



FORM - 29B

TYPE APPROVAL DATA SHEET (TADS)

In accordance with IMTAR-21, Subpart C, 21.C1.23, 21.C1.24, 21.C1.25, 21.C1.26

Sl. No.	Description	Details / Document Reference
1	Product Name	
2	Part number ¹	
3	Name & address of Design & Development Agency ²	
4	Name and Address of the Manufacturing agency ³	
5	Brief Product end use application (about 10 words)	
6	Type Approval Basis (TAB)	
7	Technical Specification ⁴	
8	Master Drawing Index (MDI) and Bill of Materials (BOM) ⁵	
9	Standard of Preparation (SOP) /ACBS ⁶	
10	Qualification Test Schedule (QTS) / Qualification Test Plan (QTP) / Qualification Test Procedure (QTP) ⁷	
11	Qualification Test Report (QTR) ⁸	
12	Provisional Clearance & renewals / extensions (PC) ⁹	
13	Any other relevant information	

QTS / QTP Compliance Statement

(as per QTS / QTP Reference No. _____ Issue x, Dated _____)

Sl. No.	QTS / QTP Clause No.	Name of Test	Requirement	Compliance Status / Remarks	Means of Compliance (By testing /Analysis / Simulation/ Similarity Basis / any other means)	Test Report / Supporting Document Reference Number

Note

- Part number shall be unique to the product type approved (as in Provisional Clearance) and shall not be changed even if the product undergoes modifications in due course. In exceptional cases where the form, fit and function of the product is affected due to major modifications arising due to end use requirements, the modified product shall be taken up for supplementary type approval with a new part number. The extent of modification and the incremental qualification required for supplementary TA shall be evolved in consultation with RCMA and adequately documented as supplementary type record.



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2. Generally, IPR rests with D&D agency and D&D agency(ies) shall be responsible for any Design changes, Modifications, Defect Investigations, Repair schemes, Lifting studies, etc., that may arise during the life cycle. Any thing contrary to the above shall be explicitly captured in the TOT document duly approved by CEMILAC.
3. Manufacturer can be D&D agency itself or may be a development partner during D&D phase or any other agency that may acquire manufacturing rights based on TOT from the D&D agency. Although multiple agencies may manufacture the type approved item with same part number, the product label should adequately capture the name and address of the manufacturer for traceability.
4. All technical specifications shall be approved and authenticated by RCMA. Partial compliance and Deviations to Technical specifications are generally NOT acceptable. However, in exceptional cases the product deviations to the technical specification shall be adequately captured and included in the type approval data sheet duly concurred by RCMA.
5. The DAL and MDI shall be updated whenever there are issue changes and/ or modifications to the product. The same shall be approved by RCMA and taken up for incorporation in the type record and TA certificate at the time of subsequent TA renewal.
6. The product build standard shall be completely defined in the SOP/ ACBS document incorporating the latest issues of the applicable DAL/ MDI and Modifications that may be approved during the product life cycle. The mod leaflets duly approved by RCMA shall be the authority for incorporating such changes till the amendment cum renewal to the TA is issued.
7. QTS / QTP shall capture the type certification test requirements in totality and shall be approved by RCMA.
8. QTR shall adequately capture the Compliance to QTS requirements and shall be vetted by DGAQA. DGAQA to coordinate all the Test reports carried out as per the QTS. Any deviations to test procedures and results shall be addressed completely and accepted by RCMA before recommending for type approval.
9. The renewal and validity and PC shall comply with relevant CEMILAC directives. The Type Approval issued supercedes all earlier PCs issued to the product. Even if the product undergoes modification that warrant field evaluation feedback, fresh PC shall not be issued.
10. D&D agency shall follow suitable Configuration Control mechanism (Document reference number, Issue/ version numbers, Sections, Page numbers, dates) for easy identification and traceability of all the above documents and their subsequent updates from time to time.