIDED not to make the parameter optional.
iii.	1:Scope,		Exclusion of Ethylene Glycol used as Certified Reference Materials (CRMs) such as Pharmacopeial standards, Analytical Standards etc. or for R&D use only: Justification: The IS standards are not applicable to certified reference material of the notified chemical however it is not explicitly mentioned in QCO. The reference standards are used in very limited quantity during analysis and do not pose any threat to the environment or person using it. Reference material producers must meet ISO requirements (such as ISO 17034,	Scope: This standard prescribes the requirements and methods of sampling and test for ethylene glycol used in antifreeze formulations, explosives, organic intermediates and polyester fibers and filaments. Note: This standard does not cover the certified reference material of ethylene glycol such as	During deliberations the Committee NOTED that CRMs, ACS grade are the purest form and is imported in India in very less quantity. The Committee was also of the view that CRMs, ACS grade may also be covered by existing grade and thus incorporating another grade as CRMs, ACS grade may be of low significance. In the view of this, the Committee REQUESTED

			ISO/IEC 17025 and ISO Guide 31) to manufacture CRMs or RMs. Information such as purity, identity and traceability are shared with customers at batch level. Hence the quality is inbuilt and ensured during production of reference standards & IS std are not applicable to reference standards. The quantity of chemicals used in R&D application is very low in comparison to other industrial applications and hence the quality and other considerations which mandated regulating the chemical might not be applicable.	Pharmacopeial standards, Analytical Standards etc. or for R&D use only. Freezing point parameter is applicable only for general grade-ethylene glycol which is intended as an antifreeze coolant in aviation industries. This parameter is optional if general grade ethylene glycol is intended as a reagent.	BIS Sectt. to request MERCK for submitting data for CRMs, ACS grade, how it is different from the present grade. In addition to the comparison, also requested MERCK to submit data of amount of MEG manufactured by them domestically and imported by them specifying its final application. Additionally, for comments on use of MEG in pharmaceutical industry The Committee concluded that before taking a final decision on exclusion of MEG used in pharmaceutical industry (pharma grade) it is essential to hold a consultative meeting with concerned regulator to have a clarity on the need of Indian Standards for such chemicals which have application in pharmaceutical industry. Following this discussion, the Committee REQUESTED BIS Sectt. to host a meeting involving BIS, Chairman PCD 9, CDSCO, DCPC, and Indian Pharmacopoeia to address the following point: a) To discuss the scope of setting requirements for chemicals used in

					the pharmaceutical industry in Indian Standards formulated by PCD 9 that is to determine whether these will be covered by the Indian Pharmacopoeia or BIS. Based on the conclusion of above said meeting/inputs, the detailed deliberation may be taken up subsequently.

[Action to be taken: BIS Sectt.]

3.2.5 IS 4566 : 2020 — Specification For Methylene Chloride (Dichloromethane), Technical (Second Revision)

The Committee NOTED item 3.2.5 of the agenda and after deliberations DECIDED as follows:

Sl. No. **(1)**	**Clause/Sub-clause/ para/table/fig. No. commented** **(2)**	**Justification/ Proposed change** **(3)**	**Decision of the Committee in previous meeting** **(4)**	**Present Status** **(5)**	**Decision of the Committee** **(6)**
1.	3/3.1 (Grades)	Currently IS 4566 covers (a) Grade 1 - for the use in photo film industry, and (b) Grade 2 - suitable for industrial and other applications. IS 4566 does not include Analytical grade of Dichloromethane used as in analytical lab for Gas chromatography and HPLC or other analytical testing application. In absence of clear guidance by IS std, the industry can use either of the two grades for analytical	During the deliberations in last meeting, the Committee felt a need that a deliberation is required, if the analytical grade is to be incorporated in the standard or not. For	The 1st meeting of Panel is scheduled on 10 September 2024. Inputs are awaited.	The Committee ENDORSED the recommendation of the working group (*formerly called Panel*) about ACS grade being the purest form and being imported in India in very less quantity. Further, agreed that ACS

		applications and this will not harmonize quality of analytical grade of DCM. Also the specifications of our grade for use in photo film industry requires excessive testing putting testing burden on manufacturer. Hence suggesting to frame a new Grade as Analytical grade of Dichloromethane with mandatory testing parameters such as Description, Density, Residue on evaporation, Moisture, Acidity, UV Transmittance and Percentage purity. These parameters would make the analytical grade suitable for analytical application without burdening the industry with excessive testing. Additionally, the application listed in this IS 4566 do not include application in pharmaceutical industry (manufacturing and quality control labs). Pharma industry follows good manufacturing practices (GMP) as required by health authorities. The pharma industry uses compendial grade like IP, USP, EP, etc. and where IP grade is not available, they comply to international pharmacopoeias. Hence IS standards should clarify that Products meeting pharmacopoeial standards are not in the scope. **Proposed change** Grade 3 - Analytical grade (with limited testing parameters with respect to Analytical grade). Addition of statement recommending that IS 4566 excludes pharmaceutical grade of Dichloromethane.	deliberation on the incorporation of analytical grade, the Committee constituted the following Panel: Composition of the Panel: a) Dr M. J. Kapadia (Personal Capacity) b) Shri C S Patel, GNFC c) Dr Ravindra, NCL or any other institute d) One of the members from MDC manufacturers e) Shri O.P Sharma, DCPC f) Merk Group g) User Industry		Microsoft Word Document	grade may also be covered by existing grade and thus incorporating another grade as ACS grade may be of low significance. In the view of this, the Committee REQUESTED BIS Sectt. to request MERCK for submitting data for ACS grade, how it is different from the present grade. In addition to the comparison, also requested MERCK to submit data of amount of Carbon disulphide manufactured by them domestically and imported by them specifying its final application. Additionally, for comments on use of MDC in pharmaceutical industry The Committee concluded that before taking a final decision on exclusion of MDC used in pharmaceutical industry (pharma grade) it is essential to hold a consultative meeting with concerned regulator to have a clarity on the need of Indian Standards for such chemicals which have application in pharmaceutical industry. Following this discussion, the Committee
2.	Annex A/A-14	The method of analysis for Determination of Total impurities due to methyl chloride and chloroform requires using Methyl chloride as				

		standard for GC analysis of impurities. Using Methyl chloride as standard requires accurate measurement of Methyl chloride and injection of defined quantity in the GC column for analysis as per IS 4566. However, as Methyl Chloride is available in the gaseous form in the pure state it vaporized when aliquoted for preparation of standard for injection. Being a pressurized gas it is difficult to handle and measure accurately. The liquid forms of Methyl chloride are available as "Methyl chloride in Methanol" which is a mixture and IS 4566 does not provide provision to use such a mixture as standard. Hence we seek clarification on how to conduct this test. **Proposed change** Determination of Total impurities due to methyl chloride and chloroform is not a critical testing parameter for Analytical applications, hence for analytical applications this test should be optional for conformance to pure grade of IS 4566.			REQUESTED BIS Sectt. to host a meeting involving BIS, the Chairman of PCD 9, CDSCO, DCPC, and the Indian Pharmacopoeia to address the following point: a) To discuss the scope of setting requirements for chemicals used in the pharmaceutical industry in Indian Standards formulated by PCD 9 that is to determine whether these will be covered by the Indian Pharmacopoeia or BIS. Based on the conclusion of above said meeting/inputs, the detailed deliberation may be taken up subsequently by working group (*formerly called Panel*).
3.	Annex A/A-7	For testing of Free chlorine, there are alternates methods available that the industry is effectively using which are proposed by ACS and Analar utilizing reagents such as Potassium iodide and Cadmium iodide, respectively. Moreover, Analar method suggests the quantitative method which is more accurate and precise. **Proposed change**			

		Addition of alternative testing method for Free chlorine test such as ACS or Analar method. Kindly find the enclosed methods.  cmt_1698415200_65 3bc25ebb010.pdf			

[Action to be taken: BIS Sectt.]

3.2.6 IS 15030 : 2022 — Terephthalic Acid - Specification (First revision)

The Committee NOTED item 3.2.6 of the agenda and after deliberations DECIDED as follows:

Sl. No. (1)	Clause/Sub-clause/ para/table/fig. No. commented (2)	Commentator/ Organization/ Abbreviation (3)	Decision of the Committee in previous meeting (4)	Present Status (5)	Decision of the Committee (6)
1.	Annex H, H-2 Method A, H-2.5	Dr Y.S. Jhala, M/s IOCL	Based on detailed deliberation, the Committee concluded that multi point calibration is more accurate than the existing one-point calibration method of PTA sample while determining 4-carboxybenzaldehyde (4-CBA) and p-toluic acid (p-TA) in PTA by HPLC method. Thus, the committee DECIDED to incorporate multi point calibration as an alternate to existing one point calibration method. Further, to avoid confusion, the Committee DECIDED to incorporate complete method, comprising of multi point calibration method while determining 4-carboxybenzaldehyde (4- CBA) and p-toluic	The mail was sent to Dr Y.S. Jhala, IOCL for inputs. Inputs awaited from Dr Y.S. Jhala, IOCL.	The Committee REQUESTED Dr Y.S. Jhala, IOCL to provide the inputs latest by 30 October 2024. Further, the Committee REQUESTED to prepare the draft amendment based on inputs as received and circulate to Committee for 15 days. If no comments

			acid (p-TA) by HPLC, as an alternate method, instead of just incorporating the alternate method for calibration. Further, the Committee REQUESTED Dr Y.S. Jhala, IOCL to provide complete method with multi point calibration method.		are received, the draft amendment may be issued into wide circulation for a period of 1 month as under mandatory certification.

[Action to be taken: Dr Y.S. Jhala, IOCL]

3.2.7 IS 5149 : 2020 — Specification for Maleic Anhydride, Technical (Second Revision)

The Committee NOTED item 3.2.7 of the agenda and after deliberations DECIDED as follows:

Sl. No. **(1)**	**Clause/Sub-clause/ para/table/fig. No. commented** **(2)**	**Proposed change** **(3)**	**Decision of the Committee in previous meeting** **(4)**	**Present Status** **(5)**	**Decision of the Committee** **(6)**
1	Clause 2.2, Table 1, A-7.1 & A-7.2	**A-7.3 (Referee Method)** Alternatively it can be analyzed by any established/validated test method such as ICP-OES, ICP-MS, etc.	• During deliberation, BIS Sectt. informed the Committee that there exist IS 1448 (Part 172) ICP-OES Method for Determination of Trace Elements in Petroleum Products. In the view of this, the Committee, REQUESTED BIS Sectt. to forward it to I.G. Petrochemical for seeking inputs regarding compatibility of IS 1448 (Part 172), for determination	The mail was sent to Shri Sanjay, I.G. Petrochemical ltd for inputs. The inputs as received are given below: Informed that existing test method for iron content is used by the industry further, proposed that IS 1448 Part 172 which is ICP-OES may be used as alternate one .	The Committee NOTED and AGREED to incorporate IS 1448 Part 172 which is ICP-OES as an alternate method for determination of iron content, based on the inputs received from I.G. Petrochemical regarding compatibility of IS 1448 (Part 172). Further, DECIDED to make Method B (Spectrophotometric or Photoelectric Absorptio-

			of iron content in maleic anhydride.		metric Method) as referee method, in case of disputes. Further, the Committee REQUESTED to prepare the draft amendment based on inputs as received and circulate to Committee for 15 days. If no comments are received, the draft amendment may be issued into wide circulation for a period of 1 month as under mandatory certification.

[Action to be taken: BIS Sectt.]

Item 4 DRAFTS STANDARD/AMENDMENTS FOR APPROVAL FOR WIDE CIRCULATION

The Committee NOTED item 4 of the agenda and after deliberations DECIDED as follows:

Sl No.	Subject	Decision of the Committee in last meeting	Status	Decision of the Committee
		REVISION		
1	IS 14707 Methyl Acrylate – Specification	During the deliberation in its previous meeting, BIS Sectt. informed the Committee that BASF has provided HPLC method for determination of inhibitor and not GC method. After reviewing the HPLC method, the Committee NOTED that information like detector, chromatograph are not available and thus requested BIS	The revised test method as received from BASF is attached as: Determination of MeHQ Content in m	During the deliberations, Dr Amarish Samel, BASF informed that the method is common for all acrylates, while is not calibrated particularly for methyl acrylate. In the view of this, the Committee REQUESTED Dr Amarish Samel, BASF to do the calibration of the said method that is HPLC method

Sl No.	Subject	Decision of the Committee in last meeting	Status	Decision of the Committee
		Sectt. to seek complete method from BASF.	P-draft IS 14707 Methyl Acrylate.doc Draft — The Committee may **CONSIDER** for issuing the draft into wide circulation for a period of 1 month as under mandatory certification.	and submit it to BIS Sectt. within 3 weeks. Once the test method and calibrated data is received, the Committee REQUESTED BIS Sectt. to circulate it to Committee for 15 days. If no comments are received on the test method circulated, incorporate the test method as alternate method in the working draft and issue it into wide circulation for a period of 1 month as under mandatory certification.
2	IS 869 : 2020 Ethylene Dichloride (EDC) – Specification	The Committee in its previous meeting REQUESTED BIS Sectt. to circulate the draft revision as prepared by BIS Sectt. to Panel for 15 days. If no comments are received on the circulated draft, it may be issued into wide circulation for a period of 1 month time, as it is under mandatory certification. Composition of the Panel: a) Shri Sanjeev, Sanmar Group (**Convenor**) b) Shri Jayasekharan, DCW c) Shri Anil Satpathy, Finolex **d)** Shri Pramod Mall, RIL	Based on the decision of the Committee, the draft revision as prepared was circulated to Panel for 15 days on 9 August 2024. The comments as received from Shri Pramod Mall, Reliance are given at item **4.1**. The Committee may **CONSIDER**	See item **4.1**
3	IS 17442 : 2020 Vinyl Chloride Monomer – Specification		The draft is under preparation. On preparation of draft, it will be circulated to Panel for 15 days and then to wide circulation, if no comments, for a period of 1	During the deliberation, BIS Sectt. informed the Committee that the draft is under preparation and will be completed with one month time. The Committee NOTED the

Sl No.	Subject	Decision of the Committee in last meeting	Status	Decision of the Committee
			month time, as decided in the last meeting The Committee may **NOTE.**	information and further REQUESTED BIS Sectt. to expedite the process of preparing working draft based on the decision of the Committee in its last meetings and circulate to Panel for 15 days and then to wide circulation, if no comments, for a period of 1 month time as under mandatory certification.
4.	IS 539 : 1974 Specification for naphthalene (Second Revision)	The Committee in its previous meeting requested BIS Sectt. to prepare the draft revision by incorporating the comments as received from Shri Aabid Hussain, BIS and circulate to BIS licensees for a period of 1 month. If no comments are received, the draft is to be issued into wide circulation for a period of 2 months. However, if comments are received from the licensees on the circulated draft, BIS Sectt. was requested to schedule a meeting with the licensees and discuss the inputs received and prepare the wide circulation draft accordingly.	Based on the decision of the Committee in last meeting, the draft was prepared and circulate to BIS licensees for a period of 1 month, with last date for comments as 8 September 2024. No comments have been received till date.  The Committee may **CONSIDER** for issuing the draft into wide circulation for a period of 2 month	During the deliberations, the Committee NOTED that no comment has been received on the working draft, circulated to BIS licensees for a period of 1 month. Thus, DECIDED to issue the draft into wide circulation for a period of 2 months.
5.	IS 7330:1988 Methods of sampling and test for ion - Exchange resins (First Revision)	REQUESTED BIS Sectt. to prepare the working draft by incorporating the following inputs	While preparing the draft, it came to notice that IS 4165 Thermostats for general purpose electric ovens used as a reference	The Committee NOTED the preparation of working draft after incorporating the agreed changes. Further, the Committee

Sl No.	Subject	Decision of the Committee in last meeting	Status	Decision of the Committee
		and issue it into wide circulation for a period of 2 month. — IS 7330 was reaffirmed in 2014 and 2019. However, Amendment No. 1, issued in 1995, is required to be referred since it points out many critical corrections of IS 7330. — In case, there are no further suggestions for IS 7330 now, it is necessary to republish IS by incorporating all details of Amendment 1 into main body of IS 7330.	for thermostat in existing IS has been withdrawn. In the view of this, it is informed that since it is not the mandatory IS to be referred and thus reference of IS 4165 may be deleted. Further, on preparation of draft, it will issued into wide circulation for a period of 2 month time, as decided in the last meeting The revised draft as prepared is attached as : IS 7330 (2).docx The Committee may **CONSIDER** and **NOTE.**	REVIEWD the working draft and after deliberations DECIDED to issue it into wide circulation for a period of 2 months.
NEW STANDARDS				
6.	PCD 9 (26135) — 2,4-Di-Tertiary Butyl Phenol — Specification	— After deliberations, the Committee DECIDED to issue the drafts as P-draft for 15 days and if no comments are received, the drafts are to be issued into	Based on the decision of the Committee, the working draft as prepared was circulated as P-draft Panel for 15 days on 23 July 2024, with last date of comments as 7 August 2024. The comments as received are given at item **4.2**.	See item **4.2**

Sl No.	Subject	Decision of the Committee in last meeting	Status	Decision of the Committee
		wide circulation for a period of 2 month. — Further, if the comments are received on P-draft, the Panel is REQUESTED to deliberate on the comments and prepare wide circulation draft. The wide circulation draft so prepared are then issued into wide circulation for a period of 2 months time.	The Committee may **CONSIDER**	
7.	PCD 9 (26205) — 2,6-Di-Tertiary Butyl Phenol — Specification		Based on the decision of the Committee, the working draft as prepared was circulated as P-draft Panel for 15 days on 23 July 2024, with last date of comments as 7 August 2024. The comments as received are given at item **4.3.** The Committee may **CONSIDER**	See item **4.3**
8.	PCD 9 (26206) — o-Tertiary Butyl Phenol — Specification		Based on the decision of the Committee, the working draft as prepared was circulated as P-draft Panel for 15 days on 23 July 2024, with last date of comments as 7 August 2024. The comments as received are given at item **4.4**. The Committee may **CONSIDER**	See item **4.4**

Item 4.1 IS 869 : 2020 Ethylene Dichloride (EDC) – Specifications

The Committee NOTED item 4.1 of the agenda about the comments as received on working draft and after detailed deliberations DECIDED as follows:

Sl. No.	Clause/Sub-clause/ para/table/fig. No. commented	Commentator/ Organization/ Abbreviation	Proposed change	Justification	Decision of the Committee

1	Clause 3.2: solubility	RIL	The material shall be completely soluble either in rectified spirit (see IS 323) or methanol (see IS 517) in all proportions. Instead of The material shall be completely soluble in rectified spirit (see IS 323) or methanol (see IS 517) in all proportions.	Rectified spirit (alcohol) is prohibited in certain states (Gujarat, Bihar, etc). Moreover, requirement is to ensure solubility of EDC in alcohol hence changes are necessary for compliances in these states.	AGREED to modify the existing statement to allow the use of either rectified spirit or methanol for dissolving the material, as rectified spirit (alcohol) is prohibited in certain states. The modified statement is as given below: The material shall be completely soluble either in rectified spirit (see IS 323) or methanol (see IS 517) in all proportions.
2	Table 1 Requirements for Ethylene Dichloride	RIL	Propose to remove Residue on evaporation test from specification.	Residue on evaporation is not part of ASTM D 5960 specification. EDC is highly carcinogenic and there is no possibilities of any heavies in EDC due to latest manufacturing process. Hence, proposed to remove ROE considering high cacogenic nature of EDC.	NOT AGREED to delete the requirement as justification was insufficient to delete the parameter.
3	A-2 Method B – Digital Density Meter	RIL	Note to added at the end of Annexure A-2.7.2: Latest digital density meter has inbuilt calculation of variables. These density meter may also be used and should be calibrated using manufacturers instruction using air and water.	While using old density meter, user should manually calculate constants A & B. Now, latest density meter has inbuilt calculation mechanism and user should calibrate with air and water at desired temperature. These latest digital density meter has inbuilt data of density of air and water at various temperatures. User should follow manufacturers	AGREED to incorporate the following statement after A-2.7.2: NOTE — Digital density meter having inbuilt calculation of variables may also be used and shall be calibrated as per equipment manual.

				instructions and calibrate these digital density meters.	
4	E-3 Method A	RIL	E-3 Method A: Coulometric Karl Fisher Titration Method.	This method covers coulometric KF method and hence including "Coulometric KF method" will have better clarity.	AGREEED to modify title as: E-3 Method A: Coulometric Karl Fisher Titration Method
5	E-3.3.2 Table 3	RIL	Note to be added below Table 3: Above are recommended quantity of samples. Alternate quantity of samples may also be taken which is more suitable and gives good precision.	Latest Coulometric KF are more precise and gives better precision with less quantity of samples. Hence, provision should be given for these latest instruments.	NOT AGREED to incorporate the proposed note as the values given in table 3 are already recommending in nature.
6	E-4 Method B	RIL	E-4 Method B: Potentiometric or Volumetric Karl Fisher Titration Method.	This method covers Potentiometric KF method and hence including "Potentiometric or volumetric KF method" will have better clarity.	AGREEED to modify title as: Method B: Potentiometric or Volumetric Karl Fisher Titration Method.
7	E-4.3.3 Table 4	RIL	Note to be added below Table 4: Above are recommended quantity of samples. Alternate quantity of samples may also be taken which is more suitable and gives good precision	Latest Potentiometric KF are more precise and gives better precision with less quantity of samples. Hence, provision should be given for these latest instruments.	NOT AGREED to incorporate the proposed note as the values given in table 4 are already as recommendatin in nature.
8	Annex F, Sampling of Ethylene Dichloride	RIL	Note after F-4.3: IS 1447: P1 or alternate sampling techniques may also be used complying to integrity of sampling process and	Note after F-4.3 should be added for alternate sampling techniques without comprising sample integrity and safety aspect.	AGREED to incorporate 1447 (Part 1) as alternate method to Annex F.

			incorporating adequate safety precautions.		

The Committee REQUESTED BIS Sectt. to prepare the draft after incorporating the above agreed changes and issue into wide circulation for a period of 2 months.

4.2 PCD 9 (26135) — 2,4-Di-Tertiary Butyl Phenol — Specification

The Committee NOTED item 4.2 of the agenda about the comments as received on p-draft and after detailed deliberations DECIDED as follows:

Sl No. **(1)**	**Clause/Sub-clause/ para/table/ fig. No. commented** **(2)**	**Commentator / Organization/ Abbreviation** **(3)**	**Justification** **(4)**	**Proposed change** **(5)**	**Decision of the Committee** **(6)**
i)	Foreword	Shri Mayur J. Kapadia; mjkapadia61@gmail.com; 9427116575	For better understanding	Structure of 2,4-Di-Tertiary Butyl Phenol may be incorporated for better understanding	AGREED to incorporate Structure of 2,4-Di-Tertiary Butyl Phenol in foreword for better understanding.
ii)	Clause 3.2		**3.1 Description** The material shall be white solid below **55 °C** and colourless to pale yellow liquid at **60 °C** and shall be free from any foreign matter. **Comment:** The existing statement of description leaves ambiguity for temps in between 55 & 60 deg C		NOT AGREED to modify the description as the material will be tested for temperature below 55 °C and above 60 °C. The state of the material between these temperatures is not considered relevant.
iii)	Clause 4.2.1	Shri Pravin R Gaval; pravingaval@vinatiorganics.c	Clause 4.2.1 – b is missing a) Name of the material;	The numbering may be changed: a) Name of the material;	AGREED to modify the serial number of marking, as the comment is editorial in nature.

Sl No. (1)	Clause/Sub-clause/ para/table/ fig. No. commented (2)	Commentator / Organization/ Abbreviation (3)	Justification (4)	Proposed change (5)	Decision of the Committee (6)
		om; +91-7350 012842	c) Name of the manufacturer and his recognized trade-mark, if any; d) Month and year of manufacture. e) Net mass of the material in the container; f) Lot or batch number; and g) Any other statutory requirements.	b) Name of the manufacturer and his recognized trade-mark, if any; c) Month and year of manufacture; d) Net mass of the material in the container; e) Lot or batch number; and f) Any other statutory requirements.	
iv)	A-2/A-2.1.1	Shri C. S. Patel; cspatel@gnfc.in; 9898906163	Column: 100 % dimethylpolysiloxane (PDMS) with 30 m length **of 30m**, 0.32 mm internal diameter and 1.0 µm film thickness or equivalent. Remove word **of 30 m**	Column: 100 % dimethylpolysiloxane (PDMS) with 30 m length, 0.32 mm internal diameter and 1.0 µm film thickness or equivalent.	AGREED to delete, as length 30 m is being repeated twice
v)		Shri Pravin R Gaval; pravingaval@vinatiorganics.com; +91-7350 012842	" of 30 m " printed twice.	Delete one '30 m'	
vi)		Shri Mayur J. Kapadia;	" of 30 m " seems duplicated	Delete one '30 m'	

Sl No. (1)	Clause/Sub-clause/ para/table/ fig. No. commented (2)	Commentator / Organization/ Abbreviation (3)	Justification (4)	Proposed change (5)	Decision of the Committee (6)
		mjkapadia61@gmail.com; 9427116575			
vii)	Clause A-3	Shri Mayur J. Kapadia; mjkapadia61@gmail.com; 9427116575	All these chemicals are used for calibration of GC, hence they should be Certified Reference material	Replace 'known purity' of reagents by 'certified reference material'	AGREED to modify the known quality with certified reference material as know purity material can be any material with wide range of purity. Thus, to have traceability CRM shall be allowed. Further DECIDED to incorporate the following NOTE in case the CRMs of the material are not available: NOTE — In cases where a Certified Reference Material (CRM) for the reagent is unavailable, high-purity chemicals may be also usedas an alternative for CRM reagents. Additionally delete A-3.6 2,5-DTBP as not part of test method.
viii)	A-4.1 & 4.2; Table 2	Shri Mayur J. Kapadia; mjkapadia61@	It seems that the weights mentioned could be for 100% pure chemicals. It is a better idea to not mention weight to	Weight of each compound may be deleted.	After detailed deliberation the Committee DECIDED to modify the standard preparation and standardization procedure for

<table>
<tr><th>Sl No.

(1)</th><th>Clause/Sub-clause/ para/table/ fig. No. commented

(2)</th><th>Commentator / Organization/ Abbreviation

(3)</th><th>Justification

(4)</th><th>Proposed change

(5)</th><th>Decision of the Committee

(6)</th></tr>
<tr><td></td><td rowspan="2"></td><td>gmail.com; 9427116575</td><td>be taken, as it will vary with the purity of CRM used by the user.</td><td></td><td rowspan="2">better understanding, as given below:

a) Standard Preparation

To prepare calibration mixture, weigh each interested component (see item A-3.1 to A-3.6) as per the concentration given in Table 2.

b) Standardization Procedure

Make sure that the GC instrument is adjusted to the conditions stated as above. Weigh 2 g standard solution as prepared at A-4.1 in 10 ml volumetric flask and dilute it with methanol up to the mark. Inject 1.0 µl of the standard mixture as prepared above, by using syringe or auto sampler, in column taking care that no air bubble is trapped and obtain the chromatogram. Calculate the relative response factors (RRF) of each impurity by dividing the respective area in</td></tr>
<tr><td>ix)</td><td>Shri C. S. Patel; cspatel@gnfc.in; 9898906163</td><td>1. In Standard preparation, as per table-2, weight of each component is around 0.10 gm and concentration is around 19 to 22 % which is not correct. Prepare the standard as per the composition of specification. (i.e. 2,4 DTBP is 99.5 % and rest impurity is 0.30 %).

2. In standardization procedure, not mention about the dilution of standard in methanol. Whereas, in sample procedure A-5, mentioned that “take 2 gm sample in to 10 ml volumetric flask and dilute up to mark with Methanol”.

As per the thumb rule, standard and sample procedure must be same.</td><td>1. Table-2: Proposed Typical weight:

<table>
<tr><th>Sr. No.</th><th>Compound</th><th>Wt. gm</th><th>Concentration %</th></tr>
<tr><td>1</td><td>Phenol</td><td>0.1</td><td>0.1001</td></tr>
<tr><td>2</td><td>OTBP</td><td>0.1</td><td>0.1001</td></tr>
<tr><td>3</td><td>PTBP</td><td>0.1</td><td>0.1001</td></tr>
<tr><td>4</td><td>2,6-DTBP</td><td>0.1</td><td>0.1001</td></tr>
<tr><td>5</td><td>2,4-DTBP</td><td>99.5</td><td>99.59</td></tr>
<tr><td>6</td><td>2,4,6-TTBP</td><td>0.01</td><td>0.001</td></tr>
<tr><td colspan="2">Total</td><td>99.9010</td><td>100.00</td></tr>
</table>

2. Standardization procedure:</td></tr>
</table>

<table>
<tr><th>Sl No.

(1)</th><th>Clause/Sub-clause/ para/table/ fig. No. commented

(2)</th><th>Commentator / Organization/ Abbreviation

(3)</th><th>Justification

(4)</th><th>Proposed change

(5)</th><th>Decision of the Committee

(6)</th></tr>
<tr><td></td><td></td><td></td><td></td><td>Weight 2.0 gm standard in 10 ml volumetric flask and dilute with Methanol up to the mark.

Injection volume: 1.0 µl.</td><td>its chromatogram by concentration of each impurity.

Table-2: Proposed Typical weight:

<table><tr><th>Compound</th><th>Concentration %</th><th>RRT, min</th></tr><tr><td>Phenol</td><td>0.1001</td><td rowspan="6">Requested Vinati Organics Ltd to provide RRT</td></tr><tr><td>OTBP</td><td>0.1001</td></tr><tr><td>PTBP</td><td>0.1001</td></tr><tr><td>2,6-DTBP</td><td>0.1001</td></tr><tr><td>2,4-DTBP</td><td>99.59</td></tr><tr><td>2,4,6-TTBP</td><td>0.001</td></tr><tr><td>Total</td><td>100.00</td><td></td></tr></table></td></tr>
<tr><td>x)</td><td>Annex A; A-6</td><td>Shri Pravin R Gaval; pravingaval@vinatiorganics.com; +91-7350 012842</td><td>A-6 PROCEDURE

Inject 1 µl of sample by using manual or auto sampler, without any air bubble trapped in the syringe.
Allow approximately 50 min for components to elute from the column. Determine the mass</td><td>Approximately 50 minutes but it should be 30 minutes.</td><td>AGREED to modify the time to 30 min as the total run time is 30 min and not 50 min</td></tr>
</table>

Sl No. (1)	Clause/Sub-clause/ para/table/ fig. No. commented (2)	Commentator / Organization/ Abbreviation (3)	Justification (4)	Proposed change (5)	Decision of the Committee (6)
			concentration of all components by area normalization method.		
xi)		Shri Mayur J. Kapadia; mjkapadia61@gmail.com; 9427116575	A 2.1.1, run time is shown as 30 min. Parity in run time should be made at both places.	Replace 50 min by 30 min	
xii)	Clause B-2.1.1	Shri Mayur J. Kapadia; mjkapadia61@gmail.com; 9427116575	Range may be revised as 50 to 110 deg C, as thermometer's range is 0 to 110 deg C. Moreover, specification of material is also 56-60	Range of thermometer may be revised as 50 to 110 deg C	AGREED to modify the range to 50 to 110 deg C as melting point of material is in the range of 56-60 deg C and thus range of 50 to 300 deg C is not required.

The Committee REQUESTED BIS Sectt. to prepare the draft after incorporating the above agreed changes and issue into wide circulation for a period of 2 months

Item 4.3 PCD 9 (26205) — 2,6-Di-Tertiary Butyl Phenol — Specification

The Committee NOTED item 4.3 of the agenda about the comments as received on p-draft and after detailed deliberations DECIDED as follows:

Sl No. (1)	Clause/Sub-clause/ para/table/ fig. No. commented (2)	Commentator / Organization/ Abbreviation (3)	Justification (4)	Proposed change (5)	Decision of the Committee (6)
i)	Foreword	Shri Mayur J. Kapadia; mjkapadia61@gmail.com; 9427116575	For better understanding	Structure of 2,6-Di-Tertiary Butyl Phenol may be incorporated for better understanding	AGREED to incorporate Structure of 2,6-Di-Tertiary Butyl Phenol in foreword for better understanding.
ii)	Clause 3.2		**3.1 Description** The material shall be white solid below 35 °C and colourless to pale yellow liquid at 40 °C and shall be free from any foreign matter. Comment: The existing statement of description leaves ambiguity for temps in between 35 & 40 deg C		NOT AGREED to modify the description as the material will be tested for temperature below 35 °C and above 40 °C. The state of the material between these temperatures is not considered relevant.
iii)	Clause 4.2.1	Shri Pravin R Gaval; pravingaval@vinatiorganics.com; +91-7350 012842	Clause 4.2.1 – b is missing a) Name of the material; c) Name of the manufacturer and his recognized trade-mark, if any; d) Month and year of manufacture. e) Net mass of the material in the container; f) Lot or batch number; and g) Any other statutory requirements.	The numbering may be changed: a) Name of the material; b) Name of the manufacturer and his recognized trade-mark, if any; c) Month and year of manufacture; d) Net mass of the material in the container; e) Lot or batch number; and f) Any other statutory requirements.	AGREED to modify the serial number of marking, as the comment is editorial in nature.
iv)	A-2/A-2.1.1	Shri C. S. Patel; cspatel@gnfc.in; 9898906163	Column: 100 % dimethylpolysiloxane (PDMS) with 30 m length **of 30m**, 0.32 mm internal diameter and 1.0	Column: 100 % dimethylpolysiloxane (PDMS) with 30 m length, 0.32 mm internal diameter	AGREED to delete 30 m, as length 30 m is being repeated twice

Sl No. (1)	Clause/Sub-clause/ para/table/ fig. No. commented (2)	Commentator / Organization/ Abbreviation (3)	Justification (4)	Proposed change (5)	Decision of the Committee (6)
			µm film thickness or equivalent. Remove word **of 30 m**	and 1.0 µm film thickness or equivalent.	
v)		Shri Pravin R Gaval; pravingaval@vinatiorganics.com; +91-7350 012842	" of 30 m " printed twice.	Delete one '30 m'	
vi)		Shri Mayur J. Kapadia; mjkapadia61@gmail.com; 9427116575	" of 30 m " seems duplicated	Delete one '30 m'	
vii)	Clause A-3	Shri Mayur J. Kapadia; mjkapadia61@gmail.com; 9427116575	All these chemicals are used for calibration of GC, hence they should be Certified Reference material	Replace 'known purity' of reagents by 'certified reference material'	AGREED to modify the known quality with certified reference material as know purity material can be any material with wide range of purity. Thus, to have traceability CRM shall be allowed. Further DECIDED to incorporate the following NOTE in case the CRMs of the material are not available: NOTE — In cases where a Certified Reference Material (CRM) for the

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(3)</th><th>Justification

(4)</th><th>Proposed change

(5)</th><th>Decision of the Committee

(6)</th></tr>
<tr><td></td><td></td><td></td><td></td><td></td><td>reagent is unavailable, high-purity chemicals may be also used as an alternative for CRM reagents.

Additionally, DECIDED TO delete A-3.6 2,5-DTBP, as not part of test method.</td></tr>
<tr><td>viii)</td><td rowspan="2">A-4.1 & 4.2; Table 2</td><td>Shri Mayur J. Kapadia; mjkapadia61@gmail.com; 9427116575</td><td>It seems that the weights mentioned could be for 100% pure chemicals. It is a better idea to not mention weight to be taken, as it will vary with the purity of CRM used by the user.</td><td>Weight of each compound may be deleted.</td><td rowspan="2">After detailed deliberation the Committee DECIDED to modify the standard preparation and standardization procedure for better understanding, as given below:

a) Standard Preparation

To prepare calibration mixture, weigh each interested component (see item A-3.1 to A-3.6) as per the concentration given in Table 2.

b) Standardization Procedure

Make sure the GC instrument is adjusted to the conditions stated as above. Weigh 2 g standard solution as prepared at A-4.1 in 10 ml volumetric flask and dilute it with methanol up to the mark. Inject 1.0 µl of the standard mixture as prepared above, by using syringe or</td></tr>
<tr><td>ix)</td><td>Shri C. S. Patel; cspatel@gnfc.in; 9898906163</td><td>1. In Standard preparation, as per table-2, weight of each component is around 0.10 gm and concentration is around 19 to 22 % which is not correct. Prepare the standard as per the composition of specification. (i.e. 2,6 DTBP is 99.5 % and rest impurity is 0.30 %).

2. In standardization procedure, not mention about the dilution of standard in methanol. Whereas, in sample procedure A-5, mentioned that</td><td>1. Table-2: Proposed Typical weight:

<table>
<tr><td>Compound</td><td>Wt. gm</td><td>Concentration %</td></tr>
<tr><td>Phenol</td><td>0.1</td><td>0.1001</td></tr>
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<tr><td>PTBP</td><td>0.1</td><td>0.1001</td></tr>
<tr><td>2,6-DTBP</td><td>99.50</td><td>99.59</td></tr>
<tr><td>2,4-DTBP</td><td>0.1</td><td>0.1001</td></tr>
</table>
</td></tr>
</table>

<table>
<tr><th>Sl No.

(1)</th><th>Clause/Sub-clause/ para/table/ fig. No. commented

(2)</th><th>Commentator / Organization/ Abbreviation

(3)</th><th>Justification

(4)</th><th>Proposed change

(5)</th><th>Decision of the Committee

(6)</th></tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>“take 2 gm sample in to 10 ml volumetric flask and dilute up to mark with Methanol”.
As per the thumb rule, standard and sample procedure must be same.</td>
<td>
<table>
<tr><td>2,4,6-TTBP</td><td>0.01</td><td>0.001</td></tr>
<tr><td></td><td>99.9010</td><td>100.00</td></tr>
</table>
2. Standardization procedure:

Weight 2.0 gm standard in 10 ml volumetric flask and dilute with Methanol up to the mark.

Injection volume: 1.0 µl.
</td>
<td>auto sampler, in column taking care that no air bubble is trapped and obtain the chromatogram. Calculate the relative response factors (RRF) of each impurity by dividing the respective area in its chromatogram by concentration of each impurity.

c) Table-2: Proposed Typical weight:

<table>
<tr><td>Compound</td><td>Concentration %</td><td>RRT, min</td></tr>
<tr><td>Phenol</td><td>0.1001</td><td rowspan="7">Requested Vinati Organics Ltd to provide RRT</td></tr>
<tr><td>OTBP</td><td>0.1001</td></tr>
<tr><td>PTBP</td><td>0.1001</td></tr>
<tr><td>2,6-DTBP</td><td>0.1001</td></tr>
<tr><td>2,4-DTBP</td><td>99.59</td></tr>
<tr><td>2,4,6-TTBP</td><td>0.001</td></tr>
<tr><td>Total</td><td>100.00</td><td></td></tr>
</table>
</td>
</tr>
<tr>
<td>x)</td>
<td>Annex A; A-6</td>
<td>Shri Pravin R Gaval; pravingaval@vinatiorganics.c</td>
<td>A-6 PROCEDURE

Inject 1 µl of sample by using manual or auto sampler,</td>
<td>Approximately 50 minutes but it should be 30 minutes.</td>
<td>AGREED to modify the time to 30 min as the total run time is 30 min and not 50 min</td>
</tr>
</table>

Sl No. (1)	Clause/Sub-clause/ para/table/ fig. No. commented (2)	Commentator / Organization/ Abbreviation (3)	Justification (4)	Proposed change (5)	Decision of the Committee (6)
		om; +91-7350 012842	without any air bubble trapped in the syringe. Allow approximately 50 min for components to elute from the column. Determine the mass concentration of all components by area normalization method.		
xi)		Shri Mayur J. Kapadia; mjkapadia61@gmail.com; 9427116575	A 2.1.1, run time is shown as 30 min. Parity in run time should be made at both places.	Replace 50 min by 30 min	
xii)	Clause B-2.1.1	Shri Mayur J. Kapadia; mjkapadia61@gmail.com; 9427116575	Range may be revised as 50 to 110 deg C, as thermometer's range is 0 to 110 deg C. Moreover, specification of material is also 56-60	Range of thermometer may be revised as 50 to 110 deg C	AGREED to modify the range to 50 to 110 deg C as melting point of material is in the range of 36-40 deg C and thus range of 50 to 300 deg C is not required.

The Committee REQUESTED BIS Sectt. to prepare the draft after incorporating the above agreed changes and issue into wide circulation for a period of 2 months

4.4 PCD 9 (26206) — o-Tertiary Butyl Phenol — Specification

The Committee NOTED item 4.4 of the agenda about the comments as received on p-draft and after detailed deliberations DECIDED as follows:

Sl No.	Clause/Sub-clause/ para/table/fi	Commentator/	Justification	Proposed change	Decision of the Committee

(1)	g. No. commented (2)	Organization/ Abbreviation (3)	(4)	(5)	(6)
i)	Foreword	Shri Mayur J. Kapadia; mjkapadia61 @gmail.com; 9427116575	For better understanding	Structure of o-Tertiary Butyl Phenol may be incorporated for better understanding	AGREED to incorporate Structure of o-Tertiary Butyl Phenol in foreword for better understanding.
ii)	Clause 4.2.1	Shri Pravin R Gaval; pravingaval @vinatiorganics.com; +91-7350 012842	Clause 4.2.1 – b is missing a) Name of the material; c) Name of the manufacturer and his recognized trade-mark, if any; d) Month and year of manufacture. e) Net mass of the material in the container; f) Lot or batch number; and g) Any other statutory requirements.	The numbering may be changed: a) Name of the material; b) Name of the manufacturer and his recognized trade-mark, if any; c) Month and year of manufacture; d) Net mass of the material in the container; e) Lot or batch number; and f) Any other statutory requirements.	AGREED to modify the serial number of marking, as the comment is editorial in nature.
iii)	B-2/B-2.1.1	Shri C. S. Patel; cspatel@gnfc.in; 9898906163	Column: 100 % dimethylpolysiloxane (PDMS) with 30 m length **of 30m**, 0.32 mm internal diameter and 1.0 µm film thickness or equivalent. Remove word **of 30m**	Column: 100 % dimethylpolysiloxane (PDMS) with 30 m length, 0.32 mm internal diameter and 1.0 µm film thickness or equivalent.	AGREED to delete 30 m, as length 30 m is being repeated twice
iv)		Shri Pravin R Gaval; pravingaval @vinatiorgan	" of 30 m " printed twice.	Delete one '30 m'	

<table>
<tr><td></td><td></td><td>ics.com; +91-7350 012842</td><td></td><td></td><td></td></tr>
<tr><td>v)</td><td></td><td>Shri Mayur J. Kapadia; mjkapadia61@gmail.com; 9427116575</td><td>“ of 30 m “ seems duplicated</td><td>Delete one ‘30 m’</td><td></td></tr>
<tr><td>vi)</td><td>Clause B-3</td><td>Shri Mayur J. Kapadia; mjkapadia61@gmail.com; 9427116575</td><td>All these chemicals are used for calibration of GC, hence they should be Certified Reference material</td><td>Replace ‘known purity’ of reagents by ‘certified reference material’</td><td>AGREED to modify the known quality with certified reference material as know purity material can be any material with wide range of purity. Thus, to have traceability CRM shall be allowed.

Further DECIDED to incorporate the following NOTE in case the CRMs of the material are not available:

NOTE — In cases where a Certified Reference Material (CRM) for the reagent is unavailable, high-purity chemicals may be also used be used as an alternative for CRM reagents.</td></tr>
<tr><td>vii)</td><td>B-4.1 & 4.2/Table 2</td><td>Shri C. S. Patel; cspatel@gnfc.in; 9898906163</td><td>1. In Standard preparation, as per table-2, weight of each component is around 0.10 gm and concentration is around 19 to 22 % which is not correct. Prepare the standard as per the composition of specification. (i.e. OTBP is 99.5 % and rest impurity is 0.30 %).</td><td>1. Table-2: Proposed Typical weight:
<table><tr><th>Compound</th><th>Wt. gm</th><th>Concentra-tion %</th></tr><tr><td>Phenol</td><td>0.1</td><td>0.1001</td></tr><tr><td>OTBP</td><td>99.50</td><td>99.59</td></tr><tr><td>PTBP</td><td>0.1</td><td>0.1001</td></tr><tr><td>2,6-DTBP</td><td>0.1</td><td>0.1001</td></tr></table></td><td>After detailed deliberation the Committee DECIDED to modify the standard preparation and standardization procedure for better understanding, as given below:

a) Standard Preparation

To prepare calibration mixture, weigh each interested component (see item A-3.1 to A-3.6) as per the concentration given in Table 2.</td></tr>
</table>

			2. In standardization procedure, not mention about the dilution of standard in methanol. Whereas, in sample procedure B-5, mentioned that "take 2 gm sample in to 10 ml volumetric flask and dilute up to mark with Methanol". **As per the thumb rule, standard and sample procedure must be same.**	<table><tr><td>2,4-DTBP</td><td>0.1</td><td>0.1001</td></tr><tr><td>2,4,6-TTBP</td><td>0.01</td><td>0.001</td></tr><tr><td></td><td>99.9010</td><td>100.00</td></tr></table> **2.** Standardization procedure: Weight 2.0 gm standard in 10 ml volumetric flask and dilute with Methanol up to the mark. Injection volume: 1.0 µl.	b) Standardization Procedure Make sure the GC instrument is adjusted to the conditions stated as above. Weigh 2 g standard solution as prepared at B-4.1 in 10 ml volumetric flask and dilute it with methanol up to the mark. Inject 1.0 µl of the standard mixture as prepared above, by using syringe or auto sampler, in column taking care that no air bubble is trapped and obtain the chromatogram. Calculate the relative response factors (RRF) of each impurity by dividing the respective area in its chromatogram by concentration of each impurity. c) Table-2: Proposed Typical weight: <table><tr><td>Compound</td><td>Concentration %</td><td>RRT, min</td></tr><tr><td>Phenol</td><td>0.1001</td><td rowspan="7">Requested Vinati Organics Ltd to provide RRT</td></tr><tr><td>OTBP</td><td>0.1001</td></tr><tr><td>PTBP</td><td>0.1001</td></tr><tr><td>2,6-DTBP</td><td>0.1001</td></tr><tr><td>2,4-DTBP</td><td>99.59</td></tr><tr><td>2,4,6-TTBP</td><td>0.001</td></tr><tr><td>Total</td><td>100.00</td><td></td></tr></table>

The Committee REQUESTED BIS Sectt. to prepare the draft after incorporating the above agreed changes and issue into wide circulation for a period of 2 months

[Action to be taken: BIS Sectt.]

Item 5 DRAFTS UNDER WIDE CIRCULATION FOR FINALIZATION

5.1 PCD 09 (24417) — Acetone - Specification (Fifth Revision) Amendment – 4

The Committee NOTED item 5.1 of the agenda and after detailed deliberations, ENDORSED the recommendation of the Panel to FINALIZE the draft amendment and send for printing.

5.2 PCD 09 (24589) — Monomethylamine Technical Specification (First Revision)

The Committee NOTED item 5.2 of the agenda and after detailed deliberations, DECIDED as follows:

Sl. No. (1)	Clause/Sub-clause/ para/table/fig. No. commented (2)	Proposed change (5)	Present Status (4)	Decision of the Committee (5)
1	Table 2 (iv); 1	Trimethyl amine, percent by mass, Max = 0.2	M/s Balaji Amines were contacted via mail 24 July 2024, the following inputs have been received: — Grade 1 (anhydrous form) - Trimethylamine content, percent by mass, *Max* - 0.1 % — Grade 2 (40 % solution) - Trimethylamine content, percent by mass, *Max* - 0.04 %	The Committee REVIEWD the inputs as received from M/s Balaji Amines. After deliberations, the Committee DECIDED to revise the limit of Trimethyl amine for grade 1 to 0.1 % and grade 2 to 0.04 %. Further, FINALIZED the draft amendment for printing.

[Action to be taken: BIS Sectt.]

5.3 PCD 09 (24831) — Phthalic Anhydride Technical Specification (Third Revision)

The Committee NOTED item 5.3 of the agenda and after detailed deliberations, DECIDED as follows:

Sl. No.	Clause/Sub-clause/ para/table/fig.	Commentator/ Organization/ Abbreviation	Justification	Proposed change	Decision of the Committee (6)

(1)	No. commented (2)	(3)	(4)	(5)	
i.	3.2 Annex A	Shri Vipul; regulife@merckgroup.com; 9513786924 Merck Regular Life	Request to amend clause 3.2-Annex A of the draft standard to update the method of analysis of Crystallizing point. Currently, the Annex A-method of analysis of Crystallizing point mentioned the apparatus like Electrically-Heated Aluminum Block, Thermometer (with specific requirements) & Flat-Based Calorimetric Tube require to perform the test. This test could be perform with help of readily available laboratory instrument such as calibrated Hot plate, graduated Beaker & Thermometer (with specific requirements). During the test hot plate temperature should be maintained at 150 ^{o}C.	Alternate method : A-3.1 Into the 200ml /250 ml graduated beaker, take a quantity of the material, sufficient to reach graduation mark 100 ml after melting. Place the beaker containing the material in the hot plate maintained at 150 °C. Allow the material to completely melt. A-3.2 Once the material is melted, carefully remove the beaker from the hot palate. Begin the cooling process by slowly cooling the melted material. Use a thermometer and insert it into the material two to three times, moving it up and down. Observe the material for the formation of crystals. Report the temperature at which crystals start forming as the crystallization point.	NOT AGREED to use hot plate maintained at 150 °C for melting the heat instead of Electrically-Heated Aluminum Block because in case of hot plate the heat from a hot plate would be localized rather than evenly distributed, which could affect the melting of the material.
ii.	Annex D; D-6	Shri Jayesh Vashi; jayesh.vashi@aarti-	2µl Injection volume is too high.	Injection volume to be 1 µl injection. GC Chart and RT table needs to be add.	AGREED to modify the injection volume to 1 µl. Further REQUESTED I.G. Petrochemical to provide RT

		industries.com; 9727782147 Aarti Industries Ltd.	Peak is saturated in this volume. Suggested to have only 1 µl injection. GC Chart and RT table needs to be add.		table and typical chromatogram, which will be incorporated in the test method for reference of user.
iii.	Clause 3.2; Table 1; Sl No. (v); col (2)	Shri Sanjay Gupta; sgupta@igpetro.com; 7798515222 IG Petrochemicals Ltd.	(v) As we are doing analysis by GC hence Purity By GC is required. Instead of Total available acidity because it is done by Titration.	Replace Total available acidity by Purity by GC, Percent by mass, *Min*	AGREED to modify total available acidity by Purity by GC, Percent by mass, *Min.*
iv.	Clause 3.2; Table 1; Sl No. (vi); col (2)		(vi) Maleic Anhydride and other impurities is required Instead of Oxidizable matters because we are getting directly the percentage of all impurities in GC graph.	(vi) Maleic Anhydride and other impurities may be required change.	The Committee concluded that replacing 'oxidizable impurities' with 'other impurities' would create ambiguity regarding which impurities should be reported. If 'oxidizable impurities' are removed from the requirements, a separate parameter specifying the requirements for aldehydes and ketones should be included. In the view of the above, the Committee REQUESETD I.G. Petrochemical to submit their viewpoint if requirement for other oxidable impurities is to be replaced by other impurities or

					not. If yes, provide the suggested requirement for aldehyde and ketone within 1 week of time.
v.	Clause 3.2; Table 1; Sl No. (ix), (x) & (xi); col (3)		(ix) Naphthquinone - Absent is required. (x) Naphthalene - Absent is required. (xi) Phthalimide - Absent is required.	Absent may be required change in all the requirements.	During deliberation, the Committee concluded that 'absent' is not a technical term suitable for specifying limits. Furthermore, the current limit of 'not detectable' depends on the detection capability of the instrument. To prevent potential misuse, the Committee decided to establish specific limits for impurities, including Naphthoquinone, Naphthalene, and Phthalimide. Thus, to specify the limit to the impurities, the Committee REQUESTED I.G. Petrochemical to provide inputs on the limit of impurities within 1 week of time.
vi.	Annex D		Determination of purity by gc, maleic anhydride, other impurities, napthaquinone, napthalene and phtahalimide wording is required.	Title of Annex D to be modified	AGREED to modify the title as : Determination of purity by GC, maleic anhydride, other impurities, naphthoquinone, naphthalene and phthalimide.

[Action to be taken: I.G. Petrochemical; BIS Sectt.]

The Committee REQUESTED BIS Sectt. to prepare the draft revision by incorporating the above changes and circulate to committee members and BIS licenses for 10 days. If no comments are received the draft will be finalized for printing with Chairman approval.

5.4 PCD 09 (25183) — Tables for Alcoholometry by Hydrometer Method (First Revision) Amendment – 2

The Committee NOTED item 5.4 of the agenda and after detailed deliberations, DECIDED to FINALIZE the draft for printing.

5.5 PCD 09 (26241) — Ethylene glycol - Specification (Third Revision) Amendment - 1

The Committee NOTED item 5.5 of the agenda and after detailed deliberations, DECIDED to FINALIZE the draft for printing.

5.6 PCD 09 (26242) — Specification for formic acid (First Revision) Amendment – 3

The Committee NOTED item 5.6 of the agenda and after detailed deliberations, DECIDED to FINALIZE the draft for printing, if no comments are received till 27 September 2024.

[Action to be taken: BIS Sectt.]

Item 6 COMMENTS ON PUBLISHED STANDARDS

6.1 IS 695 : 2020 — Acetic Acid - Specification (Fourth Revision)

The Committee NOTED item 6.1 of the agenda and after detailed deliberations, DECIDED as follows:

Sl. No. (1)	Clause/ Sub-clause/ para/table/fig. No. commented (2)	Commentator/ Organization/ Abbreviation (3)	Justification	Proposed change (5)	Decision of the Committee (6)
i)	1 Scope	Shri Vipul; regulife@merckgroup.com; 9513786924	1. Suggestion: Suggestion: Kindly exclude the pharmaceutical grade Acetic Acid which is only meant for use in pharmaceutical industries from the scope of IS 695:2020.	This standard prescribes the requirements and methods of sampling and test for acetic acid.	During deliberations the Committee NOTED that CRMs, ACS grade are the purest form and is imported

			Justification: BIS Act, 2016, Chapter V, Section 41 state that "Nothing in this Act shall affect the operation of the Agricultural Produce (Grading and Marking) Act, 1937, or the Drugs and Cosmetics Act, 1940, or any other law for the time being in force, which deals with any standardization or quality control of any goods, articles, process, system, or service." Acetic Acid is official in multiple pharmacopoeias including IP, Ph.Eur, USP, BP, ChP and JP. Such Pharmacopeia grade is utilized in the pharmaceutical industry for various applications such as solvent in a variety of pharmaceutical production process, as a buffering agent and pH adjustor. Moreover, the IS standard does not clarify about the exclusion of pharmaceutical grade if the product is complying with the specifications of multiple pharmacopoeias including IP, Ph.Eur, USP, ChP and JP which are more stringent as compared to the specifications of BIS for it's use in pharmaceutical industries. Therefore, acetic acid intended for use as an excipient in pharmaceutical applications should not fall under the scope of IS 695:2020. Additionally due to similar HS code for all the grade of Acetic Acid it may lead to further concern regrading BIS registration during custom clearance as IS 695:2020 comes under mandatory certification. 2. Suggestion: Goods or articles meant to be used as Certified Reference Materials (CRMs) such as Pharmacopeial standards, Analytical Standards etc. or for R&D use only. Justification: The IS standards are not applicable to certified reference material of the notified	This standard does not cover pharmaceutical grade of Acetic Acid, certified reference materials (CRM) of Acetic Acid such as pharmacopeial standards, analytical Standards etc. or for R&D use only.	in India in very less quantity. The Committee was also of the view that CRMs, ACS grade may also be covered by existing grade and thus incorporating another grade as CRMs, ACS grade grade may be of low significance. In view of this, the Committee REQUESTED BIS Sectt. to request MERCK for submitting data for CRMs, ACS grade, how it is different from the present grade. In addition to the comparison, also requested MERCK to submit data of amount of Acetic acid manufactured by them domestically and imported by them specifying its final application. Additionally, for comments on use of acetic acid in pharmaceutical industry The Committee concluded that before taking a final decision on exclusion of acetic acid used in pharmaceutical industry (pharma grade) it is essential to hold a consultative meeting with concerned regulator to have a clarity on the need of Indian Standards for such chemicals which have

			chemical however it is not explicitly mentioned in QCO. The reference standards are used in very limited quantity during analysis and do not pose any threat to the environment or person using it. Reference material producers must meet ISO requirements (such as ISO 17034, ISO/IEC 17025 and ISO Guide 31) to manufacture CRMs or RMs. Information such as purity, identity and traceability are shared with customers at batch level. Hence the quality is inbuilt and ensured during production of reference standards & IS std are not applicable to reference standards. The quantity of chemicals used in R&D application is very low in comparison to other industrial applications and hence the quality and other considerations which mandated regulating the chemical might not be applicable.		application in pharmaceutical industry. Following this discussion, the Committee REQUESTED BIS Sectt. to host a meeting involving BIS, the Chairman of PCD 9, CDSCO, DCPC, and the Indian Pharmacopoeia to address the following point: a) To discuss the scope of setting requirements for chemicals used in the pharmaceutical industry in Indian Standards formulated by PCD 9 that is to determine whether these will be covered by the Indian Pharmacopoeia or BIS. Based on the conclusion of above said meeting/inputs, the detailed deliberation may be taken up subsequently.

[Action to be taken: BIS Sectt.]

6.2 IS 2252 : 2018 — Diacetone alcohol - Specification (Fourth Revision)

The Committee NOTED item 6.2 of the agenda and after detailed deliberations, DECIDED as follows:

Sl No. (1)	Clause/Sub-clause/ para/table/fig. No. commented (2)	Existing BIS Requirement (3)	Proposed (4)	Justification (5)	Decision of the Committee (6)
i.	Appearance	Clear pale straw coloured liquid, free from sediments and also shall be free from matter in suspension	Clear liquid, free from suspended matter.	This product is considered non-toxic but can cause irritation and injury if it comes in contact with eyes. Additionally, it should be completely miscible with water and free from sediments and suspended matter. Over time, the quality of this important product has significantly improved globally, and the latest standards are now available. There is an urgent need to incorporate the latest requirements into the standard to ensure the manufacturing and importation of quality products into the country. As observed, the proposed specification values provided will result in a purer form of Diacetone alcohol with fewer emissions, making it more environmental friendly. Furthermore, moisture content should not exceed	AGREED to modify the existing statement of appearance as the material is clear colourless liquid.
ii.	Purity (New parameter is to be added)	Not part of requirement	Value: 99.5, Min Test method: GC		AGREED to incorporate purity parameter with 99.5, Min limit, as it is an important requirement for diacetone alcohol.
iii.	Moisture Content	0.2, Max	Value: 0.1, Max Test method: ASTM D 1364		During deliberations, Shri Gaurang Parikh from Prasol Chemicals informed the Committee that recycled, non-virgin, inferior quality material is being imported into the country. Since this material has various applications, including use as a solvent in paints and coatings, as well as in the treatment of textiles and leather, which has indirect contact with humans. The Committee NOTED the information and AGREED to modify the moisture content limit to 0.1, Max
iv.	Colour, Pt-Co	25, Max	Value: 15, Max Test method: ASTM D1209		AGREED to modify the colour as the liquid is colourless liquid.
v.	Acetic Acid, %	0.02, Max	Value: 0.01 Max		During deliberations, Shri Gaurang Parikh from Prasol Chemicals informed the Committee that recycled, non-virgin, inferior quality material is

			Test method: ASTM D 1613	0.1%, which will improve quality of coating and thinner, along with better shine in humid environment. This will be user/consumer choice from above to differentiate and select premium virgin grade of Diacetone alcohol over the recycled nonvirgin inferior quality product. This improvement of the standard will empower consumer to make informed choice to choose the quality product for their intended use.	being imported into the country. Since this material has various applications, including use as a solvent in paints and coatings, as well as in the treatment of textiles and leather, which has indirect contact with humans. The Committee NOTED the information and AGREED to modify the moisture content limit to 0.01, Max
vi.	Distillation Range	145-172	Value: 150-170 Test method: ASTM D 1078		After deliberations, the Committee DECIDED to make distillation range [which is also used to determine purity of product] optional a parameter new requirement of purity by GC have been incorporated. Distillation range method indirectly reports purity only. Further, REQUESTED Shri Gaurang Parikh, Prasol Chemicals to provide input on the distillation range if it should be 160-170 °C as its boiling point is around 166 °C and giving such large range will not suffice the case.
vii.	Relative Density	0.931-0.937 at 27 deg C	Value: 0.938-0.941 at 20 deg C Test method: ASTM D1298		NOT AGREED to modify the relative density reporting temperature from 27°C to 20°C, as the standard ambient temperature considered in the country is 27°C.
viii.	Non-volatile matter, g/100 ml	0.01 Max	Value: 0.01 Max		The Committee NOTED that there is no change required for the requirement.
ix.	Water Miscibility	Shall be miscible with water in all proportions	To pass the test Test method: ASTM D 1722		NOT AGREED to incorporate water miscibility in Table 1 with a test method, as it is already addressed under clause 3 Requirements.

Additionally, BIS Sectt. presented a comparison between the proposed ASTM method and the existing method. After reviewing the comparison, the Committee concluded that the existing test method is similar to the ASTM method. Therefore, felt no need to incorporate the ASTM method. Further, REQUESTED Shri Gaurang Parikh Prasol Chemicals to review the existing test method aligning with ASTM method proposed once and in case they feel the changes are required, the comments may be submitted within 1 month time.

If no comments are received within 1 month, the Committee REQUESTED BIS Sectt. to prepare the draft revision based on the above agreed changes in the requirement and issue it into wide circulation for a period of 2 month. In case the comments are received from Shri Gaurang Parikh, Prasol Chemicals, the same may be put up to Committee in next meeting.

[Action to be taken: M/s Prasol Chemicals; BIS Sectt.]

6.3 IS 10745 : 1983 — Specification For Acetophenone

Due to paucity of time, the Committee DECIDED to discuss item 6.3 in next meeting.

6.4 IS 6971 : 1998 — 2-Ethylhexan-1-ol – Specification (First Revision)

Due to paucity of time, the Committee DECIDED to discuss item 6.4 in next meeting.

6.5 IS 8058 : 2018 — Pyridine – Specification (First Revision)

Due to paucity of time, the Committee DECIDED to discuss item 6.5 in next meeting.

6.6 IS 517 : 2020 — Specification For Methanol (Methyl Alcohol) (Third Revision)

The Committee NOTED item 6.6 of the agenda and after detailed deliberations, DECIDED as follows:

Sl No. **(1)**	**Clause/Sub-clause/ para/table/fig. No. commented** **(2)**	**Commentator / Organization/ Abbreviation** **(3)**	**Justification** **(4)**	**Proposed change** **(5)**	**Decision of the Committee** **(6)**

i.	Clause 8; Table 1	Shri Mukulesh Baruah (stakeholder); kreeti.das@bis.gov.in; 8787366106	The Permanganate Fading Test to be included in the standard pertaining to Methanol as it is an important indicator of the quality of methanol. This input was received from Shri Mukulesh Baruah Sr. Manager (Q/C). Assam Petrochemicals Ltd. Namrup, Assam, during DG BIS interaction meeting held on 05 June 2024 at Shillong. His mobile no. is 8787366106, and he may be contacted for any further details.	The Permanganate Fading Test to be included in the standard pertaining to Methanol.	Due to paucity of time, the Committee DECIDED to discuss item 6.6 in next meeting.
ii.	1 Scope	Shri Vipul; regulife@merckgroup.com; 9513786924	1. Suggestion: Kindly exclude the pharmaceutical grade Methanol which is only meant for use in pharmaceutical industries from the scope of IS 517:2020. Also exclude the Methanol Used For Antibiotics since this is already been covered in the Pharmaceutical grade. Justification: BIS Act, 2016, Chapter V, Section 41 state that "Nothing in this Act shall affect the operation of the Agricultural Produce (Grading and Marking) Act, 1937, or the Drugs and Cosmetics Act, 1940, or any other law for the time being in force, which deals with any standardization or quality control of any goods, articles, process, system, or service." Menthol is official in multiple pharmacopoeias including Ph.Eur, USP, ChP and JP. Such pharmaceutical grade is utilized in the pharmaceutical industry for various applications such as solvent in a variety of pharmaceutical production process, including tablet coating or microsphere production. Inline with these pharmaceutical application and based on Drugs and Cosmetics Act (D&C Act 1940 & Rule 1945) definition of a drug (drug includes all substances used as components of a drug, including empty capsules) it categorized as drug. Moreover, the IS standard does not clarify about the exclusion of pharmaceutical grade if the product is complying with the specifications of multiple pharmacopoeias including Ph.Eur, USP, ChP and JP which are more stringent as compared to the specifications of BIS for its use in pharmaceutical	Scope: This standard prescribes the requirements and the methods of sampling and test for methanol (methyl alcohol). This standard does not cover pharmaceutical grade, Methanol Used For Antibiotics & Certified Reference Materials (CRMs) of Methanol such as Pharmacopeial standards, Analytical Standards etc or for R&D use only. Clause 4.4 to be deleted.	

			industries. Therefore, methanol intended for use as an excipient in pharmaceutical applications should not fall under the scope of IS 517:2020. Additionally due to similar HS code for all the grade of Methanol it may lead to further concern regarding BIS registration during custom clearance as IS 517:2020 comes under mandatory certification. 2. Suggestion: Goods or articles meant to be used as Certified Reference Materials (CRMs) such as Pharmacopeial standards, Analytical Standards etc or for R&D use only. Justification: The IS standards are not applicable to certified reference material of the notified chemical however it is not explicitly mentioned in QCO. The reference standards are used in very limited quantity during analysis and do not pose any threat to the environment or person using it. Reference material producers must meet ISO requirements (such as ISO 17034, ISO/IEC 17025 and ISO Guide 31) to manufacture CRMs or RMs. Information such as purity, identity and traceability are shared with customers at batch level. Hence the quality is inbuilt and ensured during production of reference standards & IS std are not applicable to reference standards. The quantity of chemicals used in R&D application is very low in comparison to other industrial applications and hence the quality and other considerations which mandated regulating the chemical might not be applicable.		

6.7 IS 170 : 2020 — Acetone – Specification (Fifth Revision)

The Committee NOTED item 6.7 of the agenda and after detailed deliberation DECIDED as follows:

Sl No.	Clause/Sub-clause/ para/table/fi	Justification	Proposed change	Decision of the Committee

(1)	g. No. commented (2)	(3)	(4)	(5)
i.	1 Scope	1. We request an amendment to the intended use of Acetone of IS 170 specifically to exclude pharmacopeial from the scope of this standard. The current IS 170 applicable for the Acetone intended for industrial purpose. Industrial purpose terminology doesn't clarify the specific grade of acetone covered in this IS Std. i.e. pure, technical or analytical. However Actone is official in multiple pharmacopoeias including Ph.Eur, USP, BP, ChP and JP & it is utilized in the pharmaceutical industry for various applications as follows. In line with these pharmaceutical application and based on Drugs and Cosmetics Act (D&C Act 1940 & Rule 1945) definition of a drug (drug includes all substances used as components of a drug, including empty capsules) it categorized as drug. 1.1: Acetone pharmaceutical application Acetone is an excellent solvent for coating and film production in the pharmaceutical industry due to its volatility and compatibility with various compounds. Acetone is frequently used to make drug coatings and films, which helps to improve the overall efficacy of pharmaceuticals and enable controlled release of the active ingredients It is an essential solvent in the manufacturing of oral and topical pharmaceuticals. 1.2: BIS Act, 2016, Chapter V, Section 41 state that "Nothing in this Act shall affect the operation of the Agricultural Produce (Grading and Marking) Act, 1937, or the Drugs and Cosmetics Act, 1940, or any	1 Scope This standard prescribes the requirements and the methods of sampling and test for acetone intended for industrial purpose This standard does not cover the pharmacopeial grade of Acetone which used as an excipient in pharmaceutical applications.	During deliberations, the Committee NOTED that acetone in the pharmaceutical industry is used in two main capacities: as excipients, which must adhere to pharmacopoeia standards regulated by CDSCO, and as solvents. Shri Om Sharma, DCPC also acknowledged that chemical directly used for medicine doesn't come under the preview of DCPC. Further, the Committee NOTED that PCD 9 generally formulate Indian Standards for industrial use (pure and technical grade only). The Committee concluded that before taking a final decision on the proposals it is essential to hold a consultative meeting with concerned regulator to have a clarity on the need of Indian Standards for such chemicals which have application in pharmaceutical industry. Following these discussions, the Committee REQUESTED BIS Sectt. to host a meeting involving BIS, the Chairman of PCD 9, CDSCO, DCPC, and the Indian Pharmacopoeia to address the following point:

		other law for the time being in force, which deals with any standardization or quality control of any goods, articles, process, system, or service." Therefore, Acetone intended for use as an excipient in pharmaceutical applications should not fall under the scope of IS 170. Additionally due to similar HS code for all the grade of Acetone it may lead to further concern regarding BIS registration during custom clearance as IS 170 is comes under mandatory certification. In light of the above considerations, we request that the scope of IS 170 should be revised to clearly exclude the pharmacopoeial grade of Acetone.		a) To discuss the scope of setting requirements for chemicals used in the pharmaceutical industry in Indian Standards formulated by PCD 9 that is to determine whether these will be covered by the Indian Pharmacopoeia or BIS. Based on the conclusion of above said meeting, the detailed deliberation may be taken up subsequently.

[Action to be taken: BIS Sectt.]

6.8 IS 4117 : 2008 Alcohol denaturants - Specification (Second Revision)

The Committee NOTED item 6.8 of the agenda and after detailed deliberation DECIDED as follows:

Sl No. **(1)**	**Clause/Sub-clause/ para/table/fig. No. commented** **(2)**	**Justification** **(3)**	**Proposed change** **(4)**	**Decision of the Committee** **(5)**
i.	Clause 4; SD 2b Cyclohexane + denatonium benzoate/ denatonium saccharide 2.0 litre + 4 g	Our products i.e. Agrochemical intermediates falls under category of Miscellaneous Products (processing) as per Annexure B, S.No.: 74, IS 4117:2008, Second Edition.	Present SD 2b formulae may be amended from Cyclohexane 2% + 40 ppm Bitterant to 0.5% Cyclohexane + 40 ppm Bitterant.	During deliberations, the Committee highlighted that there is currently insufficient data on how changes in the limits of denaturants would impact the alcohol distillation process and whether the changed amount of denaturant would ensure the alcohol is unfit for consumption. In light of this, the Committee DECIDED

				that further research is necessary on the subject and REQUESTED the BIS Secretariat to contact the following organizations to conduct a study on how changes in the denaturant limits would affect alcohol consumption: a) VSI, Pune b) CSIR- CDRI c) CRCL
ii.	Clause 4, SD 10 Diethyl phthalate + tertiary butyl alcohol 2.5 litre + 0.5 litre	Using TBA as denaturant in Di-Ethyl Phthalate manufacturing has following problems as compared to indigenous alcohol. • The colour of Di-Ethyl Phthalate is >90 APHA even after chemical treatment with Hydrogen Peroxide followed by Activated carbon. • Few unknown high boilers are generated with TBA is additional denaturant and contributing for high colour. Chromatograph of GC in lab batches is attached for reference (Annexure-2) • TBA has camphor smell and similar smell is observed in DEP made with ethanol denatured with DEP & TBA. Whereas DEP shall be completely odour free. • Test results of DEP lab trails with only DEP as denaturant and both DEP & TBA as denaturant is attached for reference (Annexure-3). • DEP and Ethyl Alcohol are completely miscible and it is good denaturant for Ethyl Alcohol. • Denaturant TBA addition in imported alcohol is giving high colour for DEP as well as smell, we are unable to sell such product in market. • Even with all precautions, the colour of DEP is >20 APHA thus producing off	The denaturant used for indigenous alcohol is 0.5% Di Ethyl Alcohol and bitterant 40 ppm is added either Denatonium Saccharide or Denatonium Benzoate. The approval letter as per guidelines from Dy. Commissioner, Maharashtra State Excise, Ref No: DNS-112023/868/4 dated 03 May 2023 (Annaxure-1) Letter : 1- BIS Draft letter.docx Annexures: 2- Denaturant Rule of Govt. of India.pdf 3- Annexure 1 - Exemption letter dt (4- Annexure 2 - GC of 2.5P+0.5_TBA+0.3	

		grade DEP making it tough to get customers.	5- Annexure 3 - GC of DEP Without TBA	

[Action to be taken: BIS Sectt.]

6.9 IS 361 : 2009 Normal Butyl Alcohol, Technical - Specification (Third Revision)

Due to paucity of time, the Committee DECIDED to discuss item 6.9 in next meeting.

Item 7 NEW SUBJECTS

The Committee NOTED item 7 of the agenda and after detailed deliberations, DECIDED as follows:

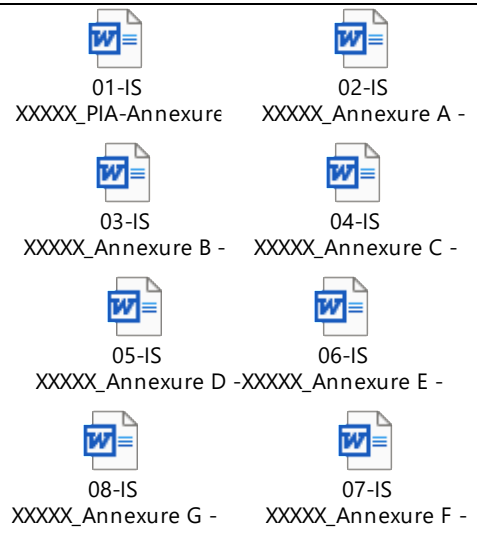
Sl No.	Subject	Received from	Present Status	Decision of the Committee
i.	2,4-Di Tertiary Butyl Phenol	Shri Mahesh K Rashinkar, M/s Vinati Organics Limited	See item 4.2	See item **4.2**
ii.	2,6-Di Tertiary Butyl Phenol		See item 4.3	See item **4.3**
iii.	*o*-Tertiary Butyl Phenol		See item 4.4	See item **4.4**
iv.	*p*-Tertiary Butyl Phenol		More deliberation is required on the working draft by the Panel. Composition of the Panel: a) Vinati Organics Limited (*Convener*) b) SII Group c) Dr M.J. Kapadia d) Member Secretary of PCD 9 The Committee may **NOTE.**	The Committee NOTED that further deliberation on the working draft by the Working group (*formerly called Panel*) is need. Therefore, REQUESTED Panel to submit the finalized working draft latest by 15 November 2024. Upon receival of finalized draft, the Committee REQUESTED BIS Sectt. to issue the drafts as P-draft for 15 days. If no comments are received, the draft is to be issued into wide circulation for a period of 2 month. **[Action to be taken: Working group]**

v.	Hexylene Glycol	Shri D. P. Shegekar, M/s Prasol Chemicals	Working draft as received from M/s Prasol Chemicals via email dated 13 May 2024 is as follows: Hexylene glycol uses: • Cosmetics and fragrances • Textiles • Paints and coatings • Hydraulic fluids • Dyes • Firefighting foams • Detergents and degreasers The Committee may **CONSIDER**.	Shri Gaurang Parikh, Prasol Chemcial Ltd briefed the Committee on hexylene glycol including its uses, manufacturing process and import quantity in India as well as the need for a standard. The Committee NOTED the information presented by Shri Gaurang Parikh. Further, REVIEWED the requirements of Hexylene Glycol as received from Prasol Chemicals. After detailed deliberations, the Committee ACCEPTED the proposal for formulation of standard on 'Hexylene Glycol – Specification' for technical grade. Further, the Committee DECIDED to constitute the following working group with a timeline of 3 months that is December 2024, to prepare working draft on the above said subject: Composition of the Working group: a) Shri Gaurang Parikh, Prasol Chemicals (***Convener***) b) User industry (details to be provided by M/s Prasol Chemicals) c) Shri RK Sharma, IGL d) Shri Sukhraj Soni, AIDA **[Action to be taken: Working group]**
vi.	Tetrahydrofuran	Shri Shrikant Nikam, M/s INEOS Solvents	Shri Shanul Pagar, Godavari Biorefineries informed that they are procuring THF from trader who import from foreign and thus not able to trace the manufacturer of the material in India. Further, Shri R.K. Sharma, Indian Glycol informed that they are not into the business of THF.	The Committee NOTED the information that THF is mostly imported in India from countries like China, Chinese Taipei, Malaysia, United Arab Emirates, and Saudi Arabia. Further, REVIEWED the requirements of THF as provided by the proposer. After detailed deliberations, the Committee REQUESTED BIS Sectt. to seek following inputs/data from the proposer:

			• In 2022, India imported $148 million worth of tetrahydrofuran, making it the world's largest importer of the product. • India's main sources of tetrahydrofuran imports in 2022 were China, Chinese Taipei, Malaysia, United Arab Emirates, and Saudi Arabia. • Tetrahydrofuran (THF) is used in a variety of applications, including: — Surface coatings — Anticorrosion coatings — Printing inks Also, MSIHC [The Manufacture, Storage and Import of Hazardous Chemical Rules, 1989] has categorized THF as hazardous/toxic Chemical  MSIHC Rules.pdf MSIHC rule –  Test Methods Marl -thf.pdf Inputs revived — and  table_1-thf.docx The Committee may **CONSIDER**.	a) Difference between THF peroxide and Peroxides as Oxygen b) Cause of acetic acid as impurity in THF (process of manufacturing) c) There should be a range of density instead of specifying only maximum value. d) Provide testing data supporting the proposed requirements. e) ASTM standards/international standard if any used for testing Further, on receival of inputs, the Committee will deliberate in next meeting. **[Action to be taken: INEOS]**

Sl No.	Subject	Received from	Proposal description	Decision of the Committee
vii.	Metaxylene - Specification	Pankaj, Reliance Industries Limited,	**Purpose and Justification :** Ensuring consistent quality, Regulatory compliance, Technical specifications and benchmarking, Minimizing health hazards to consumers, Control over proliferation of low quality grades. Currently there is no quality standard available for Isophthalic Acid. Domestic consumption is around 65000 MT per year. Availability of standard with quality specifications will ensure uniformity of material available for downstream use. Entire quantity is imported from countries like Korea, China, Taiwan, Japan, Spain etc. Isophthalic acid is used in PET manufacturing. It is also used in Pharmaceutical applications like contrast media, Isophthaloyl chloride. There are no standards available at present. Hence there can be Quality Concerns due to use of sub-standard product, Safety Hazards, Environmental impact, Resource wastage. Use of sub-standard Isophthalic acid can lead to production of sub-standard downstream product, which will impact costs, market reputation. **Users of Meta-Xylene in India:** • Deepak Nitrite Limited • Vinati Organics Limited • Innovassynth Technologies (India) Ltd. Working Draft –  NWIP Metaxylene.docx	Shri Pramod Mall, Reliance Industries Limited and Shri Pankaj, Reliance Industries Limited briefed the Committee on Metaxylene including its uses, manufacturing process and import quantity, about 5500 MT and not 65000 MT in India, which is going to increase in future as well as the need for a standard. The Committee NOTED the information presented by Shri Pramod Mall and Shri Pankaj. Further, REVIEWED the requirements of Metaxylene as received from Reliance. After detailed deliberations, the Committee ACCEPTED the proposal for formulation of standard on 'Metaxylene – Specification' for technical grade. Further, the Committee DECIDED to constitute the following working group with a timeline of 3 months that is December 2024, to prepare working draft on the above said subject: Composition of the Working group: a) Shri Pramod Mall, Reliance Industries Limited (***Convener***) b) Deepak Nitrite Limited c) Vinati Organics Limited d) Shri CS Patel, GNFC e) Dr YS Jhala, IOCL **[Action to be taken: Working group]**

			The Committee may **CONSIDER.**	
viii.	Isophthalic Acid - Specification	Pankaj, Reliance Industries Limited,	**Purpose and Justification:** Ensuring consistent quality, Regulatory compliance, Technical specifications and benchmarking, Minimizing health hazards to consumers, Control over proliferation of low quality grades. Currently there is no quality standard available for Isophthalic Acid. Domestic consumption is around 65000 MT per year. Entire quantity is imported from countries like Korea, China, Taiwan, Japan, Spain etc. Isophthalic acid is used in PET manufacturing. It is also used in Pharmaceutical applications like contrast media, Isophthaloyl chloride. **Users of PIA in India:** i) Reliance Industries Limited ii) IVL Dhunseri Petrochem Industries Pvt. Ltd. iii) Henkel Adhesives Technologies India Pvt. Ltd. iv) Transpek Industry Limited v) Blue Jet Healthcare Limited vi) Chiripal Polyfilms Limited vii) Madelin Enterprises Pvt Ltd viii) UFLEX Limited ix) Indo Rama Synthetics (India) Ltd. x) Brilliant Polymers Pvt. Ltd. Working Draft – NWIP Isophthalic acid.docx	Shri Pramod Mall, Reliance Industries Limited and Shri Pankaj, Reliance Industries Limited briefed the Committee on Isophthalic Acid including its uses, manufacturing process and import quantity in India as well as the need for a standard. The Committee NOTED the information presented by Shri Pramod Mall and Shri Pankaj. Further, REVIEWED the requirements of Isophthalic Acid as received from Reliance. After detailed deliberations, the Committee ACCEPTED the proposal for formulation of standard on 'Isophthalic Acid – Specification' for technical grade and further DECIDED as follows: • To constitute the following working group with a timeline of 3 months that is December 2024, to prepare working draft on the above said subject: Composition of the Working group: a) Shri Pramod Mall, Reliance Industries Limited (***Convener***) b) IVL Dhunseri Petrochem Industries Pvt. Ltd. (Reliance to provide the details) c) Transpek Industry Limited Reliance to provide the details) d) Shri CS Patel, GNFC e) Dr YS Jhala, IOCL • To include Other unknown impurities in formula for determination of purity, with a footnote defining other unknown impurities.

			 The Committee may **CONSIDER.**	**[Action to be taken: Working group]**
ix.	Polymer Polyols	PCD 12	Polymer Polyol request is received from Plastic Sectional Committee, PCD 12. The Committee members in its last meeting were of the opinion that polymer polyols serve as raw materials for polymer production. Hence after deliberations, the Committee resolved to seek input and comments from the Organic Sectional Committee, PCD 9, regarding the feasibility of addressing this subject within PCD 9. The Committee may **CONSIDER.**	The Committee REVIEWD the request for formulation of standard on 'Polymer Polyol' received from Plastic Sectional Committee, PCD 12. After detailed deliberation, the Committee concluded that the subject is a polymer by nature, making it more relevant to PCD 12 and outside the scope of PCD 9. Thus, DECIDED to forward the subject again to PCD 12 for reconsideration. Additionally, RECOMMENDED to transfer IS 18174 : 2023 Polyether polyols – Specification, which is also a polymer, to PCD 12, as it is more relevant to plastics. **[Action to be taken: BIS Sectt.]**

x.	Propylene Glycol	Mr B.R.Reddy Balaji Amines Ltd-Unit-III	The request for formulation of standard on these products has been received from Balaji Amines Ltd. They have informed that these products are recycled / distilled material and sold as original, which are then used in many human medicines (Which is very dangerous). Further, it is informed that BIS have IS 13702: 1993 Propylene glycol, food grade – Specification for food grade. While no standard exist for other proposed chemicals.	During deliberations, the Committee concluded that the proposed subjects pertain to formulation of standards with application in pharmaceutical industry. The Committee further noted that chemicals in the pharmaceutical industry are used in two main capacities: as excipients, which must adhere to pharmacopoeia standards regulated by CDSCO, and as solvents. Shri Om Sharma, DCPC also acknowledged that chemical directly used for medicine doesn't come under the preview of DCPC. Further, the Committee NOTED that PCD 9 generally formulate Indian Standards for industrial use (pure and technical grade only). The Committee concluded that before taking a final decision on the proposals for Indian Standards on chemicals for usage in pharmaceutical industry (pharma grade) it is essential to hold a consultative meeting with concerned regulator to have a clarity on the need of formulation of Indian Standards for such chemicals which have application in pharmaceutical industry. Following these discussions, the Committee REQUESTED BIS Sectt. to host a meeting involving BIS, the Chairman of PCD 9, CDSCO, DCPC, and the Indian Pharmacopoeia to address the following point: a) To discuss the scope of setting requirements for chemicals used in the pharmaceutical industry in Indian Standards formulated by PCD 9 that is to determine whether these will be covered by the Indian Pharmacopoeia or BIS.
xi.	N-Methyl-2-Pyrrolidone			
xii.	Acetonitrile			
xiii.	Ethylenediamine			
The Committee may **CONSIDER.**				

	Based on the conclusion of above said meeting, the detailed deliberation may be taken up subsequently.

Item 8 PROGRAMME OF WORK

Due to paucity of time, the Committee DECIDED to discuss item 8 in next meeting.

Item 9 RECENT INITIATIVES OF BIS

Due to paucity of time, the Committee DECIDED to discuss item 9 in next meeting.

Item 10 DATE AND PLACE FOR THE NEXT MEETING

The Committee NOTED item 10 of the agenda and DECIDED to conduct the next meeting in virtual mode on 15 October 2024 to complete the pending agenda.

Item 11 ANY OTHER BUSINESS

The Committee NOTED item 11 of the agenda and no new subject was tabled during the meeting.

Item 12 VOTE OF THANKS

The meeting ended up with a vote of thanks to the Dr C.V. Rode for chairing the meeting and the members present during the meeting.